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NEWS LETTER
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# J&J Talc Unit Asks Judge To Halt Cancer Lawsuits As It Pursues $8.9 Bln Settlement


A Johnson & Johnson subsidiary is again asking a U.S. judge to pause tens of thousands of lawsuits alleging the company's baby powder and other talc products cause cancer, as it seeks to resolve the litigation in bankruptcy after a federal appeals court found its first attempt improper. At a Tuesday hearing in Trenton, New Jersey, a lawyer for LTL Management argued the lawsuits, which are already stayed against LTL, should also be stopped against J&J, which has a market value of over $430 billion and has not filed for bankruptcy itself.

LTL has said litigation against J&J would imperil its effort to negotiate a comprehensive settlement of all current and future talc claims in its bankruptcy. Two groups of cancer plaintiffs and the U.S. Department of Justice's bankruptcy watchdog have opposed the company's bid for a stay, arguing it is a fraudulent attempt to evade the earlier court ruling and that the second bankruptcy has "slim to nonexistent prospects" of success.

LTL attorney Greg Gordon pushed back on those arguments at the start of the hearing, saying "the likelihood of a successful reorganization is very high." LTL believes it now has support of 70,000 to 80,000 claimants, enough to meet the 75% voting threshold required for a bankruptcy court to approve the settlement and make it binding on all claimants, Gordon said. Michael Winograd, an attorney representing talc claimants, said J&J does not have support from a single claimant, only agreements with lawyers who would recommend the deal to their clients. J&J has exaggerated the level of support for the settlement to distract from the fact that LTL's bankruptcy strategy had already been ruled illegal, he added.

"Like anyone trying to pull off a magic trick, you have to have a diversion," Winograd said. More than 38,0000 talc lawsuits have been on hold since LTL first filed for bankruptcy in 2021. Plaintiffs argue they should be allowed to proceed with their lawsuits that allege the talc products caused various forms of cancer after a federal appeals court nixed the company's attempt to offload the litigation in bankruptcy. The Philadelphia-based 3rd U.S. Circuit Court of Appeals in January ruled LTL was not eligible for bankruptcy because it was not in "financial distress." Before the talc lawsuits could resume, LTL filed for bankruptcy a second time, re-opening the legal battle over the bankruptcy's legitimacy.

It has said its second bankruptcy is different because it has less funding available and more plaintiff support for a settlement. J&J (JNJ.N) has offered $8.9 billion to settle the claims, including $6.5 billion for ovarian cancer claims, $2 billion for mesothelioma claims, and $400 million to settle consumer protection and false marketing claims brought by state attorneys general. The company has said its baby powder and other talc products are safe and do not cause cancer.

The company on Tuesday reported overall sales of $24.7 billion for the first quarter, but posted a net loss of $68 million due to a one-time charge related to LTL's second bankruptcy filing. J&J's effort to settle its talc liabilities in bankruptcy began in October 2021. The company divided its consumer business in two and offloaded the talc lawsuits onto its newly created subsidiary, LTL, which almost immediately filed for Chapter 11 in an effort to halt the litigation avalanche and force plaintiffs into a global settlement.

U.S. Bankruptcy Judge Michael Kaplan agreed to protect J&J from lawsuits during LTL's first bankruptcy, saying at the time it offered the best way to fairly resolve all of the talc lawsuits together.

Kaplan, who is also presiding over the second bankruptcy, said he will rule on Thursday on LTL's request to stop the lawsuits again and to give the company a second shot at a bankruptcy settlement. (Source: Reuters)

## People with 'Long Covid' at Higher Risk of Heart Disease, Finds New Study

Post-Chort experienced increased healthcare utilisation for Anew study has found a higher risk of heart disease, including stroke, among people experiencing "long Covid". Not only heart disease, during the follow-up period, people with symptoms of long Covid faced an increase in the relative risk of other health complications such as pulmonary embolism, coronary artery disease, heart failure, asthma and chronic obstructive pulmonary disorder (COPD). According to the study published in the Journal of the American Medical Association (JAMA) on March 3, individuals with post-Covid condition (PCC) may be at increased risk for adverse outcomes in the year following the initial infection. Centers for Disease Control and Prevention defines PCC as having new, returning, or ongoing health issues occurring more than four weeks after the onset of the initial infection. This condition among the subset of patients experiencing post-Covid symptoms has also been described as "long Covid".

The estimates of PCC incidence vary widely, with published reports estimating that between 10 percent and 25 percent of symptomatic patients experience symptoms persisting beyond the acute phase of illness. A diagnosis of PCC or 'long Covid' is based on symptoms, including fatigue, cough, pain (joint, throat, chest), loss of taste or smell, shortness of breath, thromboembolic conditions, neurocognitive difficulties, and depression.

It is one of the several studies published so far, which have tried to establish the increased chances of heart disease after a Covid infection. However, the study provides a comprehensive view of individuals with and without initial hospitalisations. The authors, by leveraging a large health insurance claims database, have ascertained health status before initial Covid-19 diagnosis, including assessment of baseline characteristics such as hypertension, obesity, depression, and COPD.

