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October 17, 2024

The Honorable Lina Khan
Chairwoman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: The FTC Should Challenge Novo Nordisk's Acquisition of Catalent Consumers

Dear Chair Khan:

The undersigned unions, consumer, and public interest organizations[1] are concerned about the lack of meaningful patient choice in life saving prescription drugs. These organizations have watched with concern as vertical integration in the healthcare industry has reduced competition, rivals' incentives to innovate, and ultimately, choices and quality of care for patients.

Today, we write to express our opposition to Novo Holdings' proposed acquisition of Catalent Inc. ("Catalent"), a $16.5 billion transaction that combines a Danish pharmaceutical giant, Novo Nordisk ("Novo"), which has the dominant market share in Glucagon-like Peptide-1, ("GLP-1") drugs used to treat diabetes and obesity, with Catalent, which has 50 facilities and is one of the most critically important full-scale global contract development and manufacturing organizations ("CDMOs") in the world.[2] Because of the importance of a full-scale CDMO like Catalent, this transaction raises vertical foreclosure concerns that could impact downstream markets in important medications for patients that suffer from obesity and diabetes as well as promising gene therapy treatments for a number of conditions that currently have no cure.

We believe this transaction, if consummated, would be harmful to competition across various therapeutic areas and ultimately reduce patients' access to these vital treatments. Below, we highlight the importance that access to an independent Catalent provides for current and future rivals to Novo; the expected entry of GLP-1 and gene therapy rivals to Novo that an independent Catalent would likely help facilitate; and the harms likely to be caused by this acquisition.

[1] The groups are United States Public Interest Research Group, Services Employees International Union, American Federation of State, County, and Municipal Employees, Consumer Action, Doctors for America, Beta Cell Action, Citizen Action/Illinois, Generation Patient, Health Care Voices, Popular Democracy, Salud y Farmacos, US, and Social Security Works.

[2] Catalent Inc., Form 8K, May 3, 2024.

I. The Transaction

As part of the transaction, Novo will pay $11 billion to acquire three of Catalent's fill-finish sites located in Indiana, Belgium, and Italy,[3] which currently fill self-injection pens for GLP-1 injectables. Novo's stated purpose for the acquisition is to boost its production capacity for these important drugs.[4] We are concerned that the merger would change Catalent's incentives and abilities to service other GLP-1 competitors and potential gene therapy rivals going forward.

II. The Transaction will harm competition and reduce patients' access to GLP-1 medications.

a. Novo is the market leader in GLP-1s and Catalent is the top positioned CDMO to support GLP-1s.

Novo is the market leader in sales of GLP-1 drugs with approximately 54% of the North America market.[5] Catalent has a first mover advantage over other CDMOs and has been involved in GLP-1 drug manufacturing since 2017, making it a "top-positioned CDMO" to support GLP-1s.[6] Indeed, Catalent is one of the very few CDMO suppliers that provides specialized fill-finish development and manufacturing services to GLP-1 manufacturers such as Novo's Ozempic and Wegovy.[7]

b. New GLP-1s are expected to launch in the future.

While there are only two GLP-1 competitors on the market today, Novo and Eli Lilly, there are a number of pharmaceutical companies and biotech firms with GLP-1s in the pipeline including Viking Therapeutics, Structure Therapeutics, Amgen, Sun Pharma, Pfizer, Roche, and AstraZeneca.[8] These firms need a CDMO partner to help with the launch of their products

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[3] Catalent Press Release, *Novo Nordisk to acquire three fill-finish sites from Novo Holdings A/S in connection with the Catalent, Inc. Transaction*, February 5, 2024.

[4] *Id.* Novo's acquisition of Catalent "aligns with its strategy of reaching more people with diabetes and obesity with current and future treatments." And "[i]t enables an expansion of the manufacturing capacity at scale and speed while providing future optionality and flexibility for Novo Nordisk's existing supply network. The acquisition is expected to gradually increase Novo Nordisk's filling capacity from 2026 and onwards."

[5] Novo Nordisk Investor Presentation, First Three Months of 2024, at 6, 111. https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/financial-results/2024/q1-2024-investor-presentation.pdf.

[6] Zoey Becker, *JPM24: Catalent poised to pounce on GLP-1 manufacturing opportunity, CEO says*, https://www.fiercepharma.com/manufacturing/jpm24-catalent-poised-take-top-spot-glp-1-drug-manufacturing-area

[7] *Id.*

[8] Brian Buntz, *An overview of the GLP-1 landscape in obesity therapeutics*, Drug Discovery Trends, October 3, 2023 available at https://www.drugdiscoverytrends.com/glp-1-drug-market-trends/; Michael Gibney, *Big Pharma players Amgen, Roche and Pfizer seek to follow in Novo and Lilly's weight loss footsteps*, PharmaVoice, February 8, 2024 available at https://www.pharmavoice.com/news/weight-loss-ozempic-zepbound-novo-nordisk-eli-lilly-pfizer-amgen-roche-glp/706919; Aztrazeneca Press Release, *Aztrazeneca licenses novel agent for the treatment of cardiometabolic conditions and obesity*, November 9, 2023 available at https://www.astrazeneca.com/media-centre/press-releases/2023/agreement-with-eccogene-for-clinical-stage-glp-1ra.html.

within the next few years, and currently, there is only one CDMO, Catalent, that has extensive experience working with GLP-1 manufacturers. Because of the proposed acquisition, there is a real question of whether these future rivals to Novo will be able to secure the expertise to bring the product to market and have available and qualified capacity to manufacture these products when they commercially launch.[9]

c. Novo would have the incentive and ability to foreclose rival GLP-1 manufacturers from obtaining Catalent services.

