

PNC PHARMA & LIFE SCIENCES

Monthly News Brief

August 2021

COVID-19

[Pfizer-BioNTech's COVID Vaccine Gets Full Approval from the FDA \(NPR\)](#)

The full FDA approval replaces the emergency use authorization issued last December and could make it easier for vaccine mandates to be instated, as well as reassure some people who are hesitant about the vaccine. As part of the approval process, the vaccine also got a brand name: Comirnaty

[The Economy could be Getting Help from Positive News on the Delta Variant \(CNBC\)](#)

Medical professionals see delta peaking in the fall, though estimates vary. Jefferies' Chief financial economist Aneta Markowska comments on the delta variant, "It's really just causing a loss of momentum rather than pronounced economic weakness..."

M&A Announcements

[FTC Trial Kicks Off, with Fate of Illumina's Acquisition of Grail Hanging in the Balance \(The San Diego Union-Tribune\)](#)

Both US and EU regulators are reviewing the sequencing company's \$7.1B purchase of cancer detection startup Grail. The FTC claims the acquisition violates antitrust laws, though the agency withdrew its injunction to block the acquisition on account that the European Commission is investigating the deal. Illumina closed the deal without complete reviews by either agency

[Sanofi bets \\$3.2B on mRNA with deal to buy Translate Bio \(BioPharma Dive\)](#)

The acquisition is the latest sign that large pharmaceutical companies see messenger RNA as a crucial and promising platform for vaccine and drug development. Sanofi recently committed \$500 million a year on mRNA vaccine development

Novel Medicine

[CRISPR Pioneer Feng Zhang's Latest Work Delivers mRNA, Gene Therapy with a Human Protein \(Fierce Biotech\)](#)

The delivery system dubbed SEND uses a specific human protein's ability to bind to its own mRNA and form a protective capsule around it. Zhang and his team believe SEND could offer a new way to deliver RNAs as therapeutics or as gene-editing tools

[First in Human: Pharma Sees mRNA's Cancer, Vaccine Potential After COVID's Success \(S&P Global\)](#)

Global success of mRNA-based COVID-19 vaccines have given momentum to early-stage trials of other vaccines and therapies using mRNA technology. BioNTech and Moderna both have mRNA vaccine candidates in early-stage trials across therapeutic areas such as oncology, autoimmune and infectious diseases

[FreeStyle Libre 2 App Receives Clearance from US FDA for Diabetes Management \(Endocrinology Network\)](#)

The new iPhone-compatible continuous glucose monitoring ("CGM") application is used with the Freestyle Libre 2 glucose sensor, and is the only app to be sensor-based. Diabetic patients can use the app for up-to-the-minute glucose data and optional real-time glucose alarms

[AbbVie Posts New Data on Drug that could Replace Glasses or Contacts for Age-Related Far-Sightedness \(Fierce Biotech\)](#)

Results from a 323-patient phase 3 trial showed significant improvements in the vision of patients with age-related far-sightedness after 30 days of dosing. A decision on FDA approval of the drug is due by the end of 2021

Other News

[Chinese Drugmakers Ramp Up US FDA Applications Amid Domestic Pricing Pressures \(S&P Global\)](#)

Chinese drug developers have filed five applications with the FDA in 2021 (compared to three total in 2019 and two in 2020), driven by limited profits available in China from innovative drugs. Gaining FDA approval allows for overseas expansion and also endorses research and development capabilities among Chinese biotechs that have not yet been recognized internationally

[Biden Calls on Congress to Tackle Soaring Prices of Prescription Drugs \(Yahoo!\)](#)

President Biden called on Congress to pass legislation allowing Medicare to negotiate directly with drug manufacturers and penalize drugmakers that increase prices faster than the rate of inflation

[Gilead Wins Reversal of \\$1.2B Penalty in CAR-T Patent Case \(BioPharma Dive\)](#)

The ruling overturns a prior judgement that would have forced Gilead to pay sizeable royalties to its rival Bristol Myers Squibb over an alleged patent infringement related to cancer cell therapy Yescarta, that Gilead inherited through an acquisition

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