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NEWS LETTER
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U.S. Surgeons Successfully Test Pig Kidney Transplant In Human Patient

NEW YORK, For the first time, a pig kidney has been transplanted into a human without triggering immediate rejection by the recipient's immune system, a potentially major advance that could eventually help alleviate a dire shortage of human organs for transplant. The procedure done at NYU Langone Health in New York City involved use of a pig whose genes had been altered so that its tissues no longer contained a molecule known to trigger almost immediate rejection.

The recipient was a brain-dead patient with signs of kidney dysfunction whose family consented to the experiment before she was due to be taken off of life support, researchers told Reuters. For three days, the new kidney was attached to her blood vessels and maintained outside her body, giving researchers access to it.

Test results of the transplanted kidney's function "looked pretty normal," said transplant surgeon Dr. Robert Montgomery, who led the study. The kidney made "the amount of urine that you would expect" from a transplanted human kidney, he said, and there was no evidence of the vigorous, early rejection seen when unmodified pig kidneys are transplanted into non-human primates. The recipient's abnormal creatinine level - an indicator of poor kidney function - returned to normal after the transplant, Montgomery said.

In the United States, nearly 107,000 people are presently waiting for organ transplants, including more than 90,000 awaiting a kidney, according to the United Network for Organ Sharing. Wait times for a kidney average three-to-five years. Researchers have been working for decades on the possibility of using animal organs for transplants, but have been stymied over how to prevent immediate rejection by the human body.

Montgomery's team theorized that knocking out the pig gene for a carbohydrate that triggers rejection - a sugar molecule, or glycan, called alpha-gal - would prevent the problem.

The genetically altered pig, dubbed GalSafe, was developed by United Therapeutics Corp's (UTHR.O) Revivicor unit. It was approved by the U.S. Food and Drug Administration in December 2020, for use as food for people with a meat allergy and as a potential source of human therapeutics. Medical products developed from the pigs would still require specific FDA approval before being used in humans, the agency said.

Other researchers are considering whether GalSafe pigs can be sources of everything from heart valves to skin grafts for human patients.

The NYU kidney transplant experiment should pave the way for trials in patients with end-stage kidney failure, possibly in the next year or two, said Montgomery, himself a heart transplant recipient. Those trials might test the approach as a short-term solution for critically ill patients until a human kidney becomes available, or as a permanent graft.

The current experiment involved a single transplant, and the kidney was left in place for only three days, so any future trials are likely to uncover new barriers that will need to be overcome, Montgomery said. Participants would probably be patients with low odds of receiving a human kidney and a poor prognosis on dialysis.

"For a lot of those people, the mortality rate is as high as it is for some cancers, and we don't think twice about using new drugs and doing new trials (in cancer patients) when it might give them a couple of months more of life," Montgomery said.

The researchers worked with medical ethicists, legal and religious experts to vet the concept before asking a family for temporary access to a brain-dead patient, Montgomery said. (Source: Reuters)

API Price Hike Hits Pharma Units

A steep rise in the prices of raw materials, including active pharmaceutical ingredients (APIs), which are largely imported from China, has adversely affected the sector, especially the micro small and medium sector enterprises (MSME), in the state. The industry is demanding a task force at the Centre to tide over the crisis. 550 manufacturers hit . The steep hike has enhanced the capital induction by three times, hitting the survival of 550 units. The situation has come to such a pass that the manufacturing of several drugs can go off the shelf if the prices are not controlled. Rajesh Gupta, President, HDMA.

The pharmaceutical industry has been battling the price rise ever since Covid hit the world. Price rise ranging from 25 per cent to 300 per cent has been registered in APIs and other raw materials from the pre-Covid era, threatening the viability of MSME units. "The steep hike has enhanced the capital induction by three times, hitting the survival of 550 units. The situation has come to such a pass that the manufacturing of several drugs can go off the shelf if the prices are not controlled," said president, Himachal Drug Manufacturers Association (HDMA), Rajesh Gupta.

Since the MSME units are finding it difficult to operate under such circumstances, the Himachal Drug Manufacturers Association (HDMA) is demanding the constitution of a pharmaceutical raw and packaging material task force to protect the industry and avoid the shortfall of medicines. "The prices of APIs like paracetamol, which stood at Rs 300 per kg in the pre-Covid era, have now increased to Rs 900-Rs 1,000 per kg," added Gupta. SL Singla, adviser, HDMA, said, "A substantial decline has been registered in the production of paracetamol-based drugs and several other formulations due to hike in the price of its API. The government should act fast to devise a mechanism to check the price rise."

