

Handling Dangerous Goods Requires Technical Competence



Gubba's
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Certified
in handling Pharma
Dangerous Goods

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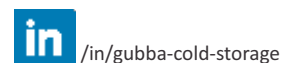
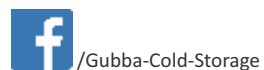
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Once India's richest man, this pharma tycoon valued his anonymity over wealth

(Dilip Shanghvi worked his way up from a tiny shop in the bylanes of Kolkata in the 1970s to create one of India's most valuable enterprises—Sun Pharmaceuticals. The billionaire is known for his frugal and reticent ways.)

Shanghvi's ascension to the peak of the Indian pharmaceuticals pyramid nearly coincided with a much larger historic event, not only for him (though he is likely to dismiss it), but for the country. Celebrated rich lists had already pronounced him the world's wealthiest pharma entrepreneur, Asia's only non-wealthy tycoon in the top ten wealthiest men, richest self-made Indian, but none of it had had the earth-shattering effects to them, as the pronouncement made by Forbes and Bloomberg in March 2015.

Shanghvi with his net worth pegged at \$21 billion (Rs1.5 lakh crore at current rates) had dethroned Mukesh Ambani to become the richest Indian. Albeit short-lived, not to last beyond months, it was a moment of axial tilt for India in many ways—and not the least because the Ambanis, who had been a synonym of wealth and power in the collective memory of this country, had never been toppled from that much-envied seat since the wealth indices started applying to this part of the world. In a welcome change, India's richest man hadn't inherited his riches; hadn't earned his fortune through cronyish connections or government concessions—common in sectors like energy, infrastructure or even telecom; hadn't multiplied wealth by some gamble in finance or real estate. Shanghvi

had earned his wealth not even by building a conglomerate, but by dint of focusing just on one sector—pharmaceuticals.

In a welcome change, India's richest man hadn't inherited his riches.

American academic Caroline Freund bracketed him in a select list of "Schumpeterian" entrepreneurs, who were building and managing big companies that fought for their lives in the global markets, "a healthy consequence of structural transformation and rapid development" of the (country's) economy. Yet, you don't have to be a businessman in India to know that cronyism is far from dead. But Shanghvi's climb to the zenith of the wealth ladder stood for a hope, that meritocracy still has a chance. As the news spread like wildfire, Indians beyond the finance world, doctors, and the pharmaceuticals industry woke up to a surname—Shanghvi, and the man who so prized and preserved his oblivion became a subject of national curiosity.

Pink papers realised that despite knowing him, they knew very little of his personal story to satisfy that curiosity. In that state of ill-preparedness, editors struggled to find a league to put Shanghvi in. Newsrooms debated whether he seemed closer to the league of Narayana Murthy and Azim Premji, but rejected it on the ground that he had shown far little commitment to philanthropy. They were in consensus that he surely didn't belong to the league of the Ambanis or Adanis, and was far removed from the Tatas and Birlas. Without exception, all

financial magazines and newspapers scrambled for an appointment with him and with or without managing one, put him on cover and page ones.

Shortly after, on a trip to China for his company's annual star awards on a rented private chartered plane, when Shanghvi was explaining to friend Sailesh Desai why he thought eggs are not non-vegetarian, his then India CEO Abhay Gandhi walked up to the magazine stands and started to flip through the pages.

Shanghvi didn't belong to the league of the Ambanis or Adanis.

Desai called him from behind, asking, "Is there anything worth reading?" Gandhi turned around holding up two magazines—Business Today and Outlook Business, both of which had the same face on their covers—Shanghvi's. This newly aroused curiosity about him spilled over to social media with questions on Quora like "Why is Dilip Shanghvi not much talked about as compared to Mukesh Ambani even though he's the richest person in India?" and "Why is India's richest person (Dilip Shanghvi) so simple when compared to some of India's richest men?"

His profiles on web multiplied by the day, and a Twitter handle that was not his surfaced and continued to tweet opinions on his name for well over two years. A friend Piyush Doshi, who had once messaged him saying he was not happy to see him at No. 2 on India's rich list, because he hoped to see him at No. 1, finally punched a congratulatory text. The boy Jai Shah who had seen him lift buckets of water from a common tube well for bath in the Paddapur building in Calcutta, gasped with excitement as he compared the "extravagant opulence of Ambanis with the austere living of Dilip uncle."

