

# Sensitivity of 510(k) Medical Device Filings to Government Shutdowns: A Brief Communication

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## Supplemental Material

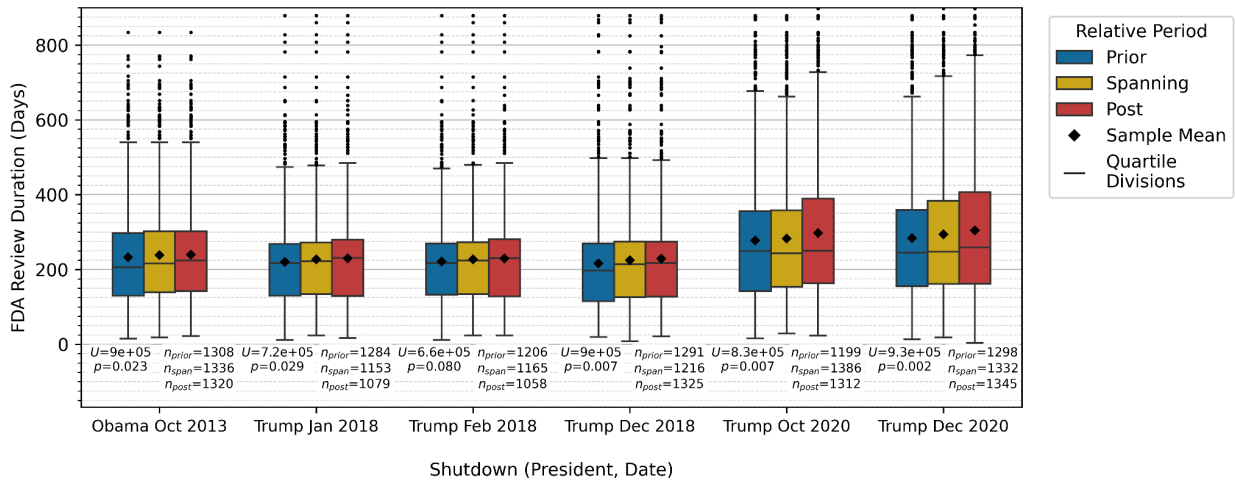


Figure S1: Windowed Sampling Analysis including all federal government shutdowns occurring from 2000 through 2020. Distributions of FDA Review Duration for 510(k) medical device filings overlapping the prior, spanning, or post shutdown windows of the subject shutdown. Summary statistics below each set of boxplots indicate a Mann-Whitney U test for the alternative hypothesis that the median of the Post window sample is greater than that of the Prior window sample, and the U-Statistic and corresponding statistical significance is reported.

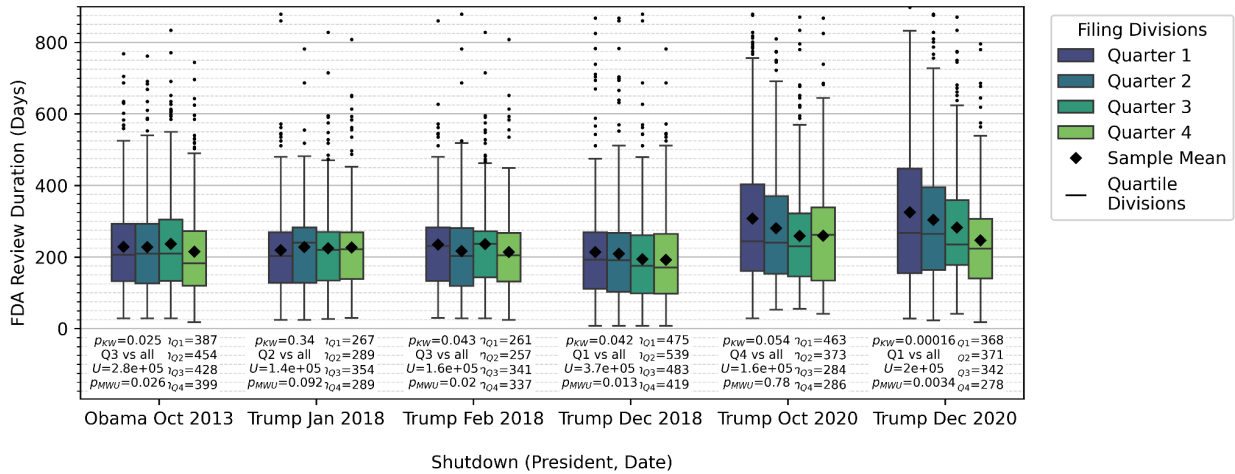


Figure S2: Quarter Overlap Analysis including all federal government shutdowns occurring from 2000 through 2020. Distributions of FDA Review Duration for 510(k) medical device filings whose 1st through 4th quarters overlap with the shutdown. Summary statistics below each set of boxplots indicate the significance of a Kruskal–Wallis test indicating which sample median differs most from the other quarter samples. The sample with the greatest median filing review time is then compared in a 1vsAll Mann-Whitney U test for if its median is significantly greater than the remaining samples and the U-Statistic and corresponding statistical p-value is reported. Sample sizes for each filing quarter divisions per shutdown are also indicated.

