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# Analysis Involving More Than 85,000 People Showed Risk of Worsening Function Was Reduced by 22%


Weight-loss drugs can reduce the risk of worsening kidney function, kidney failure and dying from kidney disease by a fifth, according to a study. Glucagon-like peptide-1 (GLP-1) receptor agonists are a family of medications that help people shed the pounds, manage blood sugar in patients with type 2 diabetes and prevent heart attacks and strokes in people with heart disease. But while the benefits of the drugs for treating obesity, type 2 diabetes and cardiovascular disease are well known, their potential impact on kidney health has been less certain.

Now the largest and most comprehensive analysis of GLP-1 receptor agonists on kidney outcomes suggests they could have significant benefits. The findings were published in the Lancet Diabetes & Endocrinology journal. Researchers conducted a meta-analysis of 11 large-scale clinical trials of weight loss drugs involving more than 85,000 people. The group included people with type 2 diabetes, and people with cardiovascular disease who were overweight or obese but did not have type 2 diabetes. ‘Skinny jabs’: weight-loss drugs set for new boom as generic versions emerge

Seven different GLP-1 receptor agonists were investigated among the trials, including semaglutide, also known as Ozempic or Wegovy, dulaglutide and liraglutide. Compared with placebo, GLP-1 receptor agonists reduced the risk of kidney failure by 16% and the worsening of kidney function by 22%, researchers said. The combined reduction in the risk of kidney failure, worsening kidney function and death due to kidney disease was 19%. The analysis also confirmed previous findings that weight-loss drugs protect cardiovascular health, with a 14% reduction in the risk of cardiovascular death, non-fatal heart attack and non-fatal stroke, compared with placebo. Death by any cause was 13% lower among patients treated with GLP-1 receptor agonists.

Lead author Prof Sunil Badve, professorial fellow at the George Institute for Global Health and UNSW Sydney, said the study expanded current knowledge about the potential benefits of the drugs. “This is the first study to show a clear benefit of GLP-1 receptor agonists on kidney failure or end-stage kidney disease, suggesting they have a key role in kidney-protective and heart-protective treatment for patients with common medical conditions like type 2 diabetes, overweight or obesity with cardiovascular disease, or CKD [chronic kidney disease],” he said.

“These results are particularly important for patients with chronic kidney disease. It is a progressive condition eventually leading to kidney failure requiring dialysis or kidney transplantation and is associated with premature death, mostly from heart disease. It has a significant impact on patients’ quality of life and incurs substantial healthcare costs.” CKD is estimated to affect one in 10 people worldwide, equivalent to about 850 million people. It is the 10th leading cause of death and is projected to become the fifth most common cause of death by 2050. Prof Vlado Perkovic, professorial fellow at the George Institute, provost at UNSW Sydney and senior author on the study, said: “This research shows that GLP-1 receptor agonists could play an important role in addressing the global burden of non-communicable diseases. “Our study will have a major impact on clinical guidelines for the management of chronic kidney disease and cardiovascular disease in people with and without diabetes. “More work is now needed to implement the results of this study into clinical practice and improve access to GLP-1 receptor agonists to people who will benefit from them.” (Source: The Guardian)

# Big Pharma Pushes Trump Team To Ease Medicare Drug Price Negotiation Rules


The U.S. pharmaceutical industry is pushing to revamp the new law that allows Medicare to negotiate prices for its costliest prescription drugs once president-elect Donald Trump is back in office, according to lobbyists, executives, analysts and healthcare policy experts. Seven lobbyists and executives who work with top pharmaceutical and biotech companies told Reuters they are pushing to delay the timeline under which medications become eligible for price negotiations by four years for small molecule drugs, which are primarily pills and account for most medicines.