A wife of a friend who had not a long time back seen him fix the dent of their Maruti

800 turned emotional at the mention of his name. "No stars in his party, no guards by his side, no twenty-seven floors in the prime of Mumbai, no private jets parked on the roof, his is a lifestyle so simple that it can shame people with one-hundredth of his net worth," Jaya Butta, wife of friend Ashok Butta, says. And how did the man who did it take it? Reluctant, very reluctant to lose his anonymity and be recognised as India's richest self-made billionaire. To those who called to congratulate, he used logic to cite how the indices had got their maths wrong.

He particularly misses experiences like sneaking into small south Indian tiffin shops like Ram Ashreya in Matunga (Mumbai) on Sunday mornings to relish his idli-sambhar. A friend recalled someone walking up to him in the modest restaurant one day to tell him, "Hey, you look so much like Dilip Shanghvi! If I hadn't spotted you in this crappy place, I would have surely mistaken you for him."

Shanghvi has stopped going for his Sunday tiffins now, but his friends still pack his favourite south Indian dishes for him, and drop it at his place after their get-togethers. "I am not comfortable at all with this tag of 'the richest Indian' and all the attention that follows for the reason," Shanghvi, for whom this label is more a distraction than a badge, said.

Benny Klener, his then global head of manufacturing, who had joined Sun from Teva, recalled an instance where Shanghvi offered him a lift. He stepped in to appreciate the fancy make of his customised limousine—a silver-grey Audi. But still new to the Sun chief's ways, he was surprised to hear his tone, almost apologetic, about using his luxury sedan.

"For me a car is a car. It's meant to serve the purpose of taking you from the source to the destination. But a few things in life you start doing because others strongly expect you to. To a business dinner party, you cannot wear slippers, even if at the end of a busy day they are the most comfortable wear. You have to wear formal shoes not to show up as an oddball and draw unnecessary stares. To me, this car is like those formal shoes, which you use not to be singled out for showing off your austerity."

And then Shanghvi's car moved on, because for him success has never been a destination.

Source : qz

Editor's Letter



Dear Readers,

It's great to have this newsletter delivered to you. We compile some interesting and informative bits happening in the industry. We strive to provide the best of information in the limited available resources.

'Pharma Vision 2020', has made the Indian Pharmaceutical Industry excited about the growth prospects and the light of economic ecstasy. Mc.Kinsley analysis projects Indian pharmaceuticals market growth to USD 55 billion by 2020 driven by a steady increase in affordability and a step jump in market access. India is close to the top of the trajectory of Pharma manufacturing world. The wall between MNCs and local players in terms of production and supply chain activities is fast blurring. Government of India aims to make India a global leader in end-to-end drug manufacturing. Being host to over 10,500 manufacturing units and 3,000 pharma companies, the prospects of growth are bright. We hope for a multi dimensional growth of Indian Pharma sector.

Hope you enjoy reading this issue!

Mail your comments at : deepthi@gubbagroup.com | support@gubbagroup.com

Gubba Kiran
CEO

Gubba Cold Storage Ltd.
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UPCOMING EVENTS OF THE INDUSTRY

Name of the event	Dates / Month	Location
PHARMA Pro&Pack Expo	19 – 21, Sep 2019	HITEX Exhibition Center Trade Fair Office Building, Izzathnagar, Kothaguda, Hyderabad, Telangana
 INDIA LAB EXPO	19 – 21, Sep 2019	Hyderabad, Telangana
International Patient Safety Conference	13 - 14, Sep 2019	Novotel Hyderabad Convention Centre Hyderabad, Telangana

CURRENT AFFAIRS

Pharma takes Wi-Fi targeting to the doctor's office to reach waiting patients on their smartphones



Checking your phone at the doctor's office? Don't be surprised if you get an ad for a drug you can talk to your doctor about. Data-as-a-service provider Semcasting is using IP address targeting to serve messages to patients' smartphones while they're waiting at appointments.

