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1. CARDIAC STENT

CARDIAC STENT: A cardiac stent is a tiny wire mesh tube. It props open an artery and is left there permanently. When a coronary artery (an artery feeding the heart muscle) is narrowed by a build-up of fatty deposits called plaque, it can reduce blood flow. If blood flow is reduced to the heart muscle, chest pain can result. If a clot forms and completely blocks the blood flow to part of the heart muscle, heart attack results.

Stents help keep coronary arteries open and reduce the chance of a heart attack. It is inserted into the clogged artery with a balloon catheter. The balloon is inflated and the stent expands and locks in place. This holds the artery open and allows blood to flow more freely.

WHY IN NEWS: The government listed the stents in National List of Essential Medicines in 2016, and later stents were included in the first list of the Drugs Price Control Orders. In 2017, The National Pharmaceutical Pricing Authority (NPPA) slashed the price of stents by up to 85%. The price of bare metal stents (BMS) was fixed at ₹7,623 and drug-eluting stents (DES) at ₹31,080; down from ₹45,000 and ₹1.21 lakh respectively. The NPPA later raised the price cap by around 2% from April to compensate for the rise in the input costs of producers.

IMPLICATIONS:

POSITIVE IMPLICATIONS:

- The control of stent prices could save as much as ₹4,450 crore a year for patients. Regulated prices can, therefore, be expected to make stents more accessible to patients who really need them. This can result in the treating of more patients and compensate for the challenges that the manufacturers have incurred on reduced stent pricing.

- Addressing the huge unethical mark-ups: There are massive margins charged at each step in the distribution and supply of stents, and by the time the patient gets it, the increase from the original cost of the stent is often in the range of 1,000-2,000%.

- Research data available showed that there was irrational use of medical technologies, including cardiac stents and knee implants. Price cut also reduces the incentive for unethical hospitals to use them needlessly.

- An increase in the use of indigenously manufactured stents that currently have a market share of less than 40%. It is time for the Indian companies to prove to the cardiologists and patients the equivalent safety and efficacy of their products when compared with products from MNCs that would have undergone vigorous testing in adequately powered clinical trials. Once such a level of competency is achieved, India could actually export stents making Make in India viable for medical devices.

NEGATIVE IMPLICATIONS:

- By adversely affecting the returns pharmaceutical companies can earn on making stents, price caps can reduce their supply. The price caps imposed on 74 drugs under the Drugs (Prices Control) Order (DPCO) 1995 led to the stoppage in production of half the drugs.

- Three international manufacturers (Abbott Healthcare, Boston Scientific, and Medtronic India) that supply stents in India threatened to pull out of the market. The NPPA refused to approve the withdrawal request of two of the companies, shedding bad light on doing business in India. The DPCO 2013, which capped the price of 348 drugs, dried up any new investments in them, seen as crucial to lowering drug prices in a sustainable manner.

- The price caps could deter companies from selling the newer-generation stents, especially in complex lesions. This could result in a situation where hospitals in the country would have older generation stents, and affect even medical tourism.

- Research on indigenous stents: Even before the price control move was instituted, only 40 per cent of the stents used in the country were indigenously manufactured; the rest were imported. With prices of imported stents and Indian stents now being the same, doctors and patients could prefer the imported devices. If the situation continues, the financial...
viability of Indian stent manufacturers could be hit. This will have a bearing on their capacity to do quality research. Ultimately, lack of indigenous research and development will make the country dependent on imported stents.

- Preference for stenting even in cases when it is not the best treatment: Several studies across the globe have shown that in patients with multiple blocks in all three vessels, open heart surgery is a better procedure than the use of multiple stents. However, with lower stent prices, ill-informed patients often choose multi-vessel angioplasty as it is cheaper (even with three stents) than open heart surgery.

RECENT DEVELOPMENTS:
- The National Pharmaceutical Pricing Authority (NPPA) has begun issuing demand-notices to hospitals for recovery of the excess amounts they have been charging patients on cardiac stents.
- After cardiac stents, the National Pharmaceutical Pricing Authority (NPPA) has capped the prices of orthopaedic knee implants. The cobalt chromium knee implant, available at over Rs 1,58,000 at hospitals, will now be available for a ceiling price of Rs 54,720. At present, such implants have a market share of 80 per cent. Implants with special metals like titanium or oxidised zirconium are priced at almost Rs 4,50,000. The new ceiling price will now be Rs 76,600.

EFFECTIVENESS OF THE MEASURE: Seven months after the price cut, the angioplasty (a procedure in which a stent is used to open a narrowed or blocked artery to improve blood flow) cost remains the same. Even though the prices of stents have gone down by at least Rs 30,000-40,000, the medical bills revealed that the cost of other components required for the procedure has shot up which include balloons and catheters, along with the other hospital expenses. So the (price) decrease in the package may not be in the same proportion as the decrease in the price of the stent, thereby, neutralising the benefits intended to be passed on to the patients.

WAY FORWARD:
- Bring in more transparency in the billing process.
- The government could also look at standardising the cost of certain treatments, so the prices don’t vary across hospitals.
- Encourage and support Indian stent manufacturers and medical device research so that there is no need to depend on imported stents. All aspects involving medical device development (clinical research, animal testing, human trials) must be fast-tracked and should be as transparent as possible. There must be a system to make sure that the latest medical devices, including stents, are priced differently, thereby incentivising the manufacturers.

LOOK BEYOND PRICE REGULATION:
Presently, India’s health care system is underfinanced and plagued by substantial infrastructure shortages. It has almost half of the World Health Organisation (WHO) average number of physicians and 45 percent of the average number of nurses. India also has a poor bed density with the fewest number of beds per 1000 patients. For India, to meet its future goals of a healthier and more productive population, all these inefficiencies need to be tackled immediately.

It is more important to ensure an extensive regulatory framework that looks beyond price caps. The state must apply a combination of healthcare financing (increased investments) and non-financing measures such as promoting joint and bulk procurement mechanisms and investment in capacity building to address the issues of access and affordability. Fixing poor supply chains that cause such low levels of vaccination in Bihar and streamlining procurement practices that otherwise cause tragedies like in Gorakhpur, are the need of the hour. Also, options for transforming out-of-pocket spending among individuals to spending on health insurance premiums with subsidies for the low-income sector should be considered. Only when proper...
access and affordability of health care services are ensured, can **universal quality healthcare be ensured.**

### 2. GM MUSTARD

Mustard is amongst the three largest oilseed crops of India with soyabean and groundnut being other two, but the yields have remained stagnant for many years. So, India is heavily dependent on import of edible oils (over 60% of India’s domestic requirement is imported)

**DMH-11**

- Stands for Genetically Modified Mustard - Dhara Mustard Hybrid 11 (DMH-11)
- Developed by Centre for Genetic Manipulation of Crop Plants of Delhi University; with support from the National Dairy Development Board and the Department of Biotechnology.
- Developed by crossing a local Indian breed, Varuna, with EH-2, an East European strain known for its higher yields. This hybridisation is achieved by means of the three gene combination (derived from soil bacteria)

**WHY IN NEWS:** Recently, Genetic Engineering Appraisal Committee (GEAC) {India’s regulator for GM products} recommended approval for commercial production of GM mustard. The final approval is to be given by Ministry of Environment, Forest and Climate Change.

**ADVANTAGES IN COMMERCIALISING GM MUSTARD:**

- GM Mustard promises **increase in yield** by around 25-30%. This can help in **reducing the oil imports.**
- Increase the **income of farmers** and attain the objective of doubling farmer income by 2022.
- GM Mustard is **developed by a public research institute with full support of public funds** from NDDB and the Government. This Swadeshi technology can counter the monopolistic seed business by large international corporations.
- Commercial approval for GM mustard will not only **boost the morale of our scientists**, whose confidence has gone down since the Bt Brinjal moratorium, but will also provide a new path for the growth of India’s largest sector — agriculture.
- A system of genes from soil bacterium that makes mustard have been used by the scientists. This is generally a self pollinating plant and is better suited to hybridization than current methods. Local crop developers can **more easily develop different varieties of hybrid mustard**, like GM cotton, and confer traits like pest resistance and potentially improving yield.

**CRITICISMS AGAINST COMMERCIALISING GM MUSTARD:**

- The **data on test trials and deliberations** done by the GEAC during its evaluation has not been placed in public domain.
- The **long term impact of GM crops on health and biodiversity** is not yet clear. Moreover, globally, there is a clear view that GM crops must not be introduced in centres of origin and diversity. India also has mega biodiversity hotspots like the Eastern Himalayas and the Western Ghats which are rich in biodiversity yet ecologically very sensitive.
- The **highest yields in mustard** are from the five countries which do not grow GM mustard — U.K., France, Poland, Germany and Czech Republic — and not from the GM-growing U.S. or Canada.
- **Experience with Bt Cotton** has not been encouraging. Even though initially, the yields had increased, gradually the Bollworm had developed resistance to Bt Cotton.
- One of the gene used for genetic manipulation, confers tolerance to glufosinate (a herbicide), making **GM Mustard herbicide resistant.** This herbicide tolerance exists in the plants that farmers will grow when they plant GM mustard hybrid seed. This would then mean greater chemical usage by farmers, as has been seen in other countries too leading to health and environment issues.
WAY FORWARD:
GM crops make for good science and good economics, and India needs to embrace both. But given that, agriculture is a state subject, it requires the consent of the states also for the introduction of GM technology. But that requires the satisfaction of few pre requisites.

✓ Prime among them is, the placing of trial reports in public domain.
✓ Also, GEAC has to be made truly independent with members from diverse fields. This is essential especially, when India has committed public participation in decision making under Cartegena Protocol on Biosafety.
✓ There is also a need for strong liability laws to hold the manufacturers responsible in any case of default (as existing in United States of America, a proponent of GM crops).
✓ A long term evaluation of GM crops, especially food crops need to be undertaken to have clarity regarding its effects on health and environment.

Meanwhile, efforts need to be made to redesign the policies related to oilseeds, to encourage farmers (who are presently complaining of inadequate returns on oilseed cultivation) to expand its cultivation. Also, adoption of the practice of System of Mustard Intensification, for which successful trials have been done in Bihar through a World Bank project (that promises successful yields and income), need to be promoted.

3. GSLV MK III

Geosynchronous Satellite Launch Vehicle (GSLV) is the largest launch vehicle developed by India, which is currently in operation. This fourth generation launch vehicle is a three stage vehicle with four liquid strap-ons. The indigenously developed Cryogenic Upper Stage (CUS), which is flight proven, forms the third stage of GSLV.

The GSLV space programme too faced many challenges in initial years. The first flight of GSLV took place from SHAR on April 18, 2001 by launching GSAT-1. It was followed by six more launches, GSLV-D2, GSLV-F01, GSLV-F02, GSLV-F04, GSLV-D3 and GSLV-F06 on December 2010, the launch vehicle turned out to have a success rate of one in three – so not very successful. However, GSLV-D5 configured as GSLV Mk II launch on January 2014, for the first time, successfully tested the indigenous CUS making the launch a success. From January 2014, the vehicle has achieved four consecutive successes, including the recent South Asia satellite launch (GSLV-F09 / GSAT-9).