Two sources said the industry is already speaking directly with members of the Trump transition team. The ability of Medicare for the first time to directly negotiate prices on selected medicines was part of the Inflation Reduction Act, considered one of the key achievements of the administration of outgoing President Joe Biden. Medicare covers 66 million Americans, mostly aged 65 and older. Since the IRA was passed in 2022, drugmakers have complained about the terms of Medicare's negotiating powers, saying it would stifle innovation. The government says the drug price negotiations will save nearly $25 billion by 2031.

In particular, the industry has opposed the time frame for negotiation eligibility for most drugs. When drugs have no competition, the law allows the government to negotiate prices for complex biologic, or biotech, drugs after 13 years on the market, but after 9 years for drugs taken as pills and capsules. Drug companies have said this will dissuade them from developing the medicines that are generally cheaper and easier to produce and more convenient for patients, and instead push them to prioritize researching biologics, which are most often given by infusion rather than taken at home. What now matters is how to find a compromise that allows for an ambitious result in relation to the new global goal.

Yet four drugmakers involved in the first U.S. Medicare negotiations reassured analysts and investors earlier this year that they did not expect a significant impact to their businesses after seeing suggested prices from the government that would take effect in 2026. S. Sean Tu, a professor of law at West Virginia University, called 13 years of market exclusivity for all drugs "a terrible idea," adding that drugmakers would have enough financial incentive to innovate with just five years on the market. Agreeing to extend the time for possible price negotiations from 9 to 13 years is "just giving a huge boon to the pharmaceutical industry with no payback," he said.

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One source at a big pharmaceutical company said the company had both phone calls and in-person meetings with members of the Trump transition team to discuss possible changes to the IRA. The company hopes a Republican Congress and the Trump administration would remove the distinction in how the easier to produce drugs are treated. "They have been receptive," the source said, declining to say whom the company had spoken to on the transition team. The Trump transition team did not respond to a request for comment.

Trump nominated industry critic Robert F. Kennedy Jr as secretary of the U.S. Department of Health and Human Services, which includes the agency that oversees Medicare and these negotiations. Drugmakers are betting Republican lawmakers and the Trump administration will be more open to changing the IRA. One drug company executive, who spoke on the condition of anonymity, said Republicans were also concerned the law will hinder development of non-biotech medicines.

"I think there is increasingly a recognition that there are unintended consequences" of the IRA among Republicans, another pharmaceutical company executive said, speaking on condition of anonymity. "That's not just wishful thinking." Pharma expects to piggyback on Republican moves to scrap some of the energy and green subsidy provisions in the legislation, three of the sources said. In the first round of price negotiations, the Biden Administration cut what it will pay for 10 prescription drugs widely used by Medicare by as much as 79%. The move is estimated to cut revenue on those drugs, just three of which are biotech medicines, by billions of dollars.

In addition to the oral medications, injectable drugs like Novo Nordisk's (NOVOb.CO), opens new tab diabetes treatment Ozempic are considered small molecule drugs and subject to the shorter market time for negotiated prices. Ozempic, known chemically as semaglutide, is expected to be selected for the next round of Medicare negotiations in February, without changes to the law. The companies expect to address the law through the budget reconciliation process, one of the industry lobbyists said. That process only requires a majority of votes in the Senate, rather than the 60 normally needed, for something to pass, and Republicans will hold a majority next year. Full repeal of drug price negotiations is unlikely, four executives and industry experts acknowledged. BMO analyst Evan Seigerman suggested Kennedy could be an impediment to pharma's plans for changing the law. Who knows if they can make that happen?," he said. "I don't think RFK would be very friendly to the industry." (Source: Reuters)

## Global Pharma Licensing Agreements See a Slow-down, Says Report

There is a slow-down in licensing activity, and the global pharmaceutical industry needs to recommit to voluntary licensing (VL) and technology transfers to bridge health inequities, says the 2024 Access to Medicine Index report. In the last two years, non-exclusive voluntary licensing (NE-VL) agreements have dipped to just two (in the review period), compared to six in Index 2022, says the report brought out by Access to Medicine Foundation (ATMF), a Netherlands-based non-profit organisation.