In a campaign beginning for an unnamed PCSK9 inhibitor, for instance, thousands of cardiologists' offices in Semcasting's Wi-Fi "Smart Zones" will send messages to waiting room patients. People who log into the Wi-Fi network—and opt in for ads—to

browse the web, read news or even play app games like Candy Crush will be served banner messages suggesting that they have a conversation about the particular PCSK9 brand with their doctor. The aggregated cardiology offices in the campaign have an average 21 minutes of waiting time Wi-Fi use, said Matthew Hedberg, Semcasting's VP and general manager of professional services.

While he declined to name the brand, only two PCSK9 inhibitors are currently on the market: Amgen's Repatha and Regeneron and Sanofi's Praluent. The two brands have battled not only each other but also payers. Praluent most recently slashed its list price by 60% in February to match the \$5,850 that Amgen had cut Repatha to in October.

While Semcasting specifically cordons off the Wi-Fi data collected around doctors' offices, hospitals and other healthcare centers for privacy and compliance, it can use some of the data, such as average time spent on Wi-Fi, to evaluate whether a campaign would likely be effective in a particular area. It can then put together Wi-Fi delivery programs for pharma and healthcare clients to deliver to desired office locations. On the back end of the campaign, healthcare analytics firms like Crossix do comparative analysis and result reporting on things like prescriptions written.

"There are incredible inefficiencies in delivering messaging to patients when they're in the point of care setting," Hedberg said. "Most of that revolves around the difficulty and cost of setting up physical displays in various offices, permissions required from the offices, delivering the materials, auditing the materials, taking down those materials and of course, the cost of production."

Digital delivery removes that hassle as well as expense, and per Semcasting, also delivers results. On average, campaigns result in a 1.5x increase in sales and a 10% halo brand effect, which is in line with a traditional POC campaign, Hedberg said.

Previous clients include an OTC pediatric drug, an acute migraine drug company and a pharma involved in rare disorders of lymphoma, he said, with 10 pharma and healthcare campaigns done since 2018 and five more in the works before the end of the year.

Source : [fiercepharma](http://fiercepharma.com)

New organisational structure at Fortis Healthcare



Fortis Healthcare Limited has announced a new organisational structure, with key leadership changes.

The organisation has announced Sanjay Sinha as the new CHRO. Prior to joining Fortis, he pursued his own entrepreneurial venture, called QUERENCIA, a management consultancy firm, as its founder and CEO. He has also worked with Hinduja Tech Limited as Sr VP and Global Head of HR, with Hinduja Global Solutions as Executive VP-M&A (HR) and New Initiatives, as well with Nortel Networks as Director-HR, and with Lucent, HFCL Infotel Limited, Siemens Ltd and Polaris Software Lab. Fortis Healthcare did not have a CHRO or CPO since veteran Rajiv Kapoor, then CPO, left in June 2016.

However, all focus is on the zonal reshuffle of the business leaders. As per the new structure, Raj Gore, COO, earlier south and west, would now be looking after the units of FMRI, FEHI, and the units of Noida, Shalimar Bagh, CDOC, Vasant Kunj, Noida, Faridabad and Gaziabad. Raj is one of the most dynamic and affable leaders of the industry with excellent business acumen.

And Ashish Bhatia as COO would now look after the units of Mohali, Kangra, Mulund, Vashi, Kalyan, SL Raheja, besides all four units of Bengaluru (BG Road, CG Road, Rajaji Nagar and Nagar Bhavi) and remaining two units of Punjab (Amritsar and Ludhiana) as well as Rajasthan (Jaipur, Bikaner and Udaipur). Former Group COO of Fortis, Bhatia is one of the most popular and well-revered industry leaders. (And as known to many of my friends, he is one of my most favourite leaders as well).

As per the new structure, Richa Debgupta has been designated as VP-Operations in charge of Anandpur, FHKI, Raigarh, Arcot Road, Malar and La Femme. Fortis has recently announced the appointment of Dr Ashutosh Raghuvanshi as Group CEO and MD and Vivek Kumar Goyal as its new CFO. Heartiest congratulations to all!

Source : linkedin.com

Former FDA Commissioner Scott Gottlieb joins Pfizer's board of directors



Scott Gottlieb, who stepped down as Food and Drug Administration Commissioner in April, will join Pfizer's board of directors, the company announced.