GSLV Mk III is a three-stage heavy lift launch vehicle developed by ISRO. The vehicle has two solid strap-ons, a core liquid booster and a cryogenic upper stage. Called the Fat Boy, the GSLV Mk III will enable India to send manned missions to space. Additionally, the satellite will also aid in making India self-reliant for launching heavier satellites.

GSLV Mk III is designed to carry 4 ton class of satellites into Geosynchronous Transfer Orbit (GTO) or about 10 tons to Low Earth Orbit (LEO), which is about twice the capability of GSLV Mk II. It will have one of the world’s heaviest solid motor engines and will have two strap-ons and is much more manoeuvrable than other rockets launched earlier, a feature which is expected to help ISRO change its position in space. Described as a ‘game-changer’, it’s launch will open up opportunities for India to launch 4-tonne class of satellites of foreign countries.

HOW IT WORKS?
The two strap-on motors of GSLV Mk III are located on either side of its core liquid booster. Designated as ‘S200’, each carries 205 tons of composite solid propellant and their ignition results in vehicle lift-off. The L110 stage is the core stage with twin engine configuration to generate a combined thrust of 1598 kN for 200 sec duration. Powered by two Vikas engines, the core stage of GSLV Mk III will be the powerhouse of the launch vehicle as it will propel the vehicle through the atmospheric phase of its flight.

C25 stage is newly developed, totally indigenous upper stage of GSLV Mk III and is powered by CE-20, India’s largest and one of the most powerful cryogenic engines of upper stages in the world. This is the terminal stage of the vehicle loaded with 28 tons of propellants (LOX &
A key component holding back India’s advancement in GSLV has been Cryogenic Engine (CE) technology, which was denied to the country in the early 1990s when the Russians backed out after sustained US pressure. In essence, CEs are high-tech steam engines, burning liquid hydrogen and liquid oxygen.

**Two aspects** make it a tricky technology to master. **One**, the two elements in question have to be liquefied and stored separately at very low temperatures of **minus 250 degrees Celsius**. **Secondly**, CEs require extremely cold fuel tanks to be placed in close proximity to extremely hot combustion chambers. But they reward by providing **higher thrust-to-weight ratios** and allowing **much heavier satellites to be launched**.

Unlike the cryogenic engine (CE 7.5) on GSLV Mk II that borrows from Russian technology, the advanced cryogenic engine (CE 20) supporting GSLV Mk III is developed from scratch by ISRO. After several failures at indigenously made CEs, two past launches — the GSLV-FO5 launching the INSAT-3DR satellite in September 2016 and the GSLV-F09 launching the GSAT-9 in May this year — paved the way for this latest success. The self-reliance in launching heavier payloads is reportedly also expected to save about **25 per cent in the cost of future launches**. The flight of GSLV MK III has conclusively proved that ISRO has finally arrived. Hardly 11 countries in the world have developed such capabilities and are able to launch satellites by using their indigenously built rocket systems. With this successful launch, India has joined this club.

**WHY IS IT IMPORTANT?**

Before GSLV Mk III, India had to depend on foreign agencies such as French Arianespace, to launch communication satellites beyond 2.3 tonnes. It will also enable India to send manned missions to space. This is set to change with the operationalising of GSLV Mk III, which even can attract foreign customers. It’s rather a simpler vehicle, and a vehicle with better payload fraction and is expected to be **future workhorse vehicle** of ISRO. The successful launch of the GSLV MK III will be another major step by ISRO towards being **self-reliant in the country’s space programme**.

This will make India an important player in the multibillion-dollar global satellite launch market, making India a cost effective and reliable partner for heavy satellite launches, generating **additional revenue for ISRO**. Given that the future satellite launch market will have a big focus on heavy communication satellites, India has a strong incentive to master this launch vehicle, as it has done with its PSLV. Lastly, the enhanced launch capability builds up India’s potential to undertake deep space exploration and planetary missions with more sophistication than the relatively underpowered instruments on Chandrayaan and the Mars Orbiter Mission.

The **Mark III will be operational with the success of one more developmental flight**, which is set to take place within a year. This will make India self-reliant in launching heavier satellites, bringing down costs substantially. With fewer propulsion stages and, therefore, control systems, the **Mk-III is far more reliable** than the GSLV Mk I & II and the PSLV.

Eight ISRO satellites launched onboard Ariane rockets between 2005 and 2016 cost the organisation almost Rs 4,200 crore. Rockets like the Mk II and Mk III are expected to help reduce these expenditures. At the same time, if ISRO is able to demonstrate that they are reliable, they also can also make for a potential revenue source as affordable medium-lift vehicles targeted at countries that need a satellite launched but don’t have the launcher for it.

**PHASE OF DEVELOPMENT**

The experimental flight of GSLV-MKIII designated as **GSLV MK-III X**, (also known as Launch Vehicle Mark – 3, LVM3-X/CARE mission) carried **Crew module Atmospheric Re-entry Experiment (CARE)** as its payload on December 2014 and successfully tested the vehicle.
**performance during the critical atmospheric phase of flight.** In the GSLV MK-III-X flight, active S200 and L110 propulsive stages, and a passive C25 stage with dummy engine are used.

The first **developmental flight (GSLV Mk III - D1)** of India’s heavy lift launch vehicle GSLV Mk III was successfully conducted on June 05, 2017 from Satish Dhawan Space Centre SHAR, Sriharikota with the launch of GSAT-19 satellite. This was the first orbital mission of GSLV Mk III which was mainly intended to evaluate the vehicle performance including that of its fully indigenous cryogenic upper stage during the flight. Weighing 3136 kg at lift-off, GSAT-19 is the heaviest satellite launched from the Indian soil. The performance of the engine and stage during the mission was as predicted. About sixteen minutes after lift-off, GSAT-19 satellite was successfully placed in orbit.

**ANALYSIS**

**Demand and supply** is of key importance in the open market for commercial satellite launches, and commercial spaceflight is an area in which ISRO aspires to do well in the medium to long term. The Mk III, therefore, assumes pole position in ISRO’s plan to cater to both domestic and international markets.

From a **domestic perspective**, there are **two principal problems**.
1. Being able to launch payloads of 3 – 4 tonnes will **reduce India’s dependence on foreign nations to launch home-built satellites**. Currently, the European company Arianespace is being used to launch many of India’s GTO satellites.
2. The communications market has been limited by the **number of transponders available in Indian skies**. So focusing on increasing the Mk III’s payload size to 4 - 5 tonnes will be key in determining whether ISRO can push the **transponder envelope to greater than 48 per satellite** and launch them onboard a domestic vehicle in the future.

Overall, **the domestic capability would augur well for ISRO – not just with respect to the 40-50% savings on launch costs but also on the R&D and human capital gained from the project.**

From an **international perspective**, the commercial market traditionally supports a **maximum of three players, with a few peripheral players**. The market is getting more crowded. Currently, the world’s main launch vehicles are Ariane 5, Soyuz, Falcon 9 and ULA’s Delta/Atlas. So with the bulk of the satellite communication launch demand today served by Ariane 5 and Falcon 9, it is their space that the Mk III will have to penetrate. It remains to be seen if this will happen – especially by also remaining as a **lower-cost option**. For starters, a **good success rate like its predecessor**, the Mk II, will go a long way in establishing international confidence in the Mk III to launch medium- to high-range communications satellites.

And in the aftermath of such success, ISRO is bound to place fewer orders to launch geosynchronous satellite launches that have been historically addressed by Arianespace. Its rise could also signal the emergence of a **new, competitive option** that fledgling space nations could look up to, other than the **US, Russia, Europe and China.**

The **Indian astronomy community** has several goals that require more than the PSLV. The first might be a **successor to Astrosat**. India has now begun to exploit the capabilities of the Astrosat mission and are already missing opportunities because of the absence of larger and more specialised instrument – perhaps an ultraviolet spectrograph – to follow-up on some of the exciting discoveries. The community is expanding heavily into solar physics, with the National Large Solar Telescope (NLST) and the complement of experiments on Aditya, a solar observatory. A possible follow-up might be an observatory to observe the solar poles. **The additional lifting capacity of the GSLV Mk III launcher will help to start planning for more such ambitious missions with more advanced instrumentation.** It will also help for **more planetary missions** efficiently in a cost effective manner.
SUGGESTIONS
An international study on the international communication satellites launched during 2005 - 2015 indicate that 12% of the satellites fall in the < 2.5 ton category; 30% in the 2.5 – 4.2 ton category; 27% in the 4.2 – 5.4 ton category; and 31% in the very heavy 5.4 ton plus category. This trend is witnessed in ISRO satellites as well. Of the twelve GSATs flown since 2010, five are in 3 + ton category. The GSAT – 11, currently under assembly at the ISRO Satellite Centre, weighs 5,700 kg and is beyond the GSLV Mk III’s capability. The following suggestions are pertinent in this regard:

- Close GSLV Mk II after GSLV Mk-III enters operational phase.
- **Increase Mk-III production capacity** through an ISRO plan for involving industry in a significant way in space production/operation activities
- **Growth options of GSLV Mk III** must be exercised – increasing its payload carry capacity. ISRO is in the process of further improving the capability of this vehicle. It could go up to a ten-tonne kind of capability.
- GSAT-19 carries a bus system experiment in **electric propulsion**. Substitution of chemical propulsion with electric propulsion in spacecraft must be done on priority.

With communication satellites becoming heavier (up to six tonnes), the capability for larger payloads is vital. This can be done by **switching over to electric propulsion** for orbit rising and to keep the satellite in the right position and orientation in the orbit through its lifetime (that is, station keeping). The switch-over would reduce the weight of the vehicle as it can do away with nearly two tonnes of propellants and carry heavier satellites. Towards this end, ISRO has started testing electric propulsion in a small way; the South Asia Satellite (GSAT-9) that was launched last month used electric propulsion for station keeping.

ISRO also needs to ramp up its **international partnership programmes**. Even today, there is resentment across the Indian community on India – US partnerships, hinging on the historical reasons of sanctions on Indian space programmes. Today, such resentments would be counterproductive. Apart from having been a blessing in disguise for setting India on the path to self-reliance, India has need for US support more than many might be willing to acknowledge if ISRO is to become a more important player. Two successes that ISRO has obtained – Chandrayaan 1 and the Mars Orbiter Mission (MOM) – would not have accrued the significance they have without American help. Some payloads onboard Chandrayaan 1 involved in discovering water-ice on the Moon were the result of the **India-US Joint Working Group on Civil Space Cooperation**.

