Friday, 17 October 2025

INSIGHTS

Healthcare Newsweekly For You

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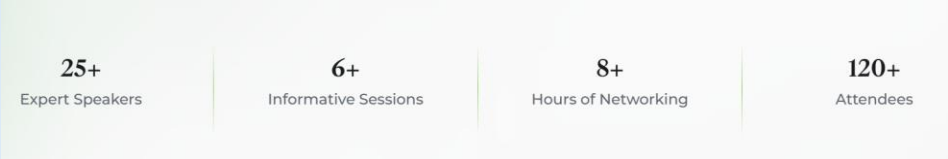
INTERESTING MEDICAL NEWS

A-601, Marathon Innova, Opp. Peninsula
Corporate Park, Off Ganpatrao Kadam Marg,
Lower Parel (W), Mumbai 400 013, India.

Tel.:+91-22-6673 6800,
Fax: 91-22-66399727
web: www.sidvim.com

UPCOMING EVENTS



Discussion Topics

- Unlocking the Potential of Biosimilars: Can India Repeat The Success of Generics?
- Bridging the Gaps: Tackling Academia, Funding & Tech Challenges Head-On
- Emerging Treatment Modalities: Designing Biotech for Local Health Needs
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- BioE3: Cracking the Code of Biotech Success — Entrepreneurship, Ecosystem & Execution in India
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Who should Attend?

- R&D and Innovation
- Biomanufacturing and Bioengineering
- Government Grant and Policy Bodies
- Process Development & Technology Transfer Teams
- Quality Assurance and Quality Control (QA/QC)
- Regulatory Affairs Scientists
- Formulations Plant Heads
- Ethics and Compliance Officers IP & Legal Teams
- IT and Digital Infrastructure Teams

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DEALS AND FUNDING

AstraZeneca to spend $445M to boost production of Lokelma at Texas plant

Fiercepharma, 15 October 2025

With sales of potential blockbuster Lokelma scaling up, AstraZeneca is bolstering its production of the hyperkalemia treatment with a $445 million injection of funds.

The investment will increase the capabilities of AZ's manufacturing facility in Coppell, Texas, which is the company's lone site in the world that produces Lokelma.

AZ will build a new 9,000-square-foot building at the complex and add two production lines, doubling its capacity to manufacture the treatment. The investment also will support upgrades for drug substance production and lab testing, as well as additional warehouse and administrative space, the company said in an Oct. 15 release.

"Our manufacturing facility in Coppell serves as both a critical pillar in global healthcare and has played an important role in supporting the local workforce over the past 10 years," Jim Fox, AZ's Americas supply operations chief, said in the release.

AZ to spend $445M to boost production of Lokelma at Texas plant

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Zenas Bio inks potential $2 billion licensing deal with China's InnoCare for autoimmune drug

Reuters, 8 October 2025

Zenas BioPharma, said on Wednesday it has secured global rights to develop and commercialize an experimental drug from China-based InnoCare Pharma (688428.SS),for multiple sclerosis and other autoimmune conditions under a licensing deal potentially worth more than $2 billion.

The deal grants Zenas worldwide rights to the drug, orelabrutinib, outside oncology. The U.S.-based drug developer will pay up to $100 million in upfront and near-term milestone payments and issue up to 7 million shares of common stock to InnoCare.

The agreement also covers two additional drug candidates, both slated for early-stage trials next year.

Orelabrutinib is being tested in a late-stage trial for a type of multiple sclerosis, a chronic disease that affects the central nervous system, with another due to begin in early 2026.

The total of the upfront payment, near-term milestone and potential development and regulatory milestone payments, along with potential commercial sales milestones across all three programs, exceeds $2 billion, Zenas said.

https://www.reuters.com/business/healthcare-pharmaceuticals/zenas-bio-inks-potential-2-billion-licensing-deal-with-chinas-innocare-2025-10-08/

★★★★★★★

Halozyme's $900M Elektrofi Buyout Brings Two Big Pharma Partners Together

Biospace, 2 October 2025

Halozyme Therapeutics will acquire Elektrofi for up to $900 million in a deal that will combine two subcutaneous drug delivery specialists that have each lent their technologies to Big Pharma companies.

