



Office of Commissioner  
Rohit Chopra

UNITED STATES OF AMERICA  
Federal Trade Commission  
WASHINGTON, D.C. 20580

## **DISSENTING STATEMENT OF COMMISSIONER ROHIT CHOPRA**

In the Matter of Fresenius Medical Care AG & Co. KGaA and NxStage Medical, Inc.  
FTC File No. 171-0227  
February 19, 2019

### **Summary**

- Entry by new, independent businesses is a pillar of a competitive market. When vertical mergers in health care markets choke off entry by small startups and other firms, long-term improvements in patient care can suffer.
- Unlike public investments in health care research and development, private investors are focused on financial returns, not patient outcomes. By cutting off a large portion of the market to future competitors, this merger will make it tougher for new entrants to obtain the sales needed to attract investment.
- Given the complexity of this and other transactions, the FTC should provide greater transparency to the public about its reasoning for a remedy – or lack thereof.

With more sectors of the economy dominated by a few incumbents, new ideas and new firms that disrupt their dominance may never see the light of day. Reduced entry and slower innovation doesn't just hurt productivity and growth, it can also slow improvements in quality of life, particularly when it comes to health care.

Fresenius Medical Care Holdings, Inc. (NYSE: FMS) is one of only two major providers of dialysis services. Fresenius is also the largest manufacturer of dialysis machinery and a major seller of supplies used in treatment. NxStage Medical, Inc. (NASDAQ: NXTM) is a much smaller medical technology firm that manufactures a machine used for in-home hemodialysis treatment. Fresenius has proposed to acquire NxStage.

The Commission proposes to settle charges that the acquisition violates the law.<sup>1</sup> To justify not seeking any remedy covering the vertical aspects of this transaction, my colleagues point to the benefits of the merged firm migrating more patients to home therapy because the merged firm will have more incentive to do so post-merger (since it will be more profitable post-merger). However, vertical mergers can choke off entry by innovators by shrinking the potential market to a point where it doesn't make economic sense for a new business to launch. This could have the unfortunate effect of slowing down long-term improvements in care for Americans suffering from kidney failure.

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<sup>1</sup> The proposed order includes a remedy to address one specific competitive concern. While I do not focus on the proposed order's requirement for the merged firm to divest its bloodlines business in this statement, I agree with this provision.

## **Kidney Failure and the Multibillion Dollar Hemodialysis Market**

Hundreds of thousands of Americans are dealing with kidney failure, also known as end-stage renal disease. After the initial years of treatment, Medicare provides coverage for hemodialysis regardless of age, financial need, or insurance coverage. The public and private sector spends billions to care for these individuals. The annual Medicare spending alone to treat this condition in the U.S. adds up to tens of billions of dollars per year. Most patients with this condition face a lifelong burden of frequent, multi-hour visits to a hemodialysis center. The hemodialysis market has grown rapidly, given the incidence of kidney disease. Compared to patients in other developed countries, hemodialysis patients in the United States have higher mortality rates.

The hemodialysis market is highly concentrated and suffers from low levels of innovation, according to experts and market participants. While there are some medium-sized and regional hemodialysis clinic chains, Fresenius and DaVita dominate the market, essentially as a duopoly. In addition to operating clinics, Fresenius is vertically integrated and is the market leader for production of in-clinic hemodialysis machines and a number of supplies used in hemodialysis treatment.

One way to improve the life of patients is for further innovation in machines that allow patients to treat themselves in the comfort and dignity of their own homes. Clinical evidence suggests that in-home hemodialysis has benefits over in-clinic hemodialysis, and is an effective treatment for many eligible patients. For example, in-home hemodialysis can often be completed during sleep, giving patients more opportunity to find full-time employment to support themselves and their families, and live a more engaged life.

In the U.S., uptake of in-home hemodialysis usage lags behind other developed countries, making up just a tiny percentage of the total hemodialysis population: out of the almost half a million hemodialysis patients in the U.S., less than two percent are performed in-home.<sup>2</sup> However, in-home hemodialysis would be beneficial for a larger portion of the patient population. Many developed countries have higher rates of in-home hemodialysis. For example, in New Zealand, almost one in five hemodialysis patients receive treatment in-home.<sup>3</sup>

One contributing factor for low adoption of in-home hemodialysis is high dropout rates. Because patients have to operate a machine to dialyze, or clean, their blood, a patient's discomfort or difficulty using the machine might lead to discontinuation. If more innovators are able to enter with better quality machines, more Americans might benefit from this treatment if new machines are more patient-friendly.

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<sup>2</sup> Healio Nephrology News & Issues, *The Largest Dialysis Providers in 2017: More Jump on Integrated Care Bandwagon*, July 16, 2017, <https://www.healio.com/nephrology/practice-management/news/online/%7Bd894132b-b577-435e-8dec-401cd89d1b1e%7D/the-largest-dialysis-providers-in-2017-more-jump-on-integrated-care-bandwagon>.

<sup>3</sup> National Renal Advisory Board, *About Dialysis Care in New Zealand*, 2014, <https://www.health.govt.nz/system/files/documents/pages/patient-summary-dialysis-2014.pdf>.

## Daunting Conditions for New Businesses to Form and Enter

The structure and concentration of the U.S. hemodialysis market is already unfriendly to new, independent businesses seeking to sell their in-home machines to clinics.<sup>4</sup> Even before the merger, the market for in-home clinic supplies is close to a duopsony. Fresenius and DaVita make up roughly 85 percent of all hemodialysis patients (in-clinic and in-home); the third-largest provider has only 191 in-home patients.<sup>5</sup> Investors know that any entrant will not only need to go through the years-long process of approval by the Food & Drug Administration (FDA), but will also need at a minimum to secure either Fresenius or DaVita (and preferably both) as a customer, given the dominance of the two market leaders.