Gottlieb resigned from the FDA this spring after nearly two years at the helm. During his tenure, Gottlieb advanced a number of prescription drug policies, including to push the FDA to speed up generic drug approvals and use its powers to encourage wider use of biosimilars, or copycat versions of complex and often costly biologic drugs.

Biosimilar manufacturers, including Pfizer, have complained about roadblocks stalling biosimilars from becoming widely used. Having Gottlieb to advise the company could help Pfizer, one of the largest biopharmaceutical companies, navigate the landscape.

CEO Albert Bourla, who succeeded Ian Read on January 1, shuffled the company's senior management team last year and is leading the effort to restructure the pharmaceutical giant into a more nimble company. Pfizer announced plans last July to reorganize into three units, separating out its consumer healthcare business that it had been trying to sell.



"We are fortunate to have Dr. Gottlieb join Pfizer's Board of Directors," Pfizer Executive Chairman and former CEO Ian Read said in a statement. "Scott's expertise

in health care, public policy and the industry will be an asset to our company and enable our shareholders to continue to benefit from a Board representing a balance of experience, competencies and perspectives."

Since leaving the FDA, Gottlieb has returned to the American Enterprise Institute as a resident fellow and as a special partner at venture capital firm New Enterprise Associates, where he worked before joining the FDA. He also joined CNBC as a contributor.

Source : usatoday



Lupin gets employees to take 'ownership' of quality at its manufacturing plants

Four of drugmaker's sites are facing USFDA regulatory actions

Drugmaker Lupin is embarking on a quality transformation initiative at its manufacturing plants, to train employees to take greater ownership, says Managing Director **Nileshe Gupta**.

Recounting a recent discussion with sister and Chief Executive Officer Vinita Gupta, Nileshe told BusinessLine that they felt **"ownership of quality has to be at site, has to be owned by the site, that's what we have to drive."**

Interestingly, Nileshe is clear that the transformation programme will not involve consultants. **"Ownership has to happen, that is a core fundamental we are driving in this project. This is something we are starting now, as I see it, it is a three-year project. We will do a lot of good stuff in the first year itself,"** he said.

USFDA action

Many Indian companies when faced with regulatory action from the United States Food and Drug Administration (USFDA) have appointed consultants, often foreign ones, to help navigate turbulent waters. Four of Lupin's sites (Mandideep, Goa, Indore and Somerset) are facing different levels of USFDA regulatory action.

Nileshe explains why appointing a consultant was a mistake the industry was making **"over and over again"**. Consultants have a role to play, he agrees, however **"this has to be a company owned."** Giving an insight on how it works, he says, "We had an Aurangabad inspection. We didn't have any consultant coming there. We had a dozen people from other Lupin sites who came into Aurangabad to say, what does this look like, just to challenge the site. That is infinitely-better and infinitely more

sustainable than having somebody else step in."

Years ago when Lupin's Mandideep plant faced USFDA action, insiders recounted how Nileshe had taken personal interest in sorting out the problem. **"It's still my responsibility.** There's no difference in that quality and technical operations report directly to me, it is all my responsibility," he says, narrating how they were up till midnight recently responding to FDA observations.

"One of the things I had stepped back a little bit (from) was on participating in the FDA audits. We changed that this year. We were very clear, whenever FDA comes to plants like Indore and Goa I would be there. To me that was a big eye-opener, I was there through the entire inspection in Indore and Goa. It didn't change the fate of the outcome by being there, it was a lot of learning," he says.

Earlier, on receiving regulatory observations or warning letters, "the lens have always been, what do I need to do to fix that," says Nileshe. While there is nothing inherently wrong in the way things are done, he says, a lot needs to be done to have the confidence that **"yes, all plants are fine."**

The focus of the quality transformation initiative is on all sites and on a sustainable basis, he says and "not something that we do as an episode in Goa or Pithampur. It has to be each and every site. And it has to be multi-year programme where we constantly challenge and make sure that we are where FDA expects us to be."

Source : thehindubusinessline

First convergent science centre launched in UK



As part of the new £13 million Cancer Research UK Convergence Science Centre at The Institute of Cancer Research, scientists are **"re-imagining ultrasound technology to develop a treatment that can liquefy cancer cells in the body using microscopic bubbles"**.