**WHAT ARE THE FINDINGS?**

The case-control study included 13,435 adults in the US with PCC and 26,870 matched adults without Covid -19. It was found that adults with PCC experienced increased risks for a number of cardiovascular outcomes, such as ischemic stroke. "During the 12-month follow-up period, 2.8% of the individuals with PCC versus 1.2% of the individuals without Covid-19 died, implying an excess death rate of 16.4 per 1,000 individuals," the study stated.

During the follow-up period, the PCC cohort compared with the non-Covid cohort experienced increased healthcare utilisation for cardiac arrhythmia with an increase in relative risk (RR) of 2.35; pulmonary embolism with an increase in RR of 3.64; ischemic stroke with an increase in RR of 2.17; coronary artery disease with an increase in RR of 1.78; heart failure with an increase in RR of 1.97; COPD with an increase in RR of 1.94; and asthma with an increase in RR of 1.95.

**EARLIER STUDIES**

Several studies have found increased risks of cardiovascular disease post-Covid. For example, a study by the American Heart Association — of 8,163 patients with Covid-19 treated in the emergency department or hospitalised – found that 1.3 percent of patients developed acute ischemic stroke during their hospital stay.

A European study of 2,292 individuals presenting at the emergency department with mild to moderate Covid found increased thrombosis risk in the subsequent 28 days: a rate of 2.3 percent in the presence of moderate Covid-19 and 0.6 percent for individuals with mild Covid.

**WHAT IS UNIQUE ABOUT THIS STUDY?**

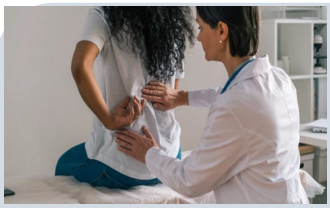
While several studies have been done earlier on a similar subject, the authors of the study said there were limitations to initial studies assessing PCC rates and outcomes. "Estimates were often based on hospitalised patients who had a higher severity of illness. Many reports were based on patient surveys that did not include comparison groups of similar individuals," the study stated.

In addition, early reports were often research letters or field reports not subject to peer review. "Finally, individuals at risk for PCC tend to have higher baseline risks due to pre-existing conditions, resulting in selection bias for the exposure cohort," it stated. The authors said subsequent to initial reports, additional work on PCC has been published, providing a more rigorous assessment of patient experiences.

"This case-control study provides a 12-month assessment of adverse outcomes for a cohort of individuals with PCC compared with a propensity-matched comparison group with similar baseline risks," they added.

The findings of the study will be useful in informing care coordination efforts for individuals with PCC, especially when it comes to careful monitoring for cardiovascular and pulmonary risks after the period of acute infection. (Source:News18)

## Medicla Device Company Founder Arrested For Selling Fake Paint Implants



The founder of a medical device company has been charged with leading a scheme to create and sell a completely non-functional plastic implant purporting to treat chronic pain, resulting in millions of dollars of fraudulent bills to government insurance programs including Medicare.

Laura Perryman, who founded Stimwave LLC in 2010 and served as its chief executive until 2019, was arrested Thursday in Delray Beach, Florida, where she lives. Perryman, 54, is charged by federal prosecutors in Manhattan with conspiracy and health care fraud, with the most serious charges carrying a maximum sentence of 20 years in prison.

Stimwave, which filed for bankruptcy last year, has also agreed to pay $10 million to avoid criminal prosecution and to settle a related civil whistleblower lawsuit, prosecutors said Thursday.

"Our office will continue to do everything in its power to bring to justice anyone responsible for perpetuating health care fraud, which in this case led to patients being used as nothing more than tools for financial enrichment," U.S. Attorney Damian Williams in Manhattan said in a statement.

Jared Dwyer of Greenberg Traurig, Perryman's lawyer, said the allegations are false and that Perryman looked forward to addressing them in court. "Every piece of that system had a function and was necessary depending on the patient's needs," he said in an email.

An attorney for Stimwave did not immediately respond to requests for comment. Florida-based Stimwave was founded to provide alternatives to opioid drugs for chronic pain. For that purpose, it marketed the StimQ PNS System, which delivered electrical currents to nerves outside the spinal cord, according to court filings.

The StimQ device consisted of an implantable array of electrodes, an external battery and another implantable component, called the receiver, that transmitted energy from the battery to the lead.

Soon after the StimQ was released in 2017, doctors began reporting that the receiver was too long to fit in some patients, according to court filings. In response, Perryman directed the company to begin selling an alternative version of the receiver that could be cut to size. That version was made entirely of plastic and did not transmit electricity, prosecutors said, even though the company claimed it was effective.