The deal, announced Wednesday, will involve a $750 million upfront payment from Halozyme, plus up to three $50-million milestone payments, each contingent on different product approvals. Halozyme and Elektrofi's respective boards of directors have unanimously signed off on the deal, and the companies expect the transaction to wrap up in the fourth quarter, pending customary closing conditions.

According to Halozyme's news release, the acquisition makes strong strategic sense, bringing together "complementary" subcutaneous technologies that boost the convenience and accessibility of innovative therapies. The Elektrofi buyout also promises to be a financial boon to Halozyme, with milestone payments potentially hitting $275 million, alongside royalty revenues from the microparticle platform that are set to begin in 2030.

https://www.biospace.com/business/halozymes-900m-elektrofi-buyout-brings-two-big-pharma-partners-together

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Eli Lilly to Invest $1 Billion in Telangana to Boost Global Pharma Supply

Newsonair, 7 October 2025

Telangana has secured an investment of one billion US dollars from US pharma major Eli Lilly to expand its manufacturing and global medicine supply capacity in Hyderabad. The announcement has been made after a delegation from the company met Telangana Chief Minister A Revanth Reddy and State Industries Minister D Sridhar Babu in Hyderabad

yesterday. The company inaugurated its Global Capability Centre (GCC) in Hyderabad in August this year.

An official release stated that despite strong interest from several other states, Eli Lilly chose Telangana owing to the favourable ecosystem, availability of skilled manpower, infrastructure, and proactive government support. It further said that with the new facilities, Eli Lilly is set to manufacture in Telangana and supply globally. The One-billion-dollar investment by Eli Lilly reflects the company's interest in Telangana beyond its GCC operations and focuses on developing new medicines to treat diabetes and obesity, Alzheimer's disease, cancer and autoimmune conditions.

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Pfizer scores again in HER2-positive breast cancer, this time with Seagen's Tukysa

Fiercepharma, 14 October 2025

Pfizer's oncology portfolio has produced a second positive phase 3 trial in HER2-positive breast cancer in the span of about a year.

This time, the drug that delivered the positive readout is Tukysa, a HER2-targeted tyrosine kinase inhibitor that Pfizer picked up in its $43 billion acquisition of Seagen.

When used as a first-line maintenance therapy in patients with HER2-positive metastatic breast cancer who've responded to standard induction therapy, Tukysa significantly prolonged the time before cancer progression or death compared with placebo, Pfizer said Tuesday. Both Tukysa and placebo were given in combination with the standard maintenance regimen of Roche's Herceptin and Perjeta.

Pfizer scores again in HER2-positive breast cancer, this time with Seagen's Tukysa | Fierce Pharma

★★★★★★★

Lupin To Invest $250 Mn For New US Pharma Plant

Businessworld, 8 October 2025

Pharmaceutical major Lupin has plans to establish a manufacturing facility in Coral Springs, Florida, US. The USD 250 million investment, covering research & development, infrastructure, and capital expenditures over five years, will enable the production of more than 25 critical respiratory therapies, including albuterol inhalers for children with asthma and service members in the US and abroad.

The expansion is expected to create over 200 long-term, skilled jobs in Broward County by 2030. The 70,000-square-foot facility will anchor Lupin's US production of respiratory medicines, diversify the supply chain, and ensure affordable, reliable access—from routine pediatric care to pandemic-scale demand.

https://www.businessworld.in/article/lupin-to-invest-250-mn-for-new-us-pharma-plant-574746

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PHARMA & BIOLOGICS

LARGE MOLECULES

Regeneron's Libtayo gains 'practice-changing' skin cancer label expansion

Fiercepharma, 9 October 2025

In 2022, Regeneron paid Sanofi $900 million to gain full rights to its partnered cancer drug Libtayo. Three years later, the pricey bet on the injected PD-1 inhibitor appears to be paying off.

Thursday, the FDA approved Libtayo as the first immunotherapy for adjuvant treatment of cutaneous squamous cell carcinoma (CSCC). The nod applies to patients who are at a high risk of recurrence after surgery and radiation.