CRITICISM
The GSLV Mk III rocket weighs 640 tonne with a capacity to carry a four-tonne satellite. But when one compares the ratio of the GSLV Mk III's **weight to its carrying capacity** to geo-transfer orbit (GTO - where communication satellites will be placed) with rockets of other countries, the former ranks low. For instance, Japan's H-IIB rocket weighs 531 tonne but can place an eight-tonne rocket in GTO. Similarly, Soyuz, Russia (312 tonne, payload to GTO 3.2 tonne); Falcon, USA (549 tonne, payload to GTO 8.3 tonne) and Proton, Russia (693 tonne, payload to GTO 6.3 tonne); Long March, China (weight 879 tonne, payload to GTO 14 tonne) and Ariane 5, Europe (777 tonne, payload 10.9 tonne).

The main reason for this is the rocket's propulsion system employed in foreign rockets. Their **lower stages** (engines at the lower part of the rocket that are fired first to lift the rocket and make it escape earth's gravitational force) are powered by semi-cryogenic or cryogenic engines, while that of GSLV is based on solid propellants. The thrust powers of semi-cryogenic or cryogenic engines are higher than that of engines fired with solid fuel. However, **solid fuels are cheaper**, when compared to that of Cryogenic fuels.

UPCOMING LAUNCHES
ISRO is planning to tweak its configuration by replacing the liquid core stage with a **semi-cryogenic engine** increasing its launch capacity to **six tonnes** as India’s satellites are growing in
weight and sophistication to level with surging global demand for high throughput satellites. An upcoming satellite, GSAT-11, weighs about 5,600 kg which is beyond the scope of GSLV Mk III. ISRO aims to test a **prototype semi-cryogenic engine soon with the possibility of a debut flight by 2021.** ISRO expects to increase its launch capacity thereafter to **10 tonnes** and eventually **15 tonnes** to GTO by introducing modularity, allowing it to feature designs SpaceX uses for Falcon 9 core stage.

The heavy lifters also add to a **string of basic critical technologies** required for human spaceflight even as a formal programme is yet to be announced. ISRO performed a space capsule recovery experiment in 2007, testing a 550-kg unmanned capsule for 12 days in orbit followed by a test of an unmanned crew module on sub-orbital trajectory during the predevelopment flight of GSLV Mk III. **The human spaceflight missions are not standalone in nature, but are a precursor to constructing a space laboratory that can be scaled up to a full-fledged space station.**

Currently, the International Space Station (ISS) is the only full-fledged space station while China is experimenting with smaller space laboratories with the eventual goal of building its own station. **The basic and applied research on the ISS has led to many innovations in fields such as medicine, engineering, metallurgy, thermodynamics, material science, and human psychology and physiology, helping improve human life on earth. The ISS is also the stepping stone for extending human presence on the moon and Mars in search of resources, eventually culminating in colonisation of space.**

### 4. FIXED DRUG COMBINATIONS

Fixed drug Combinations are **medicines that contains two or more active components in fixed proportions in a single dosage form or several medications in fixed combination to be taken together, presented in composite packaging.** In short, they are a cocktail drug of two or more therapeutic ingredients packed in a single dose. They are important from public health perspective and commonly used for the treatment of pain & inflammation, hypertension, diabetes, malaria, tuberculosis, HIV/AIDS etc.

FDC therapies offer a means to simplify complex treatment regimens. They have proved to be advantageous as they are **safe and effective.** This is because it has **reduced dosage** of the active drugs, compared with higher dose monotherapy; **reduced risk of adverse reactions** relative to higher dose monotherapy. The FDCs are **more economic** than single ingredient drugs. Such reduced "pill burden" can greatly **enhance the adherence** to the prescribed dosage, thereby **improving the overall treatment outcome.**

However, today these ailments are considered to be the **foremost threats** to health in the world today. There is **limited evidence** that FDCs are better than other dosing aids. Although one systematic review concluded that both FDC and dosing aids improved adherence, it was noted that the **quality and quantity of the studies performed in this area was poor.**

Multiple ingredients in an FDC can confuse the physician who may not remember the exact composition and dose of individual active ingredient in a particular FDC. The patient **may not actually need** all the drugs present in the combination. That may lead to **therapeutic confusion** of therapeutic aims and create false sense of superiority of two drugs over one especially in case of antimicrobials and painkillers. FDCs have given problem of **drug resistance** in the case of antimicrobial treatment especially in case of treatment of tuberculosis malaria. If one drug is contraindicated for a patient, whole FDC cannot be prescribed. In case of FDCs, dosing is **inflexible** and cannot be regulated to patient’s needs. In some instances wrong understanding of FDCs have been proved to be fatal.
FDC IN INDIA

Any new drug requires prior approval from the Drugs Controller General (India) [DCGI] before they are licensed by the State Licensing Authorities (SLAs) for manufacture and sale in the country. As FDCs are combinations of certain drugs that are combined together for the first time, these are treated as ‘New Drugs’, as per the Section 122 E of Drugs and Cosmetics Rules, 1945. This is because of the fact that by combining two or more drugs, the safety, efficacy, and bioavailability of the individual Active Pharmaceutical Ingredient (API) may change.

However, today many SLAs have granted licences to some new FDCs without the approval of the DCGI on assessment of safety, efficacy and rationality. This is due to inconsistent enforcement of laws between state and central regulators and points to a gross failure in our drug regulatory system. Because of this, the Indian drug market is flooded with hundreds of FDC formulations without any knowledge about their safety and efficacy on Indian population. While all formulations are used for the treatment or prevention of one or the other disease, only a few of them are lifesaving and essential.

HEALTH MINISTRY BANS 344 FIXED-DOSE COMBINATION DRUGS

In their 59th Report, Department-related Parliamentary Standing Committee on Health and Family Welfare, 2012 observed that some SLAs had issued manufacturing licences for a very large number of FDCs without prior clearance from Central Drugs Standard Control Organization (CDSCO) and this had resulted in the availability of many FDCs in the market which had not been tested for efficacy and safety. (Committee even noted that “On an average DCGI is approving one drug every month without trials”)

Based on it, the DCGI asked manufacturers to produce safety and efficacy data of their FDC products or stand the risk of their licences being cancelled. This direction was given for all products approved after 29 September 1988 and before 1 October 2012. Most manufacturers complied only after a lot of hesitation and procedural wrangling, and after several extensions of deadlines and reminders. An 18-month window ending on 14 July 2014 was given for applications from manufacturers justifying the safety, efficacy and rationality of their products.

Based upon this, CDSCO also set up 10 professional committees in February 2014 to analyze the rationality as well as safety and efficacy of the FDCs. However, they were unable to complete the analysis of the entire applications (nearly 6500) received within the given time frame. In the view of above and in order to examine such huge number of applications in a timely manner, Ministry of Health And Family Welfare constituted a committee under the chairmanship of Prof. C.K. Kokate. The committee concluded that these medicines lacked therapeutic effects and posed health risks to the patients. The important disadvantages pointed out were:

- Its therapeutic efficacy has not been proved scientifically.
- As two or more active drug ingredients are used, there is a chance for drug-drug interaction, resulting in side effects. There is no proper study regarding side effects.
- Fixed dose combination of drugs cause drug resistance (super bug) since we use two or more active drug ingredients in a single drug.

**Therapeutic efficacy** – the ability of a drug to achieve the desired effect.

**Drug-drug interactions** - It occur when a drug interacts, or interferes, with another drug. This can alter the way one or both of the drugs act in the body, or cause unexpected side effects

**Drugs resistance** - Ability of pathogens (bacteria, virus, fungus and protozoans) to resist drugs

Ultimately, after due consideration of the report, the Government banned 344 FDCs on 10 March 2016 under Section 26A of Drugs and Cosmetics Act which includes Vicks Action 500 Extra, Corex, Saridon and D’Cold Total.
ANALYSIS OF THE BAN

The Kokate committee had classified FDCs under four categories — irrational, require further deliberations, rational and require additional data generation. Under the irrational category, there were 963 FDCs, out of which 344 have been announced, and the list has been dismantled. After which government has moved to the ‘require further deliberations’ category. According to government estimates, the ban on 344 FDCs, which impacts over 2,700 branded drugs, will lead to a loss of about Rs 7,000 crore for the industry. The domestic pharma industry currently has a market size of Rs 1 lakh crore.

After banning 344 combination drugs, the government has turned its attention to another 500 such medicines, setting the stage possibly for another round of confrontation with the pharma industry. The central drug regulator has sent letters to nearly 300 companies, which have sought marketing approvals for fixed dose combination (FDC) drugs. Some of these firms have been issued show-cause notices and asked to conduct Phase IV trials — a post-marketing study — as evidence to show their products are safe and effective.

But in a sign that the government is not taking a totally adversarial stand on the issue, some companies have been granted no-objection certificates (NOCs) for their products.

IMPACT OF BAN

Due to the sudden prohibition, the pharmaceutical industry suffered an enormous loss of Rs. 7000Cr, which accounts for 7% of the pharmaceutical market. The impact of this ban has been significantly higher on the industry because most of the banned medicines were sold Over the Counter (OTC) without any prescription. Hence, they become fastest selling products. One can expect a surge in prices on other legal drugs by the same companies as banned drugs were hugely endorsed on various platforms. Behind every branded medicine there were massive marketing campaigns carried out over the years to establish the brand in the market. The cost-cutting factors will increase in the companies whose sales entirely relied on FDC drugs. In the long run, impact of the ban will be seen in the pharmaceutical business as there will be lesser recruitment, fewer pay hikes, soaring medicine prices, cutting down units in an industry, etc. while ruling out sudden short term effects as most of the production from pharma companies in India is exported to other countries. If all the 963 drugs, that were found irrational, were banned the industry would have to take a huge hit, which is nearly 20% of the pharmaceutical market. The industry has reason to feel betrayed given the opacity with which the entire process has been carried out. Though no one doubts the credibility of Professor Kokate or his group of scientists, the fact that the findings have not been made public is a valid reason for grievance. Banning a drug overnight would not only mean stopping production but also taking back the products that are in the supply chain pipeline. Also there has been an argument that Banning of odd-344 fixed dose combination (FDCs) drugs may show India in poor light among international pharma companies and would slow down investment.

However, earning few millions and jobs through investment is not a bigger concern than ensuring public health and safety. If the poorest of poor patient can find money to pay for the medicine, the least the industry can do without griping is give him value for his money. The industry and the authorities who cleared the drugs need to be taken to task for allowing drugs that are banned abroad to be sold in India. Pharmaceutical companies willingly shell out millions of dollars to settle cases in the US for not following proper process let alone poor quality products. It is sheer hypocrisy when they cry foul for being pulled up in India for selling products which are no longer effective.

DELHI HIGH COURT QUASHES THE BAN

Delhi high court on December 2016, set aside the decision to ban the FDCs, saying it was taken in a “haphazard manner” without consulting statutory bodies as mandated under the law. The judge also noted that section 26A of Drugs and Cosmetics Act which provides the power to stop manufacture of drugs and cosmetics in public interest, does not vest the central government
with “carte blanche” (complete freedom to act as one wishes) to regulate, restrict or prohibit the manufacture, sale or distribution of a drug. The court said the “power of regulation, restriction or prohibition under section 26A cannot be exercised in public interest, for any reason other than the drug posing a risk to consumers thereof or having no therapeutic value or no therapeutic justification”.