A release from Cancer Research UK has

announced the development of the new treatment that doesn't require invasive surgery, in an investigation that brings together scientists from two of the UK's foremost academic research institutions under the leadership of renowned cancer experts, Professor Paul Workman from The Institute of Cancer Research, London, and Professor the Lord Ara Darzi from Imperial College London.

The researchers are using novel methods that will enable teams at the Centre to work together in completely new ways, to speed up scientific discovery and innovation for people with cancer and create new treatments and technologies.

In one project at the Centre, a team of biologists, physicists, engineers and clinicians are exploring whether a specialised therapeutic version of ultrasound, called histotripsy, could be adapted to destroy pancreatic tumours located deep within the body.

Professor Paul Workman, chief executive of the Institute of Cancer Research, London, and director of the Convergence Science Centre, said: "It's fantastic to think that microbubbles could be used to blow cancer cells apart, and this is just one example of the exciting innovation we expect to see within the new Convergence Science Centre.

He continued to say that the "new Centre will be a coming together of world-class researchers in fields such as engineering, physics, chemistry and AI, collaborating closely with outstanding biologists and clinicians to create new solutions to the critical challenges we face in cancer research, diagnosis and treatment. It will open exciting new frontiers in cancer research and lead to innovative treatments, tests and technologies for patients.

"With Cancer Research UK's support, we have brought together two world-leading research organisations with complementary areas of expertise, building a vibrant collaborative culture that will nurture a new generation of truly multidisciplinary cancer researchers."

Today, two in four people survive their cancer for at least 10 years. Cancer Research UK's ambition is to accelerate progress so that by 2034, three in four people will survive their cancer for at least 10 years.

Source- pharmatimes.com

RESEARCH & DEVELOPMENT

NGOs challenge patent monopoly of leukaemia drug



Two NGOs have challenged the patent protection of a leukaemia drug produced by **Swiss pharmaceutical company Novartis**. They complain that the patent on the drug **Kymriah** allows Novartis to charge inflated prices for its use on patients. Pressure groups Public Eye and Médecins du Monde have filed their objection to the European patent office in Munich. They claim that Kymriah was not invented by Novartis because the research behind the drug was carried out by public institutions.

The medicament, which is used to treat leukaemia and lymph gland cancer on patients who have not responded to previous therapies, costs CHF370,000 (\$375,000) per infusion. This makes it the most expensive drug in Switzerland, say the NGOs.

The Swiss health insurance association Santésuisse is prepared to cover CHF200,000 of this expense for patients treated in Switzerland, according to Swiss public broadcaster SRFexternal link.

If the NGOs succeed in nullifying the patent, Novartis will still be able to sell the drug but without having a monopoly that allows it to charge more.

The decisions of the Munich patent authority are binding on Switzerland despite not being a member state of the European Union. Novartis told the Swiss news agency Keystone-SDA that its lawyers are analysing the legal challenge.

Source : swissinfo

J&J Innovation opens JLABS @ Shanghai with Shanghai Pharma Engine



The world's largest JLABS and the first in the Asia Pacific aims to support more than 50 life science start-ups from around the world with the hope to accelerate healthcare innovation in China and globally

Johnson & Johnson Innovation, Division of Johnson & Johnson (China) Investment Ltd., on 27 June 2019, announced the opening of JLABS @ Shanghai, the world's largest JLABS and the first in the Asia Pacific. The 4,400-square-meter facility, located in Shanghai's Zhangjiang Hi-Tech Park, is a collaboration with the **Shanghai Pharma Engine Company, Ltd.** JLABS @ Shanghai can accommodate more than 50 start-ups across the pharmaceuticals, medical device, consumer and health tech segments, and opens with 31 resident companies, including the three awardees of the Lung Cancer Innovation QuickFire Challenge.

Johnson & Johnson has deep roots in China with an innovation footprint dating back nearly four decades. We are committed to fuelling innovation in the region and unleashing the power of science and technology to advance the health of people in China and around the world," said **Paul Stoffels, M.D., Vice Chairman, Executive Committee and Chief Scientific Officer, Johnson & Johnson.** "The new JLABS in Shanghai will connect global and local entrepreneurs with the expertise of the Johnson & Johnson Family of Companies and our strategic partners to help transform great ideas into breakthrough solutions."

