

demonstrated the impact of shortages on clinical practice, and it would behoove regulators to pay attention.

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### Reference

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## AUTHOR REPLY



We appreciate the authors' insightful commentary on our recent study examining trends in BCG utilization during national supply shortages. We agree that the impact of even just temporary supply interruptions on BCG utilization is impressive. Certainly, exploring the impact of Sanofi's recent complete market exit is a worthwhile endeavor. However, due to a requisite time lag to allow maturation of data in the NCDB and other large administrative and population-based datasets, a more contemporary analysis is not yet feasible. Thus, while we anticipate that the recent cessation of BCG production by Sanofi may have profound effects on BCG treatment patterns, the necessary data to empirically study this question is not yet available. For this reason, we elected instead to explore the impacts of prior BCG supply

interruptions, in hopes that prior trends might inform the current discourse about ongoing BCG supply shortages.

The authors also share valuable insight into the challenges faced by BCG manufacturers and the market forces that lead to supply shortages. We agree that even if scientifically validated, an additional strain of BCG (Tokyo) entering the marketplace may ultimately suffer from the same issues facing current BCG manufacturers, and would likely not be a panacea for this challenging drug shortage issue. Thus, in our manuscript we highlight the importance of exploring potential alternatives to BCG. However, none of these appears ripe for immediate widespread clinical use, and BCG is likely to continue as a mainstay of NMIBC treatment for the foreseeable future. Thus, addressing BCG supply remains a high priority for our bladder cancer patients.

We agree wholeheartedly that regulatory reform is a requisite and central component in addressing BCG shortages. We applaud the authors for their role in bringing BCG supply issues into the national spotlight.<sup>1</sup> Hopefully our current work can help frame these drug shortages into a real-world context that can ultimately be used to advocate for durable change.

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