The green light comes seven years after Libtayo became the first drug to reach the market in CSCC, as it was endorsed for patients with metastatic CSCC or those with locally advanced CSCC who are not candidates for surgery or curative radiation.

The patient population is significant; approximately 1.8 million are diagnosed annually in the U.S. with CSCC, accounting for roughly 20% of the nation's skin cancer cases.

FDA approves Regeneron's Libtayo for adjuvant use in CSCC

★★★★★★★

REGULATORS AND REGULATORY ACTIONS

New GMP standards in India expose fault line between regulators and MSMEs: GlobalData

Expresspharma, 13 October 2025

India's small drugmakers are sounding the alarm as new good manufacturing practice (GMP) and bio-equivalence mandates could deepen the divide between regulators and

micro, small and medium enterprises (MSME). Their appeal to delay enforcement highlights growing concern that India's drive for stricter quality standards, while well-intentioned, may strain smaller manufacturers, forcing consolidation, factory shutdowns, and potential shortages of vital generic medicines, according to GlobalData.

Reportedly, MSME associations have appealed to the Union Health Minister to hit the brakes on new stringent manufacturing rules imposed by the Central Drugs Standard Control Organisation (CDSCO).

They warn that abrupt implementation timelines—especially the revised Schedule M GMP requirements and mandatory bio-equivalence studies for all generics—could financially cripple small drugmakers and force many to close, risking shortages of generic and critical medicines, as mentioned in the Q3 2025 Emerging Market Outsourcing Report.

Although the Schedule M deadline has been extended several times and currently stands at 1 January 2026, the groups want it pushed back to at least 1 April 2027, citing high compliance costs (bio-equivalence studies cost INR 250,000–500,000 per product) and the cumulative burden of other mandates like QR codes for cancer drugs, updated rules for gene therapies, and tougher penalties for quality failures.

https://www.expresspharma.in/new-gmp-standards-in-india-expose-fault-line-between-regulators-and-msmes-globaldata/

★★★★★★★

Biocon gets USFDA's tentative approval for antibacterial drug Rifaximin

Business Standard, 7 October 2025

Indian biopharma firm Biocon on Tuesday announced that its wholly owned subsidiary Biocon Pharma has received tentative approval from the United States Food and Drug Administration (USFDA) for its abbreviated new drug application (ANDA) for Rifaximin tablets, 550 mg, developed in partnership with US-based Carnegie Pharmaceuticals LLC.

The drug, a rifamycin antibacterial, is used to reduce the risk of recurrence of a liver-related condition called overt hepatic encephalopathy (HE) and to treat irritable bowel syndrome with diarrhoea (IBS-D) in adults.

According to the FDA, a tentative approval is a notification issued to drugs that otherwise meet the statutory and regulatory requirements for approval but cannot be approved for marketing in the United States because of patents or exclusivities related to the reference listed drug (RLD) upon which they rely.

https://www.business-standard.com/companies/news/biocon-usfda-tentative-approval-rifaximin-antibacterial-drug-hepatitis-125100700633_1.html

★★★★★★★

GSK touts study showing acceptability edge for its long-acting PrEP drug amid Gilead showdown

Fiercepharma, 15 October 2025

GSK's ViiV Healthcare and its bimonthly pre-exposure prophylaxis (PrEP) medicine Apretude had to make room for another long-acting PrEP option this summer, when rival Gilead Sciences rolled out Yeztugo to much fanfare. But despite Yeztugo's twice-yearly convenience factor, unprecedented efficacy performance in trials and award-winning pedigree, GSK has long maintained that one aspect of the rival drug's clinical profile would block it from snatching the entire long-acting PrEP market.

Now, armed with a new open-label crossover study, the company can back up its theory that the injection-site reactions from Gilead's drug may give some potential users pause.

GSK's CLARITY study, presented at the 20th European AIDS Conference (EACS) in Paris, examined the tolerability and acceptability of Apretude and Yeztugo to determine which drug would be preferred by the 63 HIV-negative adults who participated.

GSK touts study showing acceptability edge for its long-acting PrEP drug amid Gilead showdown | Fierce Pharma

★★★★★★★

Rocket aborts mission to get gene therapy approved by FDA for rare bone marrow disorder

Fiercebiotech, 3 October 2025

Having already altered the journey of its rare disease gene therapy to a hoped-for FDA approval, Rocket Pharmaceuticals has now aborted the mission entirely.