The momentum in licensing activity has "stalled", the report said, "signalling a missed opportunity to improve local availability of innovative medicines." And this, despite public health organisations prioritising at least ten key patented treatments across companies, in therapeutic areas including cancer - as viable for licensing, it added. The slowdown could impact Indian drugmakers, who participate in these global VL and tech transfer pacts. The scale and pace of progress in expanding access-related initiatives should have been higher, says Jayasree K . Iyer, ATMF Chief Executive Officer, attributing the slowdown to companies, possibly, not seeing "the true value of scaling up access via VLs".

Many did not prioritize low-and-middle income countries (LMICs) for access to new drugs, as they believed the infrastructure was inadequate to deliver the treatments effectively, Iyer told businessline. Besides, all licenses relied heavily on donor funded mechanisms to procure products eventually, she said, adding that companies and Governments needed to work towards addressing these issues, as funding also comes under pressure.

The two NE-VL agreements involved ViiV Healthcare's Cabotegravir, for HIV pre-exposure prophylaxis, and Novartis' nilotinib, to treat chronic myeloid leukaemia. (ViiV is owned by GSK). A third NE-VL involving Gilead's lenacapavir (HIV), was also formalized, however it was outside the scope of this study, conducted between June 1,2022 and May 31 2024. Indian drugmakers including Aurobindo, Cipla, Dr Reddy's Laboratories, Hetero and Emcure have been part of these different pacts.

"Voluntary licensing agreements, particularly when supported by technology transfers to local manufacturers, are a powerful way in which pharmaceutical companies can improve long-term and sustainable access to their essential healthcare products, especially in regions where they have limited or no operations," the report explained. Further, the report said, companies pursuing technology transfers were concentrating their initiatives in upper middle-income markets, with efforts lagging in sub-Saharan Africa (except for South Africa). Only six companies – Boehringer Ingelheim, Gilead, Merck, Novo Nordisk, Pfizer and Sanofi – report having established technology transfer initiatives in this region, it added.

The ATM Index also found that only 43 percent of clinical trials take place in the 113 LMICs, covered by its analysis, despite them being home to 80 percent of the global population. Since companies include "access planning" in countries where they conduct trials, "this leaves much of the world behind," the report noted. "Early designing and thinking on access planning helps tremendously," says Iyer, urging companies to develop better plans for broader access, and to include more regions in their clinical studies, and eventually ensure that registration, supply and affordability is planned for broader access, especially in countries with the highest burden of disease.

On countries becoming inward looking in their policies and political campaigns, she said, if funding is limited, the progress will also be affected negatively. "It's important to realize that the programmes for infectious diseases and vaccines are cornerstones of health systems and also deliver on treatments and care for non communicable diseases like Cardiovascular diseases, diabetes, cancer care.

This is not the time for industry to slow down and they need leaders in government and communities and investors to work with to drive success in access," she said. The Index report ranked Novartis at the top spot, followed by GSK - across all three technical areas analysed : Governance of Access, Research and Development and Product Delivery, a note on the report said. The Index report analysed 20 large research -based pharmaceutical companies with products for high-burden diseases in LMICs. It is endorsed by over 145 investors, collectively managing assets worth over USD 22 trillion, it added. The Foundation is funded by the UK Foreign, Commonwealth and Development Office, the Dutch Ministry of Foreign Affairs, the Bill & Melinda Gates Foundation, the Leona M. and Harry B. Helmsley Charitable Trust, the Wellcome Trust, AXA Investment Managers and Stewart Investors. (Source: Business Line)

## Lilly Pill Cuts Genetic Form Of Holesterol Nearly 86% In Study


The highest dose of an experimental pill developed by Eli Lilly dramatically lowered an inherited form of high cholesterol in a mid-stage trial, according to data presented at a medical meeting on Monday. The drug, muvalaplin, reduced levels of lipoprotein(a), or Lp (a), by 70% using a traditional blood test and by nearly 86% based on a more specific test developed by the company, researchers reported at the American Heart Association meeting in Chicago.

