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Fresenius/NxStage: Dialysis Tie-up Faces Renewed FTC Vertical Questions

FTC Update

FTC commissioners' questions about Fresenius's (ETR:FME) $2 billion acquisition of NxStage (NXTM) have led to renewed staff focus on the deal's potential impact on entry into the home hemodialysis machine market, putting in jeopardy the companies' plans to close the deal by year's end, sources familiar with the matter said.

As part of the response to the commission-level inquiries, FTC staff attorneys have as recently as this week contacted third parties with questions about whether the merger could raise entry barriers or costs for potential home hemodialysis entrants, the sources said.

Given the outstanding questions, FTC staff—which has been evaluating a settlement package since the summer—has not yet finalized a memo recommending that the commission vote out a consent order to conditionally clear the deal, the sources said.

Staff's move to negotiate a settlement and draft consent—which is typically taken with at least implicit sign-off from the FTC Chairman—signals that the questions are unlikely to lead to a full-stop challenge to the merger absent significant new evidence of harm. But the vertical inquiry nonetheless points to open commission-level questions on the merger, which could at the very least complicate the companies' plans to complete their transaction this year.

Fresenius, the largest U.S. provider of dialysis care, announced its acquisition of NxStage, whose System One machine dominates the U.S. home hemodialysis machine market, in August 2017. Fresenius said at the time that it expected to close the deal in 2018 and reiterated this guidance in an October 30 earnings release.

However, the FTC Bureau of Competition front office and the FTC commissioners each typically require two weeks to evaluate a staff recommendation and settlement package after they are finalized. And given this timeline, as well as outstanding vertical questions that have prevented staff from completing its recommendation memo, the companies now face a complicated path to a 2018 close.

The companies' merger agreement includes a February 5, 2019 end date.

The FTC declined to comment. Fresenius and NxStage did not respond to requests for comment.

Vertical questions. The proposed Fresenius/NxStage settlement package is limited to NxStage's bloodlines business and doesn't address the companies' overlap in home hemodialysis machines,

where NxStage's System One and Fresenius's 2008K@Home are the only two FDA-approved devices. The proposed settlement also doesn't seek to address vertical issues that could arise from combining the two companies.

During the FTC review, the parties pointed to potential entry from competitors including San Jose-based Outset Medical and Alcester, UK-based Quanta Dialysis Technologies, as factors that could mitigate any anticompetitive effects arising from the companies' horizontal overlap.

Outset Medical's Tablo is already FDA-approved for clinic and hospital settings, and currently in an IDE trial seeking FDA clearance for a home indication. Quanta won a CE mark (EU) for its SC+ product in the home setting in January 2015, is currently in commercial use in the United Kingdom, and has also announced plans to enter the U.S. market.

And in an unexpected move, CVS Health on April 4 announced plans to pursue entry into the home hemodialysis market, in steps including a clinical trial of a new, unnamed, home hemodialysis device.

But potential entrants to the market face substantial barriers to entry. FDA requirements in medical device markets are significant, and dialysis machines are complex capital equipment that require hundreds of millions of dollars in investment. Home entry also requires substantial investment in staffing, distribution, logistics, and tech support, which—given the nature of the home modality—represents a 24/7 proposition.

Exacerbating these issues further, and representing a significant barrier to both capital and entry, is the existing downstream market structure, in which Fresenius and DaVita constitute an effective duopoly in U.S. dialysis clinics.

Per *Nephrology News & Issues*, Fresenius served 42.7 percent of all dialysis patients in 2018, and DaVita, 42.3 percent. These numbers are even more pronounced in home hemodialysis, where Fresenius (3,693 HHD patients) serves nearly half—or 47.3 percent—of the 7,808 U.S. home hemodialysis patient population, and DaVita (3,300), treats another 42.2 percent. Satellite Healthcare, the No. 3 home provider, serves just 219 home patients, or 2.8 percent of the U.S. home population.

For potential entrants, Fresenius's acquisition of the dominant home hemodialysis machine—assuming Fresenius then uses the NxStage System One to the exclusion of any new entrants—would shrink the addressable home market by almost half. And financial models zeroing out Fresenius purchases, and leaving DaVita as the only potential buyer of scale, may limit entrants' incentives to pursue, or ability to raise money for, the expensive, time-consuming, and uncertain FDA and commercialization processes for the home indication.

However, Fresenius may point to developments since the August 2017 NxStage deal, including the CVS entry announcement and Outset's August 2018 move to close a $132 million Series D fundraising round, as demonstrating that the pending transaction has not affected the environment for new entrants, and therefore has not—and will not—raise rivals' entry barriers or costs.