As a result, authorities said, the non-functional devices were implanted in patients, and government health insurance programs were fraudulently billed "millions" of dollars. It was not clear exactly how many patients received the devices or how much was fraudulently billed. (Source: Reuters)

## Merck's Drug Boosts Exercise Capacity In Pulmonary Hypertension Patients


Merck & Co Inc (MRK.N) said on Monday its experimental therapy helped increase exercise capacity in patients with a deadly disease that causes high pressure in blood vessels of the heart and lungs in a late-stage study, lifting its shares about 4%. Sotatercept, combined with a background therapy, helped patients with pulmonary arterial hypertension to walk about 40.8 meters more in six minutes.

The drug, which Merck gained through its $11.5 billion buyout of Acceleron Pharma in 2021, also showed significant improvement in eight of the nine secondary goals, including reducing the risk of death or clinical worsening of condition by 84% compared to placebo. J.P. Morgan analyst Chris Schott said the data exceeded the brokerage's expectations and "should confirm the drug as go-to add-on therapy" for pulmonary arterial hypertension.

Schott forecast peak sales of $3 billion to $4 billion for the drug. In October, Merck said sotatercept had met the main goal of a late-stage study, but did not release the full data.

Merck has been beefing up its portfolio of cardiovascular drugs as part of its strategy to counter a possible hit to sales to its best-selling drug Keytruda from biosimilar drugs in the next few years. Another experimental heart drug, MK-0616, helped reduce levels of low-density lipoprotein (LDL) cholesterol by between 41.2% at a low 6 mg dose and 60.9% at a higher 30 mg dose in a mid-stage study, Merck said on Monday.

Analysts have said MK-0616 would need to show a more than 50% reduction in LDL level, similar to drugs from rivals Regeneron (REGN.O) and Sanofi SA (SASY.PA) and Amgen (AMGN.O). The data were presented at the American College of Cardiology's annual meeting in New Orleans.(Source: Reuters)

## Cipla Signs Licence Agreement With Novartis AG To Manufacture And Market Type-2 Diabetes Medicine

Drugmaker Cipla on Monday said that it has signed a perpetual license agreement with Switzerland-based Novartis Pharma AG to manufacture and market Galvus and Galvus combination brands which are used in the treatment of type 2 diabetes from January 1, 2026.`

The medicine is expected to contribute significantly to Cipla's portfolio in the diabetes care continuum space with the drug's reported sale of Rs 268 cr, as per IQVIA MAT February 2023.

Explaining the deal further, Cipla informed that the agreement is subject to satisfaction of certain conditions precedent. The company will however continue to market and distribute Galvus branded products.

In the oral diabetic medication category, Galvus stands as one of the leading brands in the Dipeptidyl Peptidase-4 (DPP4) space and amongst the prominent brands. Through the deal, Cipla expects to further bolster its position in India as one of the top players in the diabetes category.

In January, Cipla had launched Cippoint, a point-of-care device for non-communicable and infectious diseases. Later, in February the company went through I-T Department search at some of its offices and manufacturing units.

At that time, Cipla had informed that it is fully co-operating with the officials during the proceedings and had responded to the clarifications and details sought by the I-T Department. The business operations of co continued as usual and were not impacted due to the search, Cipla had informed during that time.

Cipla, in its Q3 results had reported a 10 percent jump in net profit which was at Rs 801 cr vs Rs 728.6 cr, the same quarter last year. The revenue had seen a rise of 6 percent on yearly basis at Rs 5,810 cr vs Rs 5,478.8 cr. (Source: CNBC)

## Global Pharma Recalls 50,000 Tubes Of Contaminated Eye Drops In US: USFDA


Global Pharma Healthcare is recalling 50,000 tubes of eye drops in the US market due to bacterial contamination, according to the US Food and Drug Administration (USFDA).

As per its latest Enforcement Report, the US health regulator noted that the Chennai-based drug firm is recalling the affected lot of eye lubricant for artificial tears which have been linked to vision loss in the US.

The lot has been manufactured by Chennai-based Global Pharma Healthcare and distributed in the US market by New York-based Delsam Pharma, the USFDA said.

Stating the reason for recall, the US health regulator said: "FDA analysis found unopened tubes to be contaminated with bacteria."

The company initiated the Class I recall on February 24 this year. As per the USFDA, a Class I recall is the most urgent of the three types of FDA recalls and usually pertains to defective products that can cause serious health problems.

In February, Global Pharma Healthcare had announced that it is recalling its entire lot of eye drops allegedly linked to vision loss in the US. Artificial Tears Lubricant eye drops are used as a protectant against irritation or to relieve dryness of the eye.

In a separate disclosure, the USFDA stated that Mumbai-based Sun Pharma is recalling 1,920 bottles of Dofetilide Capsules, which are used to treat irregular heartbeat. The affected lot has been produced at Sun's Dadra-based plant, the USFDA stated.

The US-based unit of the company — Sun Pharmaceutical Industries Inc — is recalling the lot due to "Failed content uniformity specifications," it added. The New Jersey based firm initiated the Class III recall on March 9. As per USFDA, a Class III recall is initiated in a "situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences." (Source: Business Line)