"The task force can include members of related ministeries like the Health and Family Welfare, the Ministry of Chemicals and Fertilisers, the Ministry of Commerce and Niti Ayog. They should keep a watch on the manufacturers of bulk drugs and their price," said Gupta. Prices of exicipients and solvents, used to aid manufacturing, like glycerin, propylene glycol, iso propyl alcohol have registered a steep hike. "Mono cartons and corrugated packaging prices have increased from 25 to 40 per cent while the PVC price, used for blistering of tablets and oral liquid bottles, has shown a steep increase from 25 per cent to 30 per cent. Vials, ampoules, flip-off seals, butyl seals too have registered a hike in their price," said Munnish Thakur, association general secretary.

Not only this, the freight of containers for import and export has gone up 6 to 9 times compared to the pre-Covid era globally owing to their shortage. Even the logistics have registered an increase of 10-20 per cent owing to the hike in the prices of petrol, diesel and CNG. Though an extensive data pertaining to these facts were compiled and submitted through the Chief Minister to the Prime Minister's Office almost a year back, little has been done to take preventive measures, rue investors, who are now demanding an early resolution to the problem. (Source: The Tribune)

Sehat Sathi Plans to Enable Over 25,000 Medicine Shops go Online

The app helps standalone pharma stores to go digital without any need for investment in technology Sehat Sathi, a B2B app that helps in digital transformation of local pharmacies, is planning to digitise over 25,000 stores in south India over the next 18 months. "As of today, we have a good presence in Kerala and in some parts of Bengaluru. In the next 12-18 months, we will try to cover 25,000 medical stores in the five southern States and our focus will be on pharmacies in tier-2 and tier-3 cities," Shreyans Mehta, Co-Founder, Sehat Sathi, told BusinessLine. Developed in 2017 by Mehta along with Nikhil Baheti and Saida Dhanavath, Sehat Sathi enables standalone pharmacy stores to take their business online within minutes without any need for investment in technology. Developed by online healthcare platform MedCords, Sehat Sathi is integrated with a consumer facing app Aayu, which helps end-users to search for medicines in the nearby area and get them delivered at their doorsteps.

"According to statistics, there is only one pharmacy available for every 1,700 people. So, we have built Sehat Sathi to provide efficient, quick, affordable and trusted healthcare solutions not just to people in the metros but also for those in smaller towns Bharat," Mehta said. Launched in Kota district of Rajasthan, Sehat Sathi today has a network spanning 600 towns/cities spread across 15 States. It claims to have digitised 30,000 pharmacies, enabling last mile delivery of healthcare services and products to more than 35 lakh families. The company is looking to expand its network and digitise 50,000 pharmacies across the country by the end of 2021.

Sehat Sathi has two revenue streams. While it does not charge anything from the medical stores, it charges from companies to list their products in its pharmacy network. The other source of revenue is through e-consultations services. "Today, we are able to provide medicine deliveries in less than two hours through our medical store partners. We also offer online consultation services with over 5,000 specialist doctors in less than 30 minutes," Mehta said.

The Covid-19 pandemic gave a push to telemedicine consultation. E-pharmacy growth also helped the company to scale-up faster. "We have grown our medical store network 30x in less than 12 months and all that happened only through word-of-mouth because offline pharmacies are realising the value of digitisation and are quickly adapting to technology," Mehta said. According to an EY report, the Indian e-pharmacy market was estimated at $0.5billion in 2019 and is projected to reach $4.5 billion in 2025 growing at a CAGR of 44 per cent. The report also noted that e-pharmacy is projected to represent about 10-12 per cent of the total pharmaceutical sales by 2025 up from current 2-3 per cent levels in 2019. Sehat Sathi has two revenue streams. While it does not charge anything from the medical stores, it charges from companies to list their products in its pharmacy network. The other source of revenue is through e-consultations services. (Source: Business Line)

Merck Wants Americans to Pay $712 For a Covid Drug That Taxpayers Helped Develop

Last week, Merck is planning to charge Americans 40 times its cost for a Covid drug whose development was subsidized by the American government. The situation spotlights two sets of facts that have gone largely unmentioned in the legislative debate over whether to let Medicare negotiate for lower drug prices. Fact one: Americans are facing not merely expensive drugs but prices that are examples of outright profiteering. Fact two: in many cases, the medicines we are being gouged on are those that we the public already paid for. These facts show us that pharma-bankrolled Democrats trying to kill drug pricing measures aren't just bought and paid for in this particular skirmish – they are foot soldiers in the pharmaceutical industry's larger multi-decade campaign to seal off and rig America's alleged "free market".