At the opening, JLABS @ Shanghai announced the awardees of the Lung Cancer Innovation QuickFire Challenge, which was launched in June 2018 to focus

on the prevention, interception and curing of lung cancer. The awardees will receive a total of US\$750,000 in grants; one year of residency at JLABS @ Shanghai, including a laboratory bench, workstation and access to the JLABS community; and mentorship and coaching from Johnson & Johnson Innovation. The three awardees are DNX Biopharmaceuticals, Inc., Hawkeye Bio and NE Scientific LLC. **"The opening of JLABS @ Shanghai couldn't have come at a better time for China and the world, facing the growing challenge of diabetes, cancer, and an ageing population. Together we can identify and nurture best in class science to transform how diseases are treated, cured, prevented and intercepted,"** said Melinda Richter, Global Head, Johnson & Johnson Innovation - JLABS.

"Johnson & Johnson is honoured to collaborate with the Shanghai Pharma Engine Company Limited to bring JLABS to Shanghai," said Will Song, Chairman, Johnson & Johnson China and President, Johnson & Johnson Medical China. "JLABS @ Shanghai adds to our expanding presence of R&D, and innovation centres in Shanghai to develop a regional hub for innovation across the Johnson & Johnson Family of Companies and serves as a key contributor to the government's Healthy China 2030 initiative."

JLABS sites have hosted more than 540 companies to date, advancing several biotech, pharmaceutical, medical device, consumer and health tech programs. JLABS @ Shanghai will follow the same no-strings-attached approach across all existing JLABS locations: **San Diego; San Francisco; Boston; Lowell; Houston; Toronto; Beerse, Belgium; New York City and the newly announced Washington, DC.** Johnson & Johnson released a list of companies that are first to be selected as residents of JLABS @ Shanghai.

Source : biospectrumasia

Wedding Bells

Jagruti weds Hari Teja Varma

24th May' 2019
Indukuri Sitarama Raju
Smt. Dhanalakshmi
Shantha Vaccine

BIOTECHNOLOGY

Humira and Botox, a Match Made in Patent Heaven



So it turns out that even AbbVie Inc. couldn't game the patent system forever. To listen to the company's conference call is to realize that that is the core reason for its \$63 billion merger with Allergan Plc. Its lawyers ran out of loopholes to exploit.

AbbVie owns the most lucrative drug in the world: Humira, which is used to treat rheumatoid arthritis, psoriasis and related diseases. Last year, it generated almost \$20 billion in revenue — an astonishing \$10 billion more than the runner-up, the blood-clot medication, Eliquis, co-owned by Bristol-Myers Squibb Co. and Pfizer Inc. According to a slide AbbVie distributed in the aftermath of the deal announcement, Humira accounts for 60 percent of the company's sales. All told, the company has reaped \$160 billion from its most important drug since it first came on the market.

But as I've noted before, that was 17 years ago — and Humira's core patent expired in 2016. At that point, thanks to the Biologics Price Competition and Innovation Act of 2010, generic manufacturers were supposed to be able to bring cheaper versions of Humira — biosimilars, they're called — to market. Did this happen? It did not. In the modern age, pharmaceutical industry profits depend on the companies' ability to violate the spirit of this law, which is intended to give consumers a break from high drug prices. Thus, in the years leading up to the patent expiration, AbbVie's lawyers filed more than 100 so-called add-on patents — a veritable patent fortress — designed to forestall the loss of the company's Humira monopoly. When a handful of competitors went ahead and designed Humira biosimilars, AbbVie sued them, claiming (of course) patent violation. Ultimately, those suits were settled. AbbVie agreed to allow biosimilars to enter the market in 2023, and the companies agreed to give AbbVie a royalty when that happened. During conference call, several analysts referred to what they called the

"23 LOE" — the 2023 "loss of exclusivity" for Humira. Whatever pipeline AbbVie has, it certainly has no drug likely to take the place of its cash cow. Hence the need to buy another company. The irony is that in buying Allergan, it is also acquiring another legal department with a reputation for gaming the patent system.