Novo would have the ability-and-incentive to foreclose its current and future GLP-1 rivals from obtaining access to fill-finish capacity at Catalent sites and to otherwise disadvantage current and future GLP-1 rivals in favor of Novo's own products.[10] Indeed, Novo's stated purpose of the transaction is to gain exclusive access to the fill-finish sites that it needs from Catalent with the purpose of prioritizing production of its own drugs.[11] Catalent, under Novo's direction, would have the incentive to charge higher prices, provide worse customer service, and give less favorable terms to Novo's rivals. It is reasonable to expect that Catalent's fill-finish capacity will effectively be closed to Novo's rivals, both those currently on the market and those with products in the pipeline.[12] The result would be to limit the ability of Novo's rivals to compete and to diminish patients' ability to obtain access to newly approved medications.

In addition, Novo would be able to secure access to commercially sensitive information about its rivals including product development, new characteristics being developed and plans for entry. We do not believe any behavioral remedy can prevent these anticompetitive effects.

III. The Transaction will reduce innovation and consumers' access to gene therapies.

Gene therapy represents a transformative approach to medicine that could change the landscape of how to treat a wide range of diseases. Catalent is a major player in gene therapy manufacturing, supporting the production of two FDA approved therapies, Sarepta's Elevidys and Novartis' Zolgensma.[13] Many of Catalent's facilities are focused on cell and gene therapies,

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[9] Kelly Bilodeau, 3 Questions Hanging Over the Novo Catalent Deal, Feb 13, 2024, https://www.pharmavoice.com/news/novo-catalent-eli-lilly-wegovy-fda/707309/. "In general, pharma companies have relied on contract organizations for certain research, developing and manufacturing activities but this level of need on the part of GLP-1 and GIP manufacturers is of a new order, and it is not surprising that the major manufacturers are scrambling for capacity," said Dr. Howard Forman, a professor at Yale School of Management and Yale School of Public Health.

[10] AstraZeneca's CEO stated publicly that, "It really means for us that we need to be as independent as we can, in terms of our own supply." Maggie Fick and Eva Mathews, Astrazeneca Says Catalent Deal Shows Importance in House Capacity, Reuters, February 8, 2024 available at https://www.reuters.com/markets/deals/astrazeneca-says-catalent-deal-shows-importance-in-house-capacity-2024-02-08/

[11] Novo to buy Catalent: the backlash begins, Pharmaceutical Technology, February 9, 2024 and Aayushi Pratap, Novo Nordisk parent to acquire Catalent to shore up weight-loss drug production, Chemical & Engineering News, February 9, 2024.

[12] https://www.linkedin.com/posts/noah-cockroft_astrazeneca-says-catalent-deal-shows-need-activity-7161516485234900992-qwd2/

[13] Isabel Cameron, Novo Nordisk and Catalent Deal: Net positive or negative for industry?, Biopharma Reporter, February 20, 2024.

so Novo's acquisition could impact the capacity for gene therapy manufacturing.[14] Moreover, Catalent is a critical partner for gene therapy firms in assisting the develop of intellectual property and managing the regulatory process.

Novo, which is investing in gene therapy platforms and programs, would be in a position to disadvantage rival gene therapies. Post-merger the merged firm would have the incentive and ability to prioritize its own production needs and to pick and choose which rival gene therapies would be allocated manufacturing capacity at current Catalent facilities. In addition, if any of Novo's drugs are threatened by a particular gene therapy that is in a partnership with Catalent, Novo would have the incentive and ability to delay collaboration with gene therapy rivals, ultimately delaying the approval of that gene therapy.[15] Existing gene therapy firms may face challenges in scaling up production as Novo would have the incentive and ability to fulfill its needs over any rivals. Catalent is in a critical position in collaborating with gene therapy firms. New entrants to the gene therapy market may struggle to find other qualified CDMOs, if facing discrimination from Catalent. The result would be to diminish patients' ability to obtain access to gene therapies, which could potentially provide life-saving treatments.

IV. Concluding Thoughts

We urge the Commission to challenge this transaction to ensure that competition is protected and that consumers will have full access to treatments for these critical drugs and future therapies. In our view, there is no adequate remedy that resolves the competition concerns raised by this transaction. It is important for the FTC to challenge a transaction like this one that provides a firm with the ability-and-incentive to engage in a broad range of anticompetitive conduct which could limit patients' access to critically important treatments.

If you have any questions, please contact David Balto at David.balto@dcantitrustlaw.com or 202-577-5424.

Thank you for your consideration.

Respectfully,

American Federation of State, County and Municipal Employees (AFSCME)
Beta Cell Action
Consumer Action
Doctors for America
Service Employees International Union
Social Security Works
United States Public Interest Research Group

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[14] *Id.*

[15] See, Closing Statement of FTC on the matter of Roche Holdings and Spark Therapeutics. While closing the matter, the FTC made clear that it investigated whether Roche would have the incentive and ability to terminate or delay the entry of Spark's developmental gene therapies for hemophilia that might threaten Roche's existing hemophilia drug. https://www.ftc.gov/system/files/documents/public_statements/1558049/1910086_roche-spark_commission_statement_12-16-19.pdf.

Citizen Action/Illinois
Generation Patient
Health Care Voices
Popular Democracy
Salud y Farmacos, US

cc: Commissioner Alvaro Bedoya
Commissioner Melissa Holyoak
Commissioner Rebecca Kelly Slaughter
Commissioner Andrew Ferguson
Henry Liu, Director, FTC Bureau of Competition