First, there's the price point of drugs. It's not merely that Americans are paying the world's highest prices for pharmaceuticals, it's that in many cases, we are paying prices that aren't even *close* to what consumers in other countries pay. A new Public Citizen analysis shows that the 20 top-selling medicines generated almost twice as much pharmaceutical industry revenue in the United States as in every other country *combined*. Sure, compared with others, Americans may buy a lot of prescription drugs, but this study reflects something much bigger at play: pharma-sculpted public policies that allow drug price levels to go beyond profits and into profiteering.

That term "profiteering" is important here because drugmakers aren't losing lots of money in other countries where they sell medicines at lower prices. Let's remember: pharmaceutical companies aren't altruistic charities that offer their products abroad at a loss. On the contrary, they are *still* making healthy profits at lower world-market prices – and as the Intercept's Lee Fang notes, they are making those healthy profits while boasting of innovation and job growth in countries that have allowed their governments to use bulk purchasing power to negotiate lower prices. The same arrangement could happen in the United States. We could significantly reduce medicine prices, which would save Medicare and individual consumers hundreds of billions of dollars, and in the process we would do little to significantly reduce pharmaceutical innovation. Indeed, a recent Congressional Budget Office study projected that even if profits on top drugs decreased by a whopping 25%, it would only result in a 0.5% average annual reduction in the number of new drugs entering the market over the next decade.

The reason that reduction in new drugs would be so small gets to the other inconvenient fact being left out of the conversation in Congress right now: for all the pharmaceutical industry's self-congratulatory rhetoric about its own innovations, the federal government uses your tax dollars to fund a lot of that innovation, research and development. All of this underscores how corrupt and insane the current conversation in Congress really is A study from the National Academy of Sciences tells that story: the federal government spent $100bn to subsidize the research on every single one of the 200-plus drugs approved for sale in the United States between 2010 and 2016. Because we the public invested early in these medicines, we reduced the R&D costs for pharmaceutical companies. Therefore, on the back end, the public should have received some sort of return in the form of affordable prices. After all, we took the initial risk, and we lowered the overhead costs that the drug companies might need to recoup through higher prices. In business terms, the public is the early venture investor in these products, and we deserve a share of the returns when the product proves valuable.

However, in the mid-1990s, that business axiom was tossed out when drug lobbyists persuaded the Clinton administration to repeal rules that allowed federal officials to require government-subsidized drugs to be offered to Americans at a "reasonable price". A few years later, Congress – with then-Senator Joe Biden's help – voted down legislation to reinstate these rules, and later the Obama administration rejected House Democrats' request that federal officials at least provide guidelines to government agencies about how they can exercise their remaining powers to combat drug price gouging. The result: we now routinely face immoral situations like last week's news that pharmaceutical giant Merck is planning to charge Americans $712 for a Covid drug that cost only $17.74 to produce and whose development was subsidized by the American government.

That's just the latest example of the absurd paradigm: we take the risk of investing early in the product, but instead of that investment reaping us something valuable like affordable prices, we are rewarded with price gouging by the drugmakers that bankroll the lawmakers who've rigged the rules – and aim to keep them rigged. All of this underscores how corrupt and insane the current conversation in Congress really is – and in truth, it's way more corrupt than it even seems on the surface. We aren't merely watching pharma-bankrolled lawmakers try to stop Medicare from negotiating lower prices for drugs – they are trying to stop the government from negotiating lower prices for medicines that the government *already* paid for, and that we are being charged the world's highest prices for. This opposition is just the latest crusade to keep the American market walled off for maximum manipulation. Laws written by drug lobbyists prohibit wholesalers from importing lower-priced medicines from other countries, give drug companies 20-year patents on government-subsidized medicine, prevent the government from requiring reasonable prices for drugs the government pays for and block Medicare from using its bulk purchasing power to negotiate lower prices. (Source: The Guardian)

36% of USFDA's Market Authorisations in 2020 Went to Indian Drug-Makers

In what can be seen as an indication of the primacy of India's pharma industry, 36 per cent of total market authorisation granted by the US Food and Drug Administration (USFDA) in 2020 was to drug makers from India. "This accounts for 36 per cent of a total of 1,438 market authorisations granted by the USFDA in calendar 2020 and we can take it as a positive sign with potential to boost business growth and exports going forward,"

R Uday Bhaskar, Director-General, Pharmaceutical Export Promotion Council (Pharmexcil), an arm of the Ministry of Commerce, told *BusinessLine*. ANDA approvals Market authorisations are approvals given to Abbreviated New Drug Applications (ANDAs) that allow companies to launch a product in the US market. Thus, higher market authorisations implies greater access to the US market and can boost business performance of individual players as well as overall exports of the country.