It added that these aspects have to be considered by Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC) which was not done. It also said that decision banning the 344 FDCs was issued based on the recommendations of the Kokate Committee and without consulting the DTAB, DCC or Central Drugs Laboratory which were bodies set up under the Drugs and Cosmetics Act.

In its 82-page verdict, the court said no power has been vested with the government under the Drugs Act to choose not to consult DTAB, DCC and Central Drugs Laboratory. “Even otherwise it defies logic as to why would the central government, when has available to it the machinery (DTAB and DCC) provided under the Drugs Act itself to discharge the functions of a technical nature under section 26A, would, instead of using the said machinery choose to follow another course of action,” it said.

ANALYSIS OF COURT BAN
The verdict is a lesson in how not to administer a regulatory law. The ban on combination drugs that have little therapeutic value was undoubtedly done for bona fide reasons. However, the government could not convince the court that the ban was valid despite statutory bodies such as the DTAB and the DCC not being involved in the process. There is little doubt that a number of combination drugs should be taken off the shelf. The court has correctly refrained from going into the merits of the ban, and has chosen to subject to scrutiny the process by which the decision was arrived at.

As per the instructions from the centre, when the pharma companies applied afresh to validate the safety and efficacy data of their FDC products, their applications were not considered by the Drugs Controller; instead, the Centre formed 10 committees. When these panels failed to consider all the applications, another one, the Kokate Committee, was formed. However, this panel went into the question whether these drugs posed a risk to consumers or lacked therapeutic value and justification. Based on its report, the Centre issued notifications banning these FDCs. In effect, the Centre seemed to have delegated its power to ban drugs to a non-statutory committee, when the Act itself provided for expert bodies through which technical aspects of administering the law were to be considered. The government ought to have been more mindful of the processes. It is possible that an appeal will be filed on the legal aspects of the judgment, but the real lesson from the episode concerns governance, and not the law alone.

GOVERNMENT APPROACHES SC
The Centre moved the Supreme Court seeking to enforce a ban on 344 FDCs drugs, challenging a Delhi HC order which had overturned a government notification on the issue.

The government had approached the apex court earlier, to transfer and hear all the cases filed in various high courts together and heard as a single case, months before the Delhi court delivered its verdict on the ban. The idea was to avoid confusion from any contradictory orders arising from different high courts. For instance, the Madras High Court’s double bench had recently refused to pass any interim orders to stay the ban while hearing a petition filed by pharmaceutical associations in March.

The Delhi High Court’s order is expected to have some bearing on other high courts’ decision and it will be up to those judges to agree or disagree with its judgment. The Supreme Court has granted the government a month’s time to amend its petition to club together all cases filed in various high courts against the ban on hundreds of combination drugs, in light of the Delhi High Court quashing the ban.
GOVERNMENT NEEDS TO STOP SPEAKING IN DIFFERENT VOICES ON FDCS

The Jan Swasthya Abhiyan recently analysed 580 medicines being supplied under the Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP), and found that over 100 of these were Fixed Dose Combinations (FDCs), many of them irrational. This revelation comes a few weeks after the government signalled its intention to ensure rational prescription of medicines by sending out stern directives requiring doctors to prescribe by generic names.

Clearly, different wings of the government are working at cross purposes — one requiring strict adherence to rules regarding rational prescription, and the other allowing sale of irrational FDCs from its own Janaushadhi outlets. Currently, the government is also defending, in the Supreme Court, a ban on 344 FDCs that it had imposed, and which was challenged by drug companies and overturned by the Delhi High Court in December 2016.

In short, there are different scenarios regarding use of FDCs in India — rational use of rational FDCs, irrational use of rational FDCs, and irrational use of irrational FDCs. The problem is compounded by a dysfunctional drug regulatory system that has resulted in the market being flooded with a large number of FDCs. Estimates indicate that almost 50 per cent of drugs consumed are FDCs, a much larger volume than what one would expect if FDCs were prescribed rationally. A study published in 2015 in PLOS Medicine found that of 175 FDCs studied, only 14 were approved in the UK and 22 in the US.

Three factors appear to be responsible for the Indian market being flooded with FDCs. Over time, companies have resorted to the marketing of FDCs to circumvent price control: they prefer to market FDCs that are not under price control rather than single-ingredient drugs under price control. The second is what is called ‘me too’ marketing. Companies vie with one another for a share of the market for the same class of drugs. In order to provide something ‘new’ to prescribers, they develop and market FDCs (often irrational, but promoted as a unique and innovative product by each company) purely for commercial reasons, and support its sales through sophisticated (and often unethical) marketing strategies. Finally, an understaffed and inefficient drug regulatory agency contributes to the problem by allowing irrational FDCs in the first place and then by not taking action to ban them.

The 59th report of the Parliamentary Committee on Health and Family Welfare had pointed out that CDSCO had, by various acts of omission and commission, failed to restrict the number of irrational FDCs. A glaring omission pointed out was that many FDCs were being marketed after receiving approval from State regulatory agencies, whereas marketing approval can only be provided by the CDSCO.

While every FDC needs to be treated as a new drug, and its safety and efficacy needs to be substantiated, this requirement was not adhered to in a large number of marketing approvals for FDCs. While the CDSCO imposed a ban on 344 FDCs in 2016, public health groups aver that the FDCs banned account for only a fraction of the FDCs currently being marketed.

Inappropriate use of FDCs poses a major threat to public health: they can lead to additional toxicity, limit choice of prescribing physicians, increase treatment cost, lead to under- or overdosing and, in the case of antibiotics, FDCs can contribute to more rapid development of antimicrobial resistance. It is to be hoped that the government will act to harmonise its own policy prescriptions, and take a firm position against the rampant use of irrational FDCs.

5. BITCOINS-INTRODUCTION

A cryptocurrency is a digital or virtual currency that uses cryptography for security. A cryptocurrency is difficult to counterfeit because of this security feature. A defining feature of a cryptocurrency, is its organic nature; it is not issued by any central authority, rendering it theoretically immune to government interference or manipulation. It is a decentralized digital cash system.
Cryptocurrencies make it easier to transfer funds between two parties in a transaction; these transfers are facilitated through the use of public and private keys for security purposes. These fund transfers are done with minimal processing fees, allowing users to avoid the steep fees charged by financial institutions.
However, on the negative side, because cryptocurrencies are virtual and do not have a central repository, a digital cryptocurrency balance can be wiped out by a computer crash if a backup copy of the holdings does not exist. The security structure of the account of the exchanges or the holders may also be hacked. Since prices are based on supply and demand, the rate at which a cryptocurrency can be exchanged for another currency can fluctuate widely. The anonymous nature of cryptocurrency transactions makes them well-suited for a host of illegal activities, such as money laundering and tax evasion.

A cryptocurrency consists of a network of peers. Every peer has a record of the complete history of all transactions and thus of the balance of every account which prevents double spending: to prevent that one entity spends the same amount twice. Usually, in conventional currency system, keeping record about the balances is done by a central server. In a decentralized network, there is no such server, which requires every single entity of the network to do this job. Every peer in the network needs to have a list with all transactions to check if future transactions are valid or an attempt to double spend. In cryptocurrencies, this is done through limited entries in a database, which no one can change without fulfilling specific conditions.

The transaction is known almost immediately by the whole network. But only after a specific amount of time it gets confirmed. Confirmation is a critical concept in cryptocurrencies. When a transaction is confirmed, it is set in stone. It is no longer forgeable, it can’t be reversed, it is part of an immutable record of historical transactions: of the so-called blockchain.

Only miners can confirm transactions. This is their job in a cryptocurrency-network. They take transactions, stamp them as legit and spread them in the network. After a transaction is confirmed by a miner, every node has to add it to its database.

In short, they are called CRYPTOcurrencies because the consensus-keeping process is secured by strong cryptography. Cryptocurrencies are built on cryptography. They are not secured by people or by trust, but by math. It is more probable that an asteroid falls on your house than that a bitcoin address is compromised.

**TRANSACTIONAL PROPERTIES:**

1) **Irreversible:** After confirmation, a transaction can't be reversed and by anybody.
2) **Pseudonymous:** Neither transactions nor accounts are connected to real world identities. You receive Bitcoins on so-called addresses, which are randomly seeming chains of around 30 characters. While it is usually possible to analyze the transaction flow, it is not necessarily possible to connect the real world identity of users with those addresses.
3) **Fast and global:** Transaction are propagated nearly instantly in the network and are confirmed in a couple of minutes. Since they happen in a global network of computers they are completely indifferent of your physical location.
4) **Secure:** Cryptocurrency funds are locked in a public key cryptography system. Only the owner of the private key can send cryptocurrency. Strong cryptography and the magic of big numbers makes it impossible to break this scheme.
5) **Permissionless:** One need not have to ask anybody to use cryptocurrency. It’s just a software that everybody can download for free. After you installed it, you can receive and send Bitcoins or other cryptocurrencies. No one can prevent you. There is no gatekeeper.

Cryptocurrencies are like digital gold - Sound money that is secure from political influence; Money that promises to preserve and increase its value over time. Cryptocurrencies are also a fast and comfortable means of payment with a worldwide scope, and they are private and anonymous enough to serve as a means of payment for black markets and any other outlawed economic activity.
But while cryptocurrencies are more used for payment, its use as a means of speculations and a store of value dwarfs the payment aspects. Cryptocurrencies gave birth to an incredibly dynamic, fast growing market for investors and speculators. Exchanges like Okcoin, poloniex or shapeshift enables the trade of hundreds of cryptocurrencies. Their daily trade volume exceeds that of major European stock exchanges.

**ADVANTAGES OF CRYPTOCURRENCIES**

**Fraud:** Individuals cryptocurrencies are digital and cannot be counterfeited or reversed arbitrarily by the sender, as with credit card charge-backs.

**Immediate Settlement:** Bitcoin contracts can be designed and enforced to eliminate or add third party approvals, or be completed at a future date or time for a fraction of the expense and time required to complete traditional asset transfers.

**Identity Theft:** When you give your credit card to a merchant, you give him or her access to your full credit line, even if the transaction is for a small amount. Credit cards operate on a “pull” basis, where the store initiates the payment and pulls the designated amount from your account. Cryptocurrency uses a “push” mechanism that allows the cryptocurrency holder to send exactly what he or she wants to the merchant or recipient with no further information.

**Recognition at universal level:** Since cryptocurrency is not bound by the exchange rates, interest rates, transactions charges or other charges of any country; therefore it can be used at an international level without experiencing any problems. This, in turn, saves lots of time as well as money on the part of any business which is otherwise spent in transferring money from one country to the other. Cryptocurrency operates at the universal level and hence makes transactions quite easy.