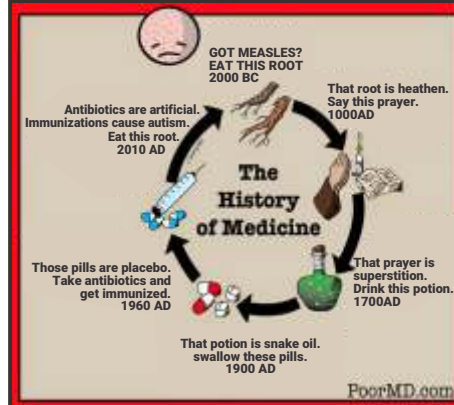
Allergan, you'll recall, is the company that tried to transfer the patent rights to its blockbuster eye medication, Restasis, to the Saint Regis Mohawk Tribe. The idea was that because the tribe was a sovereign nation, generic competitors who were then trying to void its add-on patents would be stymied. The move was denounced by critics (like me), but applauded by Wall Street analysts, who saw it as a clever way for the company to hold onto its Restasis monopoly. Ultimately, the tactic failed — a federal judge ruled it illegal — but it showed the lengths Allergan would go to prevent consumers from paying the lower prices the law was intended to provide.

Assuming this new deal goes through, AbbVie's reliance on Humira will be reduced to 40 percent of sales, according to that same AbbVie slide. And it will add a potent, brand-name drug to its arsenal as it prepares for 2023: **Botox**. Botox, an anti-wrinkle and migraine treatment, isn't protected by a patent; its "recipe" is trademarked. And trademarks, unlike patents, never expire. When a small competitor, Evolus Inc., came out with a drug that replicated the Botox recipe — which is perfectly legal — Allergan filed a complaint with the U.S. International Trade Commission, claiming its formula had been stolen. It wants to force Evolus to withdraw its competing drug from the market. "This represents another legal maneuver in a long-litany of attempts by Allergan ... to stifle competition and limit physician and consumer choice," complained Evolus in a statement. Well, yes: That's the whole point.

As for the prospect of a biosimilar that might one day compete with Botox, Richard Gonzalez, the chief executive of AbbVie, appears unworried. "When you look at Botox," he said during the conference call, "it's a very unique molecule ... and for a variety of technical reasons that I would tell you that it's highly unlikely that we would see a biosimilar against Botox for a long, long time if ever."

Source: bloomberg

NOSTALGIA



Happy Happenings at Gubba

New Borns

Mr L Naveen Kumar
(HO, Graphic Designer)
Blessed with
Baby Boy
on 28th June '2019

Mr Sultan
(M3 lab Incharge)
Blessed with
Baby Boy
on 5th July '2019

Mr D Ganesh
(Y4 Asst Supervisor)
Blessed with
Baby Girl
on 6th July '2019

Quote on Gubba

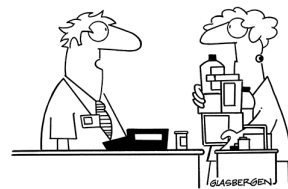


"Impressed with dedication of staff members."

Ashok Shinha
Accelerate asia Project Lead,
Monsanto

TOON TIME

PHARMACY



"Coming in for your prescription and buying a ton of other stuff you really don't need ...that's one of the side effects."

DID YOU KNOW about GUBBA

Gubba aspires to be Internationally certified Cold Storage for its Quality & Systems by 2021

06

COLLABORATIONS

Bharat Biotech to collaborate with Hilleman to develop cholera vaccine



Hilleman Laboratories announced that it will collaborate with Hyderabad-based vaccine maker **Bharat Biotech International Limited (BBIL)** for further development, manufacture and commercialisation of its next generation oral cholera vaccine, Hillchol.

Hillchol was designed at the University of Gothenburg in Sweden and subsequently developed by Hilleman Labs. The development process included demonstration of safety and immunogenicity in an age de-escalating phase I/II clinical trial conducted in Bangladesh.

For further development of the vaccine candidate, Hilleman Labs has entered into a licensing and manufacturing agreement with BBIL, which will scale the manufacturing process to commercial stage and establish product specifications required for WHO pre-qualification.

Hillchol contains a single recombinant Hikojima strain which expresses both Inaba and Ogawa antigens, resulting in a shorter and simpler manufacturing process as compared to licensed OCVs. **Hillchol**, will therefore prove to be of great importance and value to cholera afflicted countries, according to Jan Holmgren, University of Gothenburg, who invented the vaccine along with his team. "We are delighted to lead the scale-up, development, manufacturing and commercialisation efforts for Hillchol with our collaboration marking an important step. Our capacity to deliver 50 million doses per year and the addition of a WHO pre-qualification of Hillchol in the future, will not only solve the demand uncertainty but aid in affordability thereby resulting in the wider use of such a vital oral cholera vaccine worldwide," Bharat Biotech chairman and managing director Krishna Ella said.