The biotech initiated a rolling biologics license application (BLA) for the candidate—known variously as RP-L102, mozafancogene autotemcel or Fanca-cel—in the first quarter of the year. The application was specifically to treat fanconi anemia, a rare genetic disorder characterized by bone marrow failure.

The future of the application appeared in doubt back in July, when Rocket said it "anticipated delays" to the RP-L102 program as part of a wider restructuring of the company's pipeline and workforce. At the time, the biotech withdrew its approval

application to European regulators and warned that an FDA approval was "no longer scheduled for 2026."

Friday morning, the company confirmed that it has "voluntarily withdrawn" the BLA, blaming the decision on July's reprioritization, "under which Rocket is focusing its resources on programs with the clearest regulatory and commercial pathways."

https://www.fiercebiotech.com/biotech/rocket-aborts-mission-get-gene-therapy-approved-fanconi-anemia

★★★★★★★

FDA throws cold water on Xspray's latest approval bid with rejection over manufacturing, label concerns

Fiercepharma, 9 October 2025

Xspray Pharma has taken hit after hit during its repeated efforts to commercialize its leukemia prospect Dasynoc. On its third attempt to win the FDA's favor, the company has run into yet another setback.

The FDA turned down Dasynoc's latest approval bid in chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL) with a complete response letter (CRL) after identifying concerns at Xspray's contract manufacturing organization, Xspray disclosed in an update Wednesday.

Although none of the agency's observations were directed specifically at the Dasynoc production lines, the FDA is holding off on approving any new products made at the CMO's site until the deficiencies are corrected, Xspray said. The manufacturer has already implemented a remediation plan and will meet with the FDA later this year.

"It is unfortunate that manufacturing-related issues beyond our control are delaying our launch," Xspray CEO Per Andersson said in a statement.

Xspray hits FDA wall with another manufacturing-related rejection

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GSK makes nice with antifungal partner Scynexis with $22M payment to resolve trial dispute

Fiercepharma, 15 October 2025

Brexafemme (ibrexafungerp) partners GSK and Scynexis have worked out their quarrel related to a clinical trial that was previously put on hold, leaving Scynexis with a $22 million payout.

Per the resolution, Scynexis will wind down its phase 3 MARIO study of Brexafemme in invasive candidiasis, the company said in an Oct. 15 press release. Besides the $22 million sum, the company stands to receive an additional $2.3 million related to trial wind-down activities, Scynexis said.

Scynexis will not receive any further milestone payments from GSK in relation to the MARIO study.

GSK is still on board with its Scynexis collaboration and plans to commercialize Brexafemme in its approved indications of vulvovaginal candidiasis (VVC) and refractory vulvovaginal candidiasis (rVVC), according to Scynexis. After Scynexis transfers the drug's regulatory application to GSK by the end of this year, the British company hopes to begin discussions with the FDA on a relaunch of the medicine.

GSK makes nice with antifungal partner Scynexis with $22M payment to resolve trial dispute | Fierce Pharma

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Candel snags $130M loan to carry immunotherapy over the regulatory finish line

First Word Pharma, 14 October 2025

With muted investor enthusiasm for its unique viral-based immunotherapy, Candel Therapeutics has turned to Trinity Capital for a $130-million loan to fund development of CAN-2409. While the financing will help the biotech advance the asset in two indications, its ambitions in a third setting — pancreatic cancer — will now need the help of a partner to move forward.

The loan, with $50 million available at closing, will enable Candel to start a Phase III trial of CAN-2409 in non–small-cell lung cancer (NSCLC) in the second quarter of 2026, and seek FDA approval of the biologic for prostate cancer in the fourth quarter of that year.

The second and third tranches of the loan, together worth $50 million, can be drawn based on the achievement of certain regulatory, clinical and operational milestones; the fourth tranche of $30 million is available at Trinity's discretion.