**DISADVANTAGES OF CRYPTOCURRENCIES**

**Legalisation:** The biggest problem of cryptocurrencies is its lack of being accepted as legal currencies across the world. However, it is now slowly being accepted and are mulled to be regulated by the major economies (such as Japan, US, China), which can result in increasing its stability and acceptability.

**Price Volatility:** Today, rather than being used for its intended purpose of serving as a ‘currency’, it is rather used as for speculative trade and as an investment option. However, with the regulations, this may change in the future.
Anonymity: Its anonymous nature in transactions, is today misused for illegal activities, such as to purchase drugs and other illegal commodities, such as smuggled goods, and also to pay ransoms, as was evident in the recent ransomware attacks such as Wannacry etc.

Hack prone: Though the entire structure is base on Cryptography, there are chances that the cyber security structure of the exchanges and individuals may not be strong enough to protect from hackers. Especially, if one’s private keys are misplaced or lost due to human errors, there is no recourse to the damage done ie to reverse the transactions done by hackers or even to trace the hackers (in today’s context).

**BLOCKCHAIN TECHNOLOGY**

By allowing digital information to be distributed but not copied, blockchain technology created the backbone of a new type of internet. Originally devised for the digital currency, Bitcoin, the tech community is now finding other potential uses for the technology.

Central to the genius of Bitcoin, a cryptocurrency is the block chain, it uses to store an online ledger of all the transactions that have ever been conducted using bitcoins, providing a data structure for this ledger that is exposed to a limited threat from hackers and can be copied across all computers running Bitcoin software. Many experts see this block chain as having important uses in technologies, such as online voting and crowdfunding, and major financial institutions such as JP Morgan Chase see potential in cryptocurrencies to lower transaction costs by making payment processing more efficient.

The blockchain is an incorruptible digital ledger of economic transactions that can be programmed to record not just financial transactions but virtually everything of value. By design, the blockchain is a decentralized technology. Information held on a blockchain exists as a shared — and continually reconciled — database. This is a way of using the network that has obvious benefits. The blockchain database isn’t stored in any single location, meaning the records it keeps are truly public and easily verifiable. No centralized version of this information exists for a hacker to corrupt. Hosted by millions of computers simultaneously, its data is accessible to anyone on the internet.

One of the best things about the blockchain is that, because it is a decentralized system that exists between all permitted parties, there’s no need to pay intermediaries (Middle men) and it saves you time and conflict. Blockchains have their problems, but they are rated, undeniably, faster, cheaper, and more secure than traditional systems, which is why banks and governments are turning to them.

**DURABILITY AND ROBUSTNESS**

Blockchain technology is like the internet in that it has a built-in robustness. By storing blocks of information that are identical across its network, the blockchain cannot:

1. Be controlled by any single entity.
2. Has no single point of failure.

Blockchain truly is a mechanism to bring everyone to the highest degree of accountability. No more missed transactions, human or machine errors, or even an exchange that was not done with the consent of the parties involved. Above anything else, the most critical area where Blockchain helps is to guarantee the validity of a transaction by recording it not only on a main register but a connected distributed system of registers, all of which are connected through a secure validation mechanism.

**TRANSPARENT AND INCORRUPTIBLE**

The blockchain network lives in a state of consensus, one that automatically checks in with itself every ten minutes. A kind of self-auditing ecosystem of a digital value, the network reconciles every transaction that happens in ten-minute intervals. Each group of these transactions is referred to as a “block”. Two important properties result from this:
1. Transparency
   Data is embedded within the network as a whole, by definition it is public.

2. It cannot be corrupted
   Altering any unit of information on the blockchain would mean using a huge amount of computing power to override the entire network.

THE IDEA OF DECENTRALIZATION

By design, the blockchain is a decentralized technology. Anything that happens is a function of the network as a whole. Some important implications stem from this. By creating a new way to verify transactions aspects of traditional commerce could become unnecessary. **Stock market trades become almost simultaneous** on the blockchain, for instance — or it could make types of record keeping, like a land registry, fully public. And decentralization is already a reality.

A global network of computers uses blockchain technology to jointly manage the database that records Bitcoin transactions. That is, Bitcoin is managed by its network, and not any one central authority. **Decentralization means the network operates on a user-to-user (or peer-to-peer) basis.** The forms of mass collaboration this makes possible are just beginning to be investigated. It is speculated that decentralized networks will be the next huge wave in technology.

ENHANCED SECURITY

By storing data across its network, the blockchain eliminates the risks that come with data being held centrally. Its network lacks centralized points of vulnerability that computer hackers can exploit. Today’s internet has security problems as it relies heavily on the “username/password” system to protect our identity and assets online. **Blockchain security methods use encryption technology.**

The basis for this are the so-called **public and private “keys”**. A “public key” (a long, randomly-generated string of numbers) is a user’s address on the blockchain. Bitcoins sent across the network get recorded as belonging to that address. The “private key” is like a password that gives its owner access to their Bitcoin or other digital assets. Hence, storing one’s data on the blockchain means it is incorruptible. At the same time, **protecting your digital assets will also require safeguarding of your private key.**

APPLICATIONS

**1. SMART CONTRACT**

Smart contracts help you exchange money, property, shares, or anything of value in a transparent, conflict-free way while avoiding the services of a middleman. Distributed ledgers enable the coding
of simple contracts that will execute when specified conditions are met. At the technology's current level of development, smart contracts can be programmed to perform simple functions. For instance, a derivative could be paid out when a financial instrument meets certain benchmark, with the use of blockchain technology and Bitcoin enabling the payout to be automated.

2. GOVERNANCE
This model can be increasingly used to improve the efficacy of the polices by ensuring better monitoring of its implementation, better data collection, detection of leakages and avoiding double entries thus saving precious tax payers money. There are many government functions that can be replaced by blockchain equivalents. A blockchain registry of public records will ensure that birth certificates, land records, tax receipts, passports, certificates of incorporation, minutes of official meetings and a whole host of other records such as F.I.R’s are automatically recorded in a format that is tamper-resistant and publicly verifiable. If applied creatively, it will reduce our investment in governance and offer greater accountability in the provision of public services.

3. SUPPLY CHAIN AUDITING
Consumers increasingly want to know that the ethical claims companies make about their products are real. Distributed ledgers provide an easy way to certify that the backstories of the things we buy are genuine. Transparency comes with blockchain-based timestamping of a date and location — on ethical diamonds, for instance — that corresponds to a product number.

4. PROTECTION OF INTELLECTUAL PROPERTY
As is well known, digital information can be infinitely reproduced — and distributed widely thanks to the internet. This has given web users globally a goldmine of free content. However, copyright holders have not been so lucky, losing control over their intellectual property and suffering financially as a consequence. Smart contracts can protect copyright from piracy and automate the sale of creative works online, eliminating the risk of file copying and redistribution.

5. DATA MANAGEMENT
The data that has been distributed across the networks, has an extremely low chance of being tampered with or even deleted. This can ensure that the datas and files remains secured, serving its purpose for its creators.

6. FINANCIAL TRADINGS
The potential for added efficiency in share settlement makes a strong use case for blockchains in stock trading. When executed peer-to-peer, trade confirmations become almost instantaneous (as opposed to taking three days for clearance). Potentially, this means intermediaries — such as the clearing house, auditors and custodians — get removed from the process.

7. AML AND KYC
Anti-money laundering (AML) and know your customer (KYC) practices have a strong potential for being adapted to the blockchain. Currently, financial institutions must perform a labor-intensive multi-step process for each new customer. KYC costs could be reduced through cross-institution client verification, and at the same time increase monitoring and analysis effectiveness.

8. THE SHARING ECONOMY
With companies like Uber and OLA flourishing, the sharing economy is already a proven success. Currently, however, users who want to hail a ride-sharing service have to rely on an intermediary like Uber. By enabling peer-to-peer payments, the blockchain opens the door to direct interaction between parties — a truly decentralized sharing economy results.

BITCOIN
Bitcoin is a digital currency created in 2009 which follows the ideas set out in a white paper by the mysterious Satoshi Nakamoto, whose true identity has yet to be verified. Bitcoin is the first type of cryptocurrency: Balances are kept using public and private keys. Transactions can be done in smaller sub-units of a bitcoin, called satoshi — a million bits make a bitcoin. It accounts...
for less than half of the $100-billion market for virtual currencies that includes over 150 crypto currencies. The supply of bitcoins is limited — 21 million only. It is a finite resource and as demand increases, its value tends to go up ie its value is depended upon the demand supply chain.

THERE ARE MANY RISKS
Investors and regulators point to risks galore. The RBI, for instance, has expressed concern on potential financial, legal, customer protection and security-related risks on virtual currencies.

For one, its value is a matter of speculation. The currency has no underlying to which its value can be pegged. So increase in demand can lead to sharp rallies followed by equally steep declines. For instance between October 2013 and January 2014, bitcoin value increased from $130 to $985. The price then crashed to $212 by January 2015.

Two, there is no legal status as bitcoins are not authorised by the RBI. It has, over the years, advised users, holders and traders of such currencies of their potential risks. In February, RBI had also said that it has not given licence or authorisation to any entity to operate or deal with bitcoins and virtual currencies in the country.

Three, virtual currencies are in digital form, stored in digital/electronic media. They are, hence, prone to losses from hacking, loss of password, compromise of access credentials and malware attack.

Four, payments are on a peer-to-peer basis with no established framework for recourse to disputes or issues.

There is no clarity on the taxation aspects. like the long-term/short-term holding for bitcoins, its tax implication on trading or investing.

CURRENT STATUS IN INDIA
Global market capitalisation for virtual currencies is about $40 billion. Bitcoin trades at around $1,600 and is volatile. In India, Bitcoin is traded at around Rs 1 lakh a unit. India is considering tracking digital currencies like bitcoin through the central bank and capital markets regulator along with intelligence agencies to monitor money laundering and terrorist financing. With a weekly turnover of 60 million to 100 million rupees, bitcoin, the largest of the digital currencies, has gained a firm foothold in India. Currently about 10 per cent of the total bitcoin trades come from India.

EXPERT COMMITTEE
In order to better regulate this area, the Ministry of Finance had set up a panel for examining options such as banning, regulating or limited intervention for virtual currencies in India, an area that's currently neither regulated nor recognized by the government. The committee included officials from the departments of Economic Affairs, Financial Services and Revenue (CBDT) and ministries of Home Affairs, Electronics, and Information Technology, RBI, NITI Aayog and State Bank of India.

The objectives of the committee were to take stock of the present status of virtual currencies, both in India and globally, examine the existing global regulatory and legal structures governing virtual currencies, suggest a framework for regulation of virtual currencies, if considered, including issues relating to consumer protection, taxation and money laundering, among others. Earlier, Union finance ministry had invited suggestions on whether digital currencies like Bitcoin should be banned or allowed but regulated, and if so, if self-regulation is desirable.
COMMITTEE RECOMMENDATIONS
The committee had submitted its report and is under examination. The panel had discussed the possibility of asking India’s central bank, the Securities and Exchange Board, the revenue department and Financial Intelligence Unit to develop infrastructure for observing transactions in virtual currencies.