Research, development, and regulatory approval for a new machine is challenging. Because of limited research support from public investments, most health care startups are dependent on private investors that optimize on financial returns, not patient outcomes. For new ventures to make it to the market, investors will need to see that there is a high likelihood of sales and profits. Prior to the merger, potential entrants could make a case to sell to both Fresenius and DaVita, as well as the remaining fringe firms. The merger essentially eliminates the potential for sales to Fresenius, since Fresenius will have little incentive to purchase in-home hemodialysis machines from a competitor. While DaVita may welcome and support a new entrant, DaVita will be the only major customer left in the market, giving the company massive buyer power to dictate terms.

In an already unfriendly environment, venture capital and other private equity investors – the major source of funding for small startups – will see even more risk and ask even more questions. Won't you be too dependent on DaVita? How will you convince DaVita to buy your machine? Even if you do, won't DaVita squeeze you on pricing? If you can't sell to DaVita, will you also need to start your own clinics? This reduced upside and increased risk of failure will translate into less investment, entry, and innovation. For entrants, even ones with existing plans, the numbers will not add up, and fewer new machines will make it to market.

The Majority also points out that another large corporation announced potential entry. But limiting the potential sphere of entrants to only those with deep pockets or with access to a captive set of patients will not lead to the same level of vigorous competition that comes from an ecosystem of small firms. The Majority also concludes that there was no evidence that reduction in funding sources stemming from this transaction would affect competition and innovation. I disagree. There was clear evidence that the transaction will delay or inhibit entry by new firms.

While I appreciate that the Majority is carefully weighing quality and patient outcomes, the long-term consequences of reduced entry from this merger may be severe. I believe the clinical benefits of more competition at the machine level outweigh the purported benefits of this merger.

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<sup>4</sup> Importantly, patients do not purchase machines. Machines are purchased by hemodialysis clinics, and patient care is supervised by nephrologists. Clinics and nephrologists have their own commercial relationships. In some cases, nephrologists have equity or equity-like stakes in clinics.

<sup>5</sup> See Healio Nephrology News & Issues, *supra* note 2.

## Justifications for the Merger

The Majority believes that, after this transaction, the market will benefit from the standard theoretical improvements from vertical integration. In essence, they assume that Fresenius's profit motive today dissuades their affiliated nephrologists from recommending a superior treatment outcome, since it is more profitable to treat patients in-clinic. After the merger, Fresenius will increase its margins on home dialysis, since it will be able to "purchase" NxStage's machine at a reduced price, rather than at rate set by the market.

It is not clear that the bulk of these effects could only be achieved through the merger. Fresenius could achieve cost savings and other benefits through sourcing and supply agreements. In fact, these agreements are common in the renal care industry.

While I have focused on reduced entry by new businesses, the transaction certainly raises other concerns. For example, like with other vertical mergers, Fresenius might have the incentive to increase prices,<sup>6</sup> reduce service, or withhold critical information<sup>7</sup> to rival clinics. In addition, Fresenius and NxStage each produce the only FDA-approved in-home hemodialysis machine. The Commission did investigate potential competitive concerns with this overlap, but there is no discussion of this issue in the documents made available to the public to evaluate the investigation's findings.

Given the complexity of this case and the significance of this transaction to the overall market, it is important that the public and the marketplace understand the full set of issues and the reasoning behind the Commission's decision.<sup>8</sup> To help the public evaluate our investigation and proposed settlements, the Commission should look to provide more transparency in the analysis made available to the public, such as a discussion of the analyses conducted regarding potential anticompetitive effects, data relied upon to justify a remedy (or lack thereof), and discussion of entry conditions post-transaction.

## Conclusion

As noted in the Commission's complaint, this transaction harms competition in violation of the law. Like other sectors of the economy, health care markets rely upon new ideas and innovation brought by new and small businesses. But bringing about new ideas and innovation requires access to funding. Investors focus on financial returns, not patient outcomes. After this transaction, fewer new businesses will find it worthwhile to enter, and they will struggle to secure funding. This will slow the development of improved machines that would enhance the lives of patients. For these reasons, I dissent.

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<sup>6</sup> Fresenius may have the ability to profitably raise prices to rival clinics up to a certain point; I did not see evidence that sufficiently ruled out this possibility.

<sup>7</sup> For example, in 2011, Fresenius failed to send a warning letter to its competitors that it sent to its own clinics about potential medical complications from Fresenius's GranuFlo dialysis concentrate product. In 2016, a Massachusetts state court found Fresenius negligent for not distributing the warning to its competitors, and Fresenius subsequently settled over 10,000 lawsuits for \$250 million. *See* Fresenius Medical Care AG & Co. KGaA, SEC Form 6K, p. 42, [https://www.freseniusmedicalcare.com/fileadmin/data/com/pdf/investors/News\\_Publications/Financial\\_Report/2016/Q1\\_2016\\_6K.pdf](https://www.freseniusmedicalcare.com/fileadmin/data/com/pdf/investors/News_Publications/Financial_Report/2016/Q1_2016_6K.pdf); *see also* Andrew Pollack, *World's Largest Dialysis Equipment Maker Agrees to Settle a Lawsuit for \$250 million*, New York Times, Feb. 19, 2019, <https://www.nytimes.com/2016/02/19/business/dialysis-equipment-maker-settles-lawsuit-for-250-million.html>.

<sup>8</sup> While Commissioner statements can help to achieve this, it might be better achieved through the Analysis to Aid Public Comment released by the Commission, consistent with law and Commission rules protecting confidential information.