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Dr. Laine:

I am pleased to submit my brief report titled "Estimating the impact of discontinuing universal screening of donated blood for Zika virus in the 50 U.S. states."

In our 2019 publication, which your journal published, colleagues and I showed that screening for Zika in the 50 U.S. states was far from cost-effective in its first year. Our analysis was well-received academically but received less attention from policymakers. At the FDA Blood Products Advisory Committee meeting two months after publication, the claim that "no risk analysis exists for serious complications from transfusion-transmitted Zika" went unchallenged, despite a letter we had submitted explaining how our analysis included a risk assessment. Ultimately, the committee recommended that the FDA continue universal screening and reassess in April 2020. Unfortunately, that meeting has been indefinitely postponed. Blood centers in the 50 states, many of which are struggling due to the impact of COVID-19 on demand for blood products, continue to pay a collective \$8 – \$13 million for Zika screening every month, costs that are passed on to payers and patients. There have been no confirmed positive donations in the United States in 2019 or 2020 to date.

By repurposing our simulation model to address the concerns expressed by the FDA committee – chiefly uncertainty around the risk of congenital Zika syndrome and Guillain-Barré syndrome – I believe that this brief report has the potential for an immediate and important policy impact. Furthermore, I hope that it demonstrates to policymakers that decision-analytic models can be used to analyze outcomes beyond cost and cost-effectiveness, encouraging mutual understanding and future collaboration.

Thank you for considering this work.

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Sincerely,

W Alton Russell

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