According to the deliberations, the panel believes that banning digital coins will make transactions go underground, while regulating it would provide legitimacy to digital currency. Limited intervention, however, will reiterate that cryptocurrencies are not a recognized medium of exchange and send a message that dealers trade in such currencies at their own peril given their volatility. While welcoming the use of new technologies such as block chain, the committee is said to have proposed that the use of crypto-currencies should not be permitted in the country. It is also not in favour of a complete ban, but is understood to have recommended stringent provisions for regulating it. Based upon the panel’s recommendations, the Finance Ministry will work out a roadmap in consultation with RBI to regulate the use of virtual currencies such as bitcoins.

While Japan has legitimized virtual digital currencies, the U.K., the U.S. and Australia classify it as property that attracts capital-gains tax. China considers digital currencies as a virtual commodity. However, the Reserve Bank of India has repeatedly warned users, holders and traders of virtual currencies against the potential risks.

WHAT CAN BE DONE??
Bitcoin start-ups Zebpay, Unocoin, Coinsecure and Searchtrade had in February jointly launched a Digital Asset and Blockchain Foundation of India (Dabfi) as a self-regulatory body. Nishith Desai Associates, a global legal entity, was appointed advisor for developing the regulations.

They argue that currencies such as Bitcoin should be allowed self-regulation. Banning it, does not seem sensible, with its rising acceptability in parts of the world. If the government is to regulate it, there would be various issues. Digital or virtual currencies are not so defined under the laws and a mechanism to regulate it and tracking the transaction trails would have to be formulated. Experts say over-regulation risks killing an industry. Had e-commerce firms been regulated from the start, the segment would not have grown the way it has.
The best way to regulate is to first allow Bitcoin and crypto currency exchanges to operate. These companies do Know Your Customer (KYC) checks and can follow the anti-money laundering (AML) provisions and suspicious transaction reporting (STR) processes. They can help build an identity layer on top of this technology. This has been the global trend.

Recently, an Indian bitcoin exchange helped the police in Bank of Maharashtra robbery case to nab a culprit who had robbed the bank and purchased bitcoin with the money. Trade in bitcoin always leaves a trail of every transaction. It can eventually be traced back to the identity of the person when these reach a self-regulated Bitcoin company or exchange which collects KYC and follows the AML procedures. There could be a long transaction chain that needs to be traced backwards before the culprit is identified but it is possible.

If the government allows self-regulation, it would be faster and the government could set up an agency which coordinates with the self-regulating body of the industry regarding an investigation. Dabfi currently ensures that the member-exchanges do a proper KYC, will prepare norms for regulating members and blockchain ledgers, and will provide any information the government requires for investigation. It can also set up an appellate body or ombudsman to address customer complaints in collaboration with the Dafbi. And, the existing Income Tax Act could apply on profit or loss.

The government in fact lacks expertise on crypto currencies and cryptography. If it takes regulations on itself, it will be time consuming and training of enforcement agency officials will be another challenge. Hence, "allowing the industry to self-regulate, with government oversight, is the best approach".

**RBI Vs SEBI**

The government’s proposal to regulate Bitcoin crypto currency has sparked a regulatory turf war between Securities and Exchange Board of India (Sebi) and Reserve Bank of India (RBI). According to sources, the central bank is of the opinion that bitcoin is a security rather than currency and should be regulated by Sebi. The proposal has not gone down well with the latter which opposes the suggestion.

When the finance ministry called for a meeting of all stakeholders to discuss the regulatory framework of the virtual currency, RBI proposed to allow trading in bitcoin on the lines of trading in commodity derivatives such as gold or silver. It also recommended Sebi to ensure that bitcoin should not be used for any illegal activities like money laundering, terror funding while regulation.

Sebi expressed displeasure over RBI's proposal as it cannot be classified as commodity derivatives as per extant legal provisions, a view that has been echoed by the legal experts. They also believe that bitcoin cannot be categorised as commodity.

"Commodities are usually well-known items and maintain accountability. How will bitcoin, which has no existence, fit in the category? The government needs to come out with the legal definition and terms before putting into any category," asks one legal expert. For Sebi, the question is of setting the whole mechanism to deal with the virtual world. The mechanism should be foolproofed and well-versed with the environment.

### 6. ARTIFICIAL INTELLIGENCE (AI)

Artificial Intelligence is the simulation of human intelligence processes by machines, especially computer systems. These processes include learning (the acquisition of information and rules for using the information), reasoning (using the rules to reach approximate or definite conclusions), and self-correction. In short, the ideal characteristic of artificial intelligence is its ability to rationalize and take actions that have the best chance of achieving a specific goal.
Research associated with artificial intelligence is highly technical and specialized. The core problems of artificial intelligence include programming computers for certain traits such as:

- Knowledge
- Reasoning
- Problem solving
- Perception
- Learning
- Planning
- Ability to manipulate and move objects

Today, it has become an **essential part of the technology industry** and has become an **umbrella term** that encompasses everything from robotic process automation to actual robotics.

It has gained **prominence recently** due, in part, to **big data**, or the increase in speed, size and variety of data businesses are now collecting. AI can perform tasks such as identifying patterns in the data more efficiently than humans, enabling businesses to gain more insight out of their data.

Some common examples of machines with artificial intelligence include computers that play chess, which have been around for years, and self-driving cars, which are a relatively new development. Each of these machines must weigh the consequences of any action they take, as each action will impact the end result. In chess, this end result is winning the game. For self-driving cars, the computer system must take into account all external data and compute it to act in a way that prevents collision.

**Robotics** is also a major field related to AI. Robots require intelligence to handle tasks such as object manipulation and navigation, along with sub-problems of localization, motion planning and mapping.

**CORE AREAS**

**KNOWLEDGE ENGINEERING**
Machines can often act and react like humans only if they have abundant information relating to the world. Artificial intelligence must have **access to objects, categories, properties and relations** between all of them to implement knowledge engineering. Initiating common sense, reasoning and problem-solving power in machines is a difficult and tedious approach.

**AUTONOMOUS**
Autonomy means that an **AI construct doesn't need help from people**. Driver-less cars illustrate the term “autonomous” in varying degrees. **Level four autonomy** represents a vehicle that doesn’t need a steering wheel or pedals: it doesn’t need a human inside of it to operate at full capacity. If we ever have a vehicle that can operate without a driver, and also doesn’t need to connect to any grid, server, GPS, or other external source in order to function it'll have reached **level five autonomy**.

**ALGORITHM**
The most important part of AI is the algorithm. These are math formulas and/or programming commands that inform a regular non-intelligent computer on **how to solve problems with artificial intelligence**. Algorithms are rules that teach computers how to figure things out on their own.

**MACHINE LEARNING**
Machine learning is a type of artificial intelligence (AI) that allows software applications to become more accurate in predicting outcomes without being explicitly programmed. The basic premise of machine learning is to build algorithms that can receive input data and use statistical analysis to predict an output value within an acceptable range. It is a branch of artificial intelligence based on the idea that **machines should be able to learn and adapt through experience**.
They are of two types – Supervised and Unsupervised. Supervised algorithms require humans to provide both input and desired output, while Unsupervised algorithms do not need to be trained with desired outcome data. Instead, they use an iterative approach called deep learning to review data and arrive at conclusions. Unsupervised learning algorithms are used for more complex processing tasks than supervised learning systems.

ARTIFICIAL NEURAL NETWORK (ANN)
Our generally intelligent brains are made up of biological neural networks that make connections based on our perceptions and outside stimulus. When we want an AI to get better at something we create a neural network. These networks are designed to be very similar to the human nervous system and brain.

It is a subset of Machine learning. ANN uses stages of learning to give AI the ability to solve complex problems by breaking them down into levels of data. Information that flows through the network affects the structure of the ANN because a neural network changes - or learns, in a sense - based on that input and output.

ANNs are considered nonlinear statistical data modeling tools where the complex relationships between inputs and outputs are modeled or patterns are found. It takes data samples rather than entire data sets to arrive at solutions, which saves both time and money. ANNs are considered fairly simple mathematical models to enhance existing data analysis technologies.

AI WINTER
It refers to a period of time during which funding for activities aimed at developing human-like intelligence in machines is lacking. AI winter is characterized by decreased funding in artificial intelligence research, but it often coincides with a drop in public interest as well.

Ever since the inception of the idea back in 1950s, artificial intelligence has been under the public scrutiny. If we go down the pages of history, the period from 1974–80 and 1987–93 was the dark phase for artificial intelligence and was coined the name ‘AI winter’.

AI Winter Is Coming?
Computers have used their superior memory and processing power to beat top players in chess, Go, and even Jeopardy, but these tend to be limited applications. And that is fine. The concept of AI and its goals have undergone a positive change. Rather than striving to match the generalist mind that humanity has been blessed with, AI now seeks to specialize in particular tasks through techniques such as deep learning.

Artificial intelligence machines now have the capabilities to teach themselves how to get better at things as diverse as recognizing the content of images, understanding natural language and anticipating your next action on your mobile device. These successes have pushed off the arrival of another AI winter because they are commercially viable. An AI that can guide you through an online transaction is worth money, as is one that can answer your question in a chat rather than having you come into a physical location or make a phone call. These tangible benefits have companies and governments investing in AI research in house as well as in academic institutions.

As long as AI continues to advance in a direction where companies can see a potential cost savings or profit, the sector will be too hot for any kind of AI winter to set in.

TYPES OF ARTIFICIAL INTELLIGENCE
AI can be categorized in any number of ways, but generally into two types - either Weak AI or Strong AI. Weak AI, also known as narrow AI, is an AI system that is designed and trained for a particular task. Virtual personal assistants, such as Apple’s Siri, are a form of weak AI.
Strong AI, also known as artificial general intelligence, is an AI system with generalized human cognitive abilities so that when presented with an unfamiliar task, it has enough intelligence to find a solution.

While weak AI merely simulates human cognition, strong AI would actually have human cognition. With strong AI, a single system could theoretically handle all the same problems that a single human could. While weak AI can replace many low- and medium-skilled workers, strong AI might be necessary to replace certain categories of highly skilled workers.

EXAMPLES OF AI TECHNOLOGY

- **Automation** is the process of making a system or process function automatically. **Robotic process automation**, for example, can be programmed to perform high-volume, repeatable tasks normally performed by humans. RPA is different from IT automation in that it can adapt to changing circumstances.

- **Machine vision** is the science of making computers see. Machine vision captures and analyzes visual information using a camera, analog-to-digital conversion and digital signal processing. It is often compared to human eyesight, but machine vision isn't bound by biology and can be programmed to see through walls, for example. It is used in a range of applications from signature identification to medical image analysis. Computer vision, which is focused on machine-based image processing, is often combined together with machine vision.