Source: business-standard

Pfizer to buy Array BioPharma for \$11 billion



Pfizer agreed to spend \$11 billion to buy Array BioPharma, a company that is developing small molecule medicines primarily to treat cancer. Array's portfolio includes two drugs in more than 30 clinical trials for different kinds of cancer, particularly colorectal cancer.

The companies said that is the third-most-common form of cancer: 140,250 patients were diagnosed with cancer of the colon or rectum in the United States in 2018, and approximately 50,000 are estimated to die of their disease each year.

The proposed acquisition of Array "sets the stage to create a potentially industry-leading franchise for colorectal cancer alongside Pfizer's existing expertise in breast and prostate cancers," said Pfizer CEO Albert Bourla. Array is essentially a start-up, with revenue of \$174 million in its most recent fiscal year and a history of net losses. It is dwarfed in size by Pfizer which had revenue of \$53.6 billion in 2018, making in the second-largest US pharmaceutical company behind only Johnson & Johnson (JNJ). Pfizer said it will use debt and cash reserves to make the purchase.

The purchase price of \$48 a share represents a 62% premium over Array's closing price. Shares of Array (ARRY) soared 60% in premarket trading on the purchase announcement, while shares of Pfizer (PFE) were little changed. Pfizer is already in the midst of growing by combining its consumer healthcare business with that of **GlaxoSmithKline (GLAXF)**, to create a joint venture with an estimated \$12.7 billion in annual sales. That deal, expected to close in the second half of this year, will bring together Pfizer's big over-the-counter products like Centrum and Caltrate with GSK's top brands, including Excedrin and Nicorette.

Source: edition.cnn.com

Eris Lifesciences, PlexusMD join hands to offer AI powered online learning platform for doctors in India

Eris Lifesciences, a leading pharmaceutical company and PlexusMD, India's largest

professional networking platform for doctors announced their partnership for a unique artificial intelligence (AI) powered learning platform named "Saarthi". "Saarthi" is an interactive, innovative and relevant platform to simplify learning for doctors, who continuously face time-constraints in their attempt to keep abreast with latest developments in the medical field.

Through this endeavour, the companies aim to enable Indian physicians stay connected with global developments and practise evidence-based medicine to improve patient health outcomes. AI empowered technology and machine learning can help tailor the content and adapt the pace of delivery to each practising physician's unique learning needs for them to apply the insights more effectively in their practice. This app-based platform will be a one-stop destination to provide continuing medical education (CME), medical content, medico-legal precedents, medical conference feeds, case discussions, etc. for physicians. With an artificial intelligence empowered technology, Saarthi will help doctors in their evidence-based practice as each patient case can be unique. A distinctive feature of the app is a calculator that will help doctors quickly arrive at the right dosages, drug combinations and diagnostic criteria for commonly encountered situations. Highlighting the need for such an offering, **Dr. Viraj Suvarna**, president -Medical, Eris Lifesciences Ltd. said, "This is a collaboration between two very exciting pioneers, one from the pharmaceutical space and the other from technology. This partnership is a step forward in a domain that requires deep learning but where time constraints become a major deterrent for doctors".

Elaborating on the partnership, **Dr. Rohan Desai**, founder, PlexusMD, said, "E-learning is the reality in every domain, including medicine. Saarthi is a unique platform where an AI-powered engine will deliver precise and customized content to the enrolled doctors depending on their interests and learning requirements. The app will address two critical issues in today's time — information overload and fake news to ensure doctors are provided with information relevant to them." "Technology has made learning an enjoyable experience. The traditional learning that doctors were exposed to during their graduation and post-graduation days can now be made exciting with the use of technology. Doctors can learn from case studies using virtual and augmented reality". Eris Lifesciences is focused on filling up the gaps in patient care, diagnostics, therapeutics and patient compliance. PlexusMD, an online professional network for medical professionals and healthcare organisations, is centered on professional growth of doctors.

Source: pharmabiz

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