Lilly's drug is the only oral treatment in a field of several injectable therapies being tested to treat high Lp(a), a risk factor for heart disease that affects one in five individuals globally. Unlike low-density lipoprotein, or LDL, the so-called bad cholesterol that can be treated with diet and statins, there are no approved treatments for Lp(a) and few individuals even know they have it. Elevated Lp(a) can significantly increase the risk of heart attack, stroke, narrowing of the aortic valve, and peripheral artery disease, a buildup of fatty plaques in the arteries. Individuals of African and South Asian ancestry are at highest risk.

The trial compared three daily doses of muvalaplin - 10, 60 and 240 milligrams - with a placebo in 233 adults with high levels of Lp(a). Researchers tested Lp(a) levels using a traditional blood test and a new method that measures levels of intact Lp(a) particles in the blood. Muvalaplin reduced Lp(a) by 47.6% at 10 mg, 81.7% at 60 mg and 85.8% on 240 mg as measured by the intact blood test versus placebo. It was reduced by 40.4%, 70.0%, and 68.9%, respectively, as measured by the traditional test.

Ruth Gimeno, Lilly's group vice president for diabetes and metabolic research, said the company is weighing next steps for advancing to late-stage trials. "We'll have to have discussions with regulators, but we're very excited," she said in an interview. She noted that while the drug has reduced a cardiovascular risk factor, large trials are needed to prove lowering Lp(a) actually cuts heart attacks and other adverse cardiovascular events. At the same meeting, London-based Silence Therapeutics reported 60-week results of a 180-patient Phase 2 trial of zerlasiran, which works by dampening the activity of the LPA gene that leads to high levels of Lp(a) using a technology known as short interfering RNA, or siRNA.

A 300 mg or 450 mg injection of zerlasiran given every 16 or 24 weeks reduced Lp(a) by 80% to 85% during 36 to 60 weeks of follow up, with no major safety issues. "We saw profound knockdown, as we saw in the Phase one," Dr. Curtis Rambaran, the company's chief medical officer, said in an interview. Silence will test the 300 mg dose in a late-stage trial set to start in the middle of next year, he said.

Results of both studies were published in JAMA.Other injectable Lp(a) treatments in clinical testing include Lilly's lepodisiran, Amgen's olpasiran and pelacarsen from Novartis (Source: Reuters).

## Vaccine Maker Stocks Fall In US After Trump Picks Anti-Vaccine Activist RFK Jr as Health Secretary


Shares of vaccine makers plunged after President-elect Donald Trump nominated Robert F Kennedy Jr to run the Department of Health and Human Services, a post that would give the longtime vaccine sceptic influence over the nation's health and medical research agencies. Covid vaccine maker Moderna Inc. dropped 5.6 per cent at the close of regular trading Thursday and lost an additional 1.4 per cent post-market. Pfizer Inc. dropped 2.6 per cent in regular trading while its Covid vaccine partner BioNTech SE sank 7 per cent. Novavax Inc. dipped 7 per cent at the close.

Kennedy has long been critical of immunisations, contending that they lack effectiveness and have links to autism, claims that have been repeatedly debunked. While he said last week that he wouldn't take vaccines away from Americans, he assailed the science behind the shots' safety, saying it "has huge deficits, and we're going to make sure those scientific studies are done and that people can make informed choices." Kennedy will restore US regulators and public health agencies to "the traditions of Gold Standard Scientific Research," Trump said in a statement on social media where he announced the nomination.

The prospect of Kennedy's role in the next administration has alarmed public health officials who warned in recent days about the risks of curtailing vaccination efforts. Vaccines are crucial to protecting children from deadly diseases, Centers for Disease Control and Prevention Director Mandy Cohen said Wednesday at the Milken Institute Future of Health Summit in Washington. "I don't want to have to see us go backward in order to remind ourselves that vaccines work," she said. (Source: Business Line)