- **Natural language processing (NLP)** is the processing of human language by a computer program. One of the older and best known examples of NLP is spam detection, which looks at the subject line and the text of an email and decides if it's junk. Current approaches to NLP are based on machine learning. NLP tasks include text translation, sentiment analysis and speech recognition.

- **Pattern recognition** is a branch of machine learning that focuses on identifying patterns in data.

- **Robotics** is a field of engineering focused on the design and manufacturing of robots. Robots are often used to perform tasks that are difficult for humans to perform or perform consistently. They are used in assembly lines for car production or by space agencies to move large objects in space. More recently, researchers are using machine learning to build robots that can interact in social settings.

APPLICATIONS

- **Health-care**
  The biggest bets are on **improving patient outcomes and reducing costs**. Companies are applying machine learning to **make better and faster diagnosis than humans**. One of the best known healthcare technologies is **IBM Watson**. It understands natural language and is capable of responding to questions asked of it. The system mines patient data and other available data sources to form a hypothesis, which it then presents with a confidence scoring schema. Other AI applications include chatbots, a computer program used online to answer questions and assist customers, to help schedule follow-up appointments or aiding patients through the billing process, and virtual health assistants that provide basic medical feedback.

- **Business**
  Robotic process automation is being **applied to highly repetitive tasks** normally performed by humans. Machine learning algorithms are being integrated into analytics and CRM platforms to uncover information on how to better serve customers. Chatbots have been incorporated into websites to provide immediate service to customers.

- **Education**
  **AI can automate grading, giving educators more time**. AI can assess students and adapt to their needs, helping them work at their own pace. AI tutors can provide additional support to
students, ensuring they stay on track. AI could change where and how students learn, perhaps even replacing some teachers.

- **Finance**
  AI applied to personal finance applications, is revolutionizing financial institutions. Applications such as these could collect personal data and provide financial advice. Other programs, IBM Watson being one, have been applied to the process of buying a home. Today, software performs much of the trading on Wall Street.

- **Law**
  The discovery process, sifting through of documents, in law is often overwhelming for humans. Automating this process is a better use of time and a more efficient process. Startups are also building question-and-answer computer assistants that can sift programmed-to-answer questions by examining the taxonomy and ontology associated with a database.

- **Manufacturing**
  This is an area that has been at the forefront of incorporating robots into the work flow. Industrial robots used to perform single tasks and were separated from human workers, but as the technology advanced that changed.

## ARTIFICIAL INTELLIGENCE (AI)-ANALYSIS

A lot of the ideas on how AI should learn are actually more than 60 years old. Researchers in the 1950s were among the first to study how biologists thought neurons in the brain worked and approximate what they were doing with math. The idea was that one major equation might not be able to solve every problem, but what if we used many connected equations, like the human brain does?

For decades many in computer science thought the idea would never work on more complex problems—today it underlies most of the AI pursuits of major tech companies, from Google and Amazon to Facebook and Microsoft. Looking back, researchers now realize that computers were not complex enough to model the billions of neurons in our brain, and that massive amounts of data were needed to train these neural networks, as they’re known.

**These two factors, computing power and data, have only been realized in the last 10 years.** Once the tech industry saw the results, the AI boom kicked off. By 2015, Google had more than 1,000 projects that used some kind of machine learning.

Progress in AI moves at different speeds depending on the medium. Right now, we’re seeing incredible growth in the ability to understand images and video, a field called computer vision. But that progress does little to help other AI understand text, a field called natural language processing. These fields are developing “narrow intelligence,” or Weak AI, which means the AI is powerful at working with images or audio or text, but can’t learn the same way from all three. An higher form of learning would be “general intelligence,” which is what we see in humans. Many researchers hope that advancements in individual fields will uncover more shared truths about how we can make machines learn, eventually converging into a unified method for building general artificial intelligence.

**IS IT REALLY A DOOMSDAY, THAT WE ARE CALLING IN??**

Beginning with why one must not “fear” Artificial Intelligence, such questions are actually pretty dumb. The much vaunted AlphaGo (AlphaGo is a narrow AI computer program that plays the board game Go. It was developed by Google DeepMind in London in October 2015.) for instance, would find it impossible to pick out a cat from a data set of animal pictures, unless it was reprogrammed completely and made to forget how to play Go.

This is because even the most intelligent systems today have artificial specific intelligence, which means they can perform one task better than any human can, but only that one task. Any task that it is not specifically programmed for, howsoever simple it may seem to us, such a system would find impossible to undertake.
This is also not the sort of Artificial Intelligence, about which Elon Musk recently warned about. His warnings pertain to a type known as **artificial general intelligence**, which is a system that has human-level intelligence, i.e., it can do multiple tasks as easily as a human can and can engage in a “thought” process that closely resembles humans. Such artificial general intelligence, however, has so far remained theoretical, and is possibly decades away from being developed in any concrete manner, if at all. Therefore, any fear of a super-intelligent system that can turn on humans in the near future is quite baseless.

This, however, does not mean that there is nothing to fear when it comes to Artificial Intelligence. There are **three broad areas where one should fear the effects and consequences**, if not the technology itself.

**First**, and most importantly, **jobs**. While the possible negative effect of Artificial Intelligence on jobs has been a trending topic recently, there has been no academic or policy consensus on what the exact effect will be. **There can be no doubt that at least some jobs will be negatively affected by Artificial Intelligence, but the nature of these jobs and the nature of the jobs that may replace them, if at all, is hazy at best.** It is this lack of clarity that one must be wary of.

**Second**, the use of Artificial Intelligence in weapons leading to ‘**autonomous weapons**’ raises a number of difficult questions in international law. Whether a machine that has been given the ability to make life and death decisions on the battlefield can adequately account for subjective principles of war such as proportionality and precaution is an issue that has been consistently taken up by civil society groups over the past few years. **The underlying issue here is not that weaponized Artificial Intelligence would be smart, but that it would not be smart enough.**

The consequences of this have been deemed serious enough for the UN to begin deliberating on this issue in an official group of governmental experts forum this November.

**Third, privacy and data security.** It must be remembered that the **entire Artificial Intelligence ecosystem is built on the availability of great amounts of data and enhancing efficiency requires continued availability of such data.** Constant inputs and feedback loops are required to make Artificial Intelligence more intelligent.

This raises the question of where the required data comes from, and who owns and controls it. Facebook, Google, Amazon and others depend on the immense data generated by their users every day, and while the availability of this data may lead to better Artificial Intelligence, it also allows these companies, or anybody else who has access to the data, to piece together a very detailed picture of individual users, something which users themselves may not have knowingly consented to. **The possible authoritarian implications of this, ranging from indiscriminate surveillance to predictive policing, can be seen in the recent plan released by China’s state council to make China an Artificial Intelligence superpower by 2030.**

**DIFFERENTIAL PRIVACY**

Engineers and product managers at Apple’s headquarters at Cupertino these days are obsessed with the idea of embedding artificial intelligence (AI) into every aspect of consumer’s digital touch points. That’s because Apple chief Tim Cook wants AI to be like air, all pervasive yet invisible.

Apple’s stand on protecting user privacy had sort of slowed it down in the field of advancing in AI. This is because Machine learning and AI are based on tonnes of data. This means to get data, the engine needs to collect data from users. But given that Apple has a very strong stand on privacy it took a huge hit on AI development. But with differential privacy, Apple has emerged as a big winner and is back in the game big time.

Differential privacy allows Apple to build AI products that understand users without snooping on their activities. It’s based on anonymising data. Apple adds noises inside data they collect. So even when a hacker comes to hack, he will not be able to connect to a user. For example, if an user takes a picture at a certain location, Apple will introduce 20 more picture from some other location.
so that no one will get to know that the user was at a specific location. This is a huge plus for Apple.

It is necessary to be open-eyed and clear-headed about the practical benefits and risks associated with the increasing prevalence of Artificial Intelligence. It is not going to go “rogue” and turn on humans (at least in the near future), and talk of such a theoretical existential risk must not blind policymakers, analysts, and academics to the very real issues raised by Artificial Intelligence.

**THE REAL ISSUE**

However, there is one reason to fear AI. It’s been shown that AI are sensitive to picking up human biases in the data it learns from, and could also perpetuate stereotypes, like associating the word “doctor” with white males more than any other gender or race. If an AI with that bias were in charge of hiring doctors, it could be unfairly biased against hiring those who aren’t white males. An investigation found that algorithms used to sentence those convicted of crimes were racially biased, recommending harsher sentences to people of color. Healthcare data routinely excludes women, especially pregnant women, leading to systems functioning on incomplete data when making medical recommendations to those people. Since these mechanisms make the same decisions that once required humans with the speed of an endlessly powerful machine, we need to make sure they’re making those decisions fairly and consistently with our ethics.

**ARTIFICIAL INTELLIGENCE (AI)-INDIAN PERSPECTIVE**

**HOW CAN IT BENEFIT INDIA?**

Given no one really understands the enormity of the strides in artificial intelligence/tech, the doomsday predictions of what it will do for jobs could either be quite correct, or totally wrong. And while the progress is truly impressive, it is not clear if this is good enough to destroy the traditional jobs that humans do, nor is it clear what sectors tech will take over, or in what order. For now, what is clear, however, is that countries like India, so far from the productivity frontier, stand to benefit a lot more from tech—not only can this help contribute to dramatically increasing productivity, it can help overcome critical shortages in areas like healthcare and education.

Recently an intelligent first-aid kit developed by Mobilize Rescue Systems gives a hint as to how this could pan out. The emergency kit, that comes equipped with the usual suspects like gauze, bandages, ointments, etc, even has tourniquets, chest seals and clotting agents—the real game-changer, though, is the iPad embedded in its lid. An interactive app, pre-loaded on to the device, has processed data from some 1,600 pages of triage and emergency-response decision-trees to help take the most appropriate, up-to-date course of emergency response. That makes it an on-the-spot manual on how to save a life. It provides step-by-step instructions on using the supplies in the kit to address threats by degree of associated “risk of death” in the case of multiple injuries, via colour-coded illustrations, animations and planograms that play on the screen of the attached device. Such intelligent kits could do to fix India’s broken healthcare system, short of both doctors and expertise, especially in rural or far-flung areas.

India’s education system, as the annual ASER studies show, is in tatters; and with increasing numbers of educated-unemployed, it is clear there is a big gap between what is required and what is delivered. But, include a laptop pre-loaded with good AI-based learning solutions or, say, Coursera-type modules, and there can be a rapid step-up in the quality and relevance of education imparted by teachers aided by smart technology. Big data, going by what the taxman has been saying, is being used to detect tax-fraud and, in the case of agriculture, artificial intelligence and deep learning are coming up with solutions to, for instance, accurately predict crop production and help in timely insurance payouts. In the case of the Railways, use of AI by GE is already helping in predictive maintenance … The list of AI-based solutions is a long one and while there will be areas of large job losses, for now, India is going to benefit a lot more than it can possibly lose.
NEED FOR PRIORITISING AI IN INDIA

In July this year, China announced its ambitious plan to become the world leader in AI by 2030, building an AI-based industry worth $150 billion. China, in fact, has been heavily investing in American AI start-ups, alarming the US government enough for it to seriously consider strengthening its existing strategic foreign investment regulatory mechanism – the Committee on Foreign Investment in the United States (CFIUS).