"We believe Candel's strong clinical data and innovative approach positions them well to make a real impact for patients facing prostate cancer and NSCLC — conditions with large commercial opportunities and a continued unmet need," said Rob Lake, senior managing director of life sciences at Trinity.

https://firstwordpharma.com/story/6321708

MEDTECH

What J&J's ortho spinoff means for the industry

Analysts expect that DePuy Synthes could become a stronger competitor as a standalone company.

Johnson & Johnson's plan to spin out its orthopedics segment could give the business a chance to become a stronger competitor, experts told MedTech Dive.

J&J announced on Tuesday that it would separate its orthopedic business into a standalone company, called DePuy Synthes, in the next 18 to 24 months. The decision follows a history of medtech spinoffs — with recent examples including GE Healthcare, ZimVie, and Medtronic's planned split of its diabetes business — where companies look to divest slower-growing segments in hopes that both remaining entities will be stronger.

J&J CEO Joaquin Duato told investors this week that the orthopedics spinoff would allow J&J to focus on faster-growing medtech markets such as cardiovascular and robotic surgery. In the long term, analysts expect the decision will lead to more investment and faster growth in the standalone orthopedics business.

Market share

Duato told investors that he expects DePuy to be the "largest, most comprehensive orthopedics company" as a standalone firm.

J&J's orthopedics business reported sales of $9.2 billion last year, making up about 29% of J&J's total medical device sales. Most of the orthopedic device market is divided between four companies: Stryker, J&J, Zimmer Biomet and Smith & Nephew.

https://www.medtechdive.com/news/jnj-ortho-spinoff-industry-impact/802983/

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Everstone Capital-backed Integris Medtech files DRHP for ₹3,500-4,000 cr IPO; key details

Fortuneindia, 10 October 2025

Diversified medical technology platform Integris Medtech has filed its draft red herring prospectus (DRHP) for a public issue with market regulator Securities and Exchange Board of India (SEBI). The IPO comprises a fresh issue of equity shares up to ₹925 crore and an offer for sale of up to 21,674,531 equity shares. The OFS includes 15,174,251 equity shares by Evercure Holdings Pte. Ltd., 3,250,140 shares by Gurmit Singh Chugh, and 3,250,140 shares by Punita Sharma.

Overall, the entire issue is pegged between ₹3,500 crore and ₹4,000 crore, people familiar with the matter said.

In consultation with the BRLMs, the company may consider a pre-IPO placement of ₹185 crore before the filing of the RHP with the ROC. The company plans to use the funds raised from the net proceeds to repay or prepay certain loans, along with any interest and prepayment charges amounting to ₹696.39 crore, taken by its wholly owned subsidiaries as well as by its step-down subsidiaries. A portion of the funds will also be used for general corporate purposes.

https://www.fortuneindia.com/markets/ipo/everstone-capital-backed-integris-medtech-files-drhp-for-925-crore-ipo-key-details/127418

★★★★★★

INTERESTING MEDICAL NEWS

Both diet and regular sodas are linked to liver disease, new study finds

Medical News Today, 7 October 2025

- Diet versions of beverages are often hailed as healthier than the sugar-sweetened original versions.
- Research is ongoing regarding the potential dangers of sugar-sweetened and artificially sweetened drinks.
- Recent study results identified a link between drinking higher amounts of sugar-sweetened beverages and low or non-sugar-sweetened beverages and an increased risk for metabolic dysfunction-associated steatotic liver disease (MASLD).

Metabolic dysfunction-associated steatotic liver disease (MASLD) involves a buildup of fat in the liver that did not result from drinking alcohol. People with this condition have a possible risk for more significant liver problems or other conditions like cardiovascular disease.

A recent study focused on how sugar-sweetened and low or non-sugar-sweetened beverages related to liver health. Based on analysis of over 103,000 participants, higher consumption of both beverage types was linked to a higher risk for MASLD.

Additionally, low or non-sugar-sweetened beverages were linked to a greater risk for liver-related mortality. While the study hasn't been published yet, the findings shed light on the potential risks of these beverages, particularly low or non-sugar-sweetened

beverages.

The study results were presented at UEG Week 2025, the annual congress of United European Gastroenterology. They are yet to appear in a peer-reviewed journal.