"All market authorisations may not immediately translate into revenue and export growth. It depends on the timing of launch of the product. But this is a crucial step in taking India's products to the US market,'' he said. The number of sites registered with the USFDA both for formulations as well as bulk drugs in India stands at 741 as of now. This has also been helping drug-makers have a smooth sail in obtaining ANDA approvals.

Pharma exports The higher number of market authorisations also contributed to growth of pharma exports last year. In FY21, pharma exports rose 18 per cent at $24.4 billion ($24,469 million), which was the highest in the last seven years. In FY20, pharmaceutical exports were at $20.7 billion. Industry experts expect better performance in the current year in ANDA approvals. "As approval for an ANDA after filing takes about a year or so, those approved last year may not have included many Covid-related products. But this year, things may be better as research on Covid-19 related products and other therapeutic areas has been progressing well," the Vice-President of a Hyderabad-based listed pharma company said. There has been a 'good pipeline' of ANDAs with leading Indian players that might qualify. First To File (FTF) status in market authorisations with exclusive rights for the first six months which would push up revenues, he added. According to Industry estimates, oncology and immunology are expected to grow at a high rate of 9-12 per cent during the next five years while vaccines are likely to clock 15 per cent growth. As of now, India is ranked 10th among the top ten formulations exporting countries and is the 11th largest market. It is expected to be ranked the ninth largest market by 2025. (Source: Business Line)

Covaxin Shot Recommended For Children In India

New Delhi: An expert panel on Tuesday recommended Covaxin - Bharat Biotech's COVID-19 vaccine - for use on children between the ages of two and 18. "Bharat Biotech has submitted data from clinical trials in the two - 18 age group for Covaxin to CDSCO (Central Drugs Standard Control Organisation). The data has been thoroughly reviewed by the Subject Expert Committee (SEC)... provided positive recommendations," the Hyderabad-based company said. "This represents one of the first approvals worldwide for COVID-19 vaccines for the two - 18 age group... We now await further regulatory approvals prior to product launch and market availability of Covaxin for Children," the company said.

That final approval - viewed as a formality - will be given by the Drug Controller General of India. When it does come, Covaxin will be only the second vaccine cleared for use on kids in India; in August Zydus Cadila's three-dose DNA jab was allowed to be used on adults and children over 12.A third potential vaccine for kids is Serum Institute's Novavax, for which the DCGI last month cleared trials for children between seven and 11 years. A fourth is Biological E's Corbevax, which has been cleared to conduct advanced trials on children above five. Last week manufacturers Bharat Biotech said it had submitted data on vaccine trials on children.

The Covaxin vaccine tested on children is the same formulation as used on adults, but separate trials were needed to guarantee safety and efficacy on younger recipients. Data on these trials has not been made public yet, but tests were conducted on 1,000+ children across the country. The panel, however, noted the trial on kids showed similar efficacy rates as that on adults. Data on the vaccine's efficacy (for adults) was submitted to the DCGI in June; the data indicated Covaxin is 77.8 per cent effective in protecting against the virus. India is slowly turning its focus towards vaccinating children against the coronavirus, having administered nearly 96 crore doses to adults. Dr Randeep Guleria, chief of Delhi's AIIMS, has stressed that children in the two-18 age group must be vaccinated "because that's the only way to get rid of the pandemic".

Earlier this month Dr NK Arora, the chief of India's vaccine task force, told news agency ANI that children with severe comorbidities would be prioritised and that other (healthier) kids would be immunised subsequently. "We are trying to identify (children) at highest risk... within the next couple of weeks, the list will be in the public domain. We are also making arrangements so these children do not have to travel (too far) to get the vaccine..." he said. As schools re-open and students (and teaching and non-teaching staff) return to classrooms, concerns have been expressed over a spike in cases and the possibility of children being infected, as well as the need to also vaccinate adults working at schools. India has so far fully vaccinated less than 30 crore of its 130 crore population. Meanwhile, the World Health Organization has yet to grant Covaxin an EUA, or emergency use authorisation. Following delays in the process - the WHO had asked Bharat Biotech for additional trial data - a decision is expected next week. Without an EUA, Covaxin will not be accepted as a valid COVID-19 vaccine by most countries around the world. This means Indians who received the jab will be forced to qarantine when travelling abroad, unlike those who received SII's Covishield. (Source: NDTV)