China’s focus on AI research and development is a calculated move clearly manifested in the intensity of its domestic investments. Large budgets have been allocated to AI advancements within its borders, prioritising cutting-edge fields such as robotics, swarm technology and machine learning. These technologies have immense potential to revolutionize warfare and change future security environments. China’s investments in its universities, research laboratories and companies include huge budgets and state-of-the-art infrastructure, attracting highly skilled researchers and practitioners from around the world, while developing their own workforce in AI and robotics research and development.

India should immediately take note of these exponential developments in its neighbourhood, as its AI capabilities are far inferior to those of the US and China. The present trajectory of AI advancement indicates that future economies and national security will be defined by it, making it among a handful of technologies that will shape global politics.

At present, the bulk of leading AI research is conducted or financed by a few American or Chinese companies, allowing them, and thereby their respective governments, to control access to the technology. If India were to leverage the potential of AI, it is necessary for the government to focus on three basic steps.

SCOPE OF AI IN INDIA

The mapping of India’s existing AI capabilities with a comprehensive survey of every AI focused establishment in the country would be a good place to start. It is important that these assessments record the relatively numerous small start-ups with appropriate knowledge and expertise working in the field. Such detailed mapping would provide accurate estimations of India’s capabilities, especially in comparison to other countries, and strategically optimise its budget in the national and local contexts.

Government support in AI research and development is essential to its advancement, evident in the levels of government engagement in the US and China. The Indian government must provide the necessary policy framework and incentives, including direct funding to select companies, start-ups and research institutions, to ensure targeted capacity development. This becomes especially expedient because India does not have tech giants like Google or Baidu that can provide the investments and resources necessary for developing advanced AI capabilities.

A comprehensive long-term vision of the strategic and military role of AI is the backbone of sustained AI research and development as well as innovation. The vision must cover the various strategic facets of AI, including autonomous weapons and the role of AI in cyber-defence, and formulate distinctive policies for each of them. It is not necessary that these policies be in line with either general international opinion or policy trends in other countries on these issues, as long as they adequately serve national interests. The development of such a comprehensive vision will help the Indian government optimise the allocation of its considerable research capabilities towards the development of specific AI capabilities that would most benefit the country.

The need for India to appreciate and develop the strategic potential of AI cannot be overstated. Delaying the initial push will only widen the technology gap between India and the likes of China. AI will also become central to economic growth, revolutionising everything from manufacturing to innovation and labour market productivity, and potentially doubling the growth rates of the most advanced economies. Given this increasingly pervasive influence, the lack of an indigenous AI capacity will severely compromise India’s future.
Unfortunately, India has traditionally been two steps behind other major powers when it comes to acknowledging the strategic importance of emerging technologies. While the effect of this has been generally limited in the past, such an oversight now will lead to an inexorable gap that could severely affect India’s economic and security capabilities.

### 7. GENE EDITING

**GENE EDITING:** Gene Editing or Genome editing is a type of genetic engineering where a DNA is inserted, deleted or replaced in the genome of an organism to treat a particular disease.

**WHY IN NEWS?**
- Last year, China reported its first successful experiment using gene-editing. Using a technique called CRISPR-Cas9; scientists were able to inject a gene in a patient with lung cancer.
- Recently, United States, has gone a step ahead by editing genes in a human embryo using CRISPR, to correct a genetic mutation that thickens the heart muscle, a condition called hypertrophic cardiomyopathy.

**CRISPR-Cas9:**
CRISPR-Cas9 is a system used by bacterial cells to recognise and destroy viral DNA as a form of adaptive immunity. Using components of the CRISPR system, researchers can remove, add or alter specific DNA sequences in the genome of higher organisms.

The gene editing tool has two components - a single-guide RNA (sgRNA) that contains a sequence that can bind to DNA, and the Cas9 enzyme which acts as a molecular scissor that can cleave DNA. The genetic sequence of the sgRNA matches the target sequence of the DNA that has to be edited. In order to selectively edit a desired sequence in DNA, the sgRNA is designed to find and bind to the target.

CRISPR is the most precise genome-editing tool scientists have at their disposal.

**POTENTIAL OF GENE EDITING:**
- Permanently fixing or “editing” mutated cells, or creating safer and more potent cell-based products with this technology could provide curative, one-time treatments for patients suffering from a broad range of diseases. (eg. HIV)
- To correct genetic mutations that may cause disease: Correcting the mutation in the gene would not only ensure that the child is healthy but it would also prevent the mutation from being passed on to future generations. (eg. Diabetes, Cancer that are partly genetic)
Useful in confirming the function of various genes.

In agriculture: For improving crops. (eg. introduction of mutations or other genetic changes into plants can enhance breeding of certain crops such as rice and wheat.)

Organ transplants: In a striking advance that helps open the door to organ transplants from animals, researchers have created gene-edited piglets cleansed of viruses that might cause disease in humans.

CONCERNS: The promise of this technology is tremendous, as are the potential pitfalls:

- Could be used to create *designer babies*: possibility of altering embryos to create desired characteristics.
- Safety concerns: The possibility of CRISPR-Cas9 system recognising and cleaving different regions of the genome than the one that was intended to be edited. These “off-target” changes are very likely to take place when the gene-editing tool binds to DNA sequences that are very similar to the target one.
- Problem of accessibility: If everyone cannot access the resulting benefits of gene editing, it will be problematic (given the genetic technologies are expensive)
- Chances of misuse: According to experts, the technology involved is comparatively simple, and there is a “do-it-yourself” movement under way, with community labs training laypeople in basic molecular biology techniques. Therefore, there is a need to look into what regulations could be put into place to monitor this, and also look at how current and future regulations differentiate between private- and publicly funded laboratories.

GENE EDITING AND INDIA:

India is not at the forefront of this science but, it could take the lead in starting an international discussion about access to gene editing technology. Domestically, the government should consider asking Indian scientists to both develop capabilities in this field and consider how it can benefit Indians medically, but in an economically inclusive manner.

8. DNA PROFILING BILL

DNA Analysis: DNA analysis is an extremely useful and accurate technology in ascertaining the identity of a person from his/her DNA sample, or establishing biological relationships between individuals. A hair sample, or even bloodstains from clothes, from a scene of crime, for example, can be matched with that of a suspect, and it can, in most cases, be conclusively established whether the DNA in the sample belongs to the suspected individual. As a result, DNA technology is being increasingly relied upon in investigations of crime, identification of unidentified bodies, or in determining parentage.

WHY IN NEWS:

- Recently, the Centre informed the Supreme Court that it was preparing to finalise a fresh version of the DNA Fingerprinting Bill, a draft of which was ready in 2015 but could not be introduced in Parliament.
- Also, the Law Commission of India (in its 217th Report) released a revised draft of the Bill that is now called The DNA Based Technology (Use and Regulation) Bill, 2017 with some very important changes.

THE DNA BASED TECHNOLOGY (USE AND REGULATION) BILL, 2017

The key features of the draft Bill include:

- DNA Profiling Board: A DNA Profiling Board will be constituted as a statutory body which will be responsible for supervising, monitoring, inspecting and assessing DNA laboratories. It will advise central and state governments on “all issues relating to DNA laboratories”. It will also be the authority to make recommendations on ethical and human rights, including privacy, issues related to DNA testing.
- DNA Data Bank: The Bill proposes a National DNA Data Bank and Regional DNA Data Banks (for the states). The data banks will be responsible for storing DNA profiles received from the accredited laboratories. All regional DNA databanks will be mandated to share their information with the national databank. The databanks will maintain five sets of databases —
for DNA samples picked up from crime scenes, for suspects or undertrials, and for offenders, missing persons, and unidentified dead bodies.

- **Certain DNA Profiling Board-accredited labs** would be authorised to carry out DNA testing and analysis. These are the only places to which DNA samples, picked up from a crime scene, for example, by police, can be referred for analysis. Data from the analyses will need to be shared with the nearest regional DNA databank which will store it and share it with the national databank.

- **Only for identification**: DNA profiling would be undertaken exclusively for identification of a person and would not be used to extract any other information. Further, no bodily substances will be taken from a person unless consent is given for the same.

- **Samples picked up** from a crime scene, belonging to those who are not offenders or suspects, would not be matched with the databases. Such DNA profiles would have to be removed from the records on a written request from the individual concerned.

- **The penalty for misuse of data** remains a prison term of up to three years and a fine up to Rs 1 lakhs.

**BENEFITS OF DNA PROFILING LAW:** Over the last 25 years, most countries have adopted a DNA fingerprinting law and have developed databases for use primarily in criminal investigation (by helping to convict serious criminals, connect seemingly unrelated crimes and possibly even preventing crime), useful in aftermath of natural disasters (disaster victim identification) and forensic science.

**OBJECTIONS:**

- **Whether DNA technology is foolproof**: It has been argued that although DNA technology is the best method available to carry out this kind of identification, it is still probabilistic in nature. There are chances, however remote, that a wrong match is generated. If the DNA result is taken as the ultimate evidence, no recourse will be available to an individual who has been wrongly matched.

- **The potential for misuse of the technology**: Information from DNA samples can reveal not just how a person looks, or what their eye colour or skin colour is, but also more intrusive information like their allergies, or susceptibility to diseases. As a result, there is a greater risk of information from DNA analysis getting misused. The bigger issues with the draft Bill lie with how it plans to safeguard the privacy of the people whose DNA profiles will be stored in the databank, the safeguards the samples and databanks will have against contamination and theft, and the terms of use and availability of the profiles among law enforcement officials, scientists and foreign agencies. These issues are analogous to the implementation of Aadhaar as a unique identifier for the citizenry.

- **Individual Rights**: Missing a number of safeguards that would enable individual rights. These include a right to notification of storage and access to information on the DNA databank, the right to appeal and challenge storage of DNA samples, and right to access and review personal information stored on the DNA Data Bank.

- **Right to Privacy ruling**: Now that the Supreme Court has upheld Right to Privacy, chances of the bill being shelved is high unless all privacy and safety regulations are taken into account. Especially, when something concerns a bodily right such as the DNA of an individual, he would reserve the ultimate to invoke the breach of right to privacy as a fundamental right.

As society continues to rapidly become more and more data centric, and that data increasingly is a direct extension of the person, it is critical that legislation that is developed has clear protections of rights. In addition to amendments to the text of the draft DNA Bill, this includes enacting comprehensive privacy legislation in India. Policies need to evolve and extend to protections that are comprehensive — accounting for process and enabling the individual to control and know how her/his data is being used and by whom. Other countries have recognised this and are taking important steps to empower the individual. India needs to do the same for its citizens.