Drinking more than 1 can of any soda daily linked to liver problems

This study was a prospective cohort study where researchers used data from the UK Biobank. Researchers examined data from 103,251 participants who did not have baseline liver disease. The median follow-up was a little over 10 years, and during this time "949 participants developed MASLD, and 103 died from liver-related causes."

Participants reported on their consumption of sugar-sweetened and low or non-sugar-sweetened beverages. Researchers were also able to consider participants' liver fat content based on MRI data.

Researchers looked at the associations between drinking these beverages and someone's risk for MASLD. They also looked at liver-related mortality and liver-fat content and their association with the related beverages.

Consuming more than 330 grams (g), or about 1 can, of drinks from either beverage category daily was associated with a higher risk for developing MASLD.

Sugar-sweetened beverages were associated with about a 50% greater risk for MASLD, and low or non-sugar-sweetened beverages were associated with 60% greater risk. The results also found that consuming either beverage type was linked to liver fat content.

At the same time, drinking low or non-sugar-sweetened beverages was associated with an increased risk for liver-related mortality, but sugar-sweetened beverages did not have a significant association.

The researchers also found that the association between low or non-sugar-sweetened beverages and liver-related mortality was dose-dependent; drinking more was linked to a higher risk. Swapping soda for water helps lower liver disease risk

When looking at substituting beverages, researchers found that switching out 330 g of either beverage type daily for water helped to decrease risk for MASLD.

The effect was a little larger when switching out sugar-sweetened beverages for water, which decreased MASLD risk by 14.7%.

Researchers found that switching out the beverage types for each other did not change the risk for MASLD.

The findings highlight the potential danger of both beverages, but particularly low or non-sugar-sweetened beverages, on liver outcomes. Study author Lihe Liu, a graduate student in the Department of Gastroenterology at the First Affiliated Hospital of Soochow University in Suzhou, China, explained to *Medical News Today* that:

"Our research shows that low- or non-sugar-sweetened beverages (LNSSBs), often seen as healthier alternatives because they use sugar substitutes, may not be entirely risk-free. We found that frequent consumption was still linked with liver health risks, which challenges the common belief that these drinks are completely 'safe' or 'healthy' substitutes for sugary beverages."

Study limitations and continued research

The full study has not been published in a peer-reviewed journal yet, which makes it challenging to know the full limitations of the research. However, beverage intake was something reported by participants, which may not have been their true intake.

The data also does not establish that consumption of these beverages causes liver problems. It's also unclear what covariates researchers adjusted for in their analyses.

The UK Biobank is has its own limitations too, including the fact that it includes primarily white participants, and they tend to be healthier than the United Kingdom's general population. For this reason, additional follow-up research will be helpful.

Study author Liu explained the next steps to *MNT*, saying that:

"The next step is to complete and submit the full manuscript for peer review and publication, which will allow the scientific community to scrutinize and build upon our findings. Looking ahead, more research is needed to clarify the biological mechanisms linking artificially sweetened beverages to liver disease, and to explore whether different types of sweeteners carry different risks. Long-term studies in more diverse populations

will also be important to strengthen the evidence base."

What are the clinical implications?

While more research is required, the findings do give another reason for avoiding drinks like soda and their diet counterparts. It also highlights that opting for water instead may help to decrease MASLD risk.

"Our findings indicate that both sugary and artificially sweetened drinks may carry risks for liver health. Clinically, this highlights the need to guide people toward healthier beverage choices, with water remaining the safest and healthiest option," Liu explained to *MNT*.

Registered dietitian nutritionist Karen Z. Berg, MS, RD, CSO, CDN, who was not involved in this research, advised that:

"Many people have the misconception that diet drinks are healthier for you than regular drinks, but this study demonstrates how both are positively associated with MASLD. I highly encourage all patients to stick with water, or carbonated water, for the best health outcomes. Just because something says 'zero calories' or 'less sugar' [it] does not automatically equate with [being] healthier. There are a lot of chemicals that go into those beverages to give them the flavors people crave. Plain water, fruit infused water (homemade), unsweetened homemade iced tea, or seltzer [are] the way to go."

https://www.medicalnewstoday.com/articles/diet-and-regular-sodas-are-linked-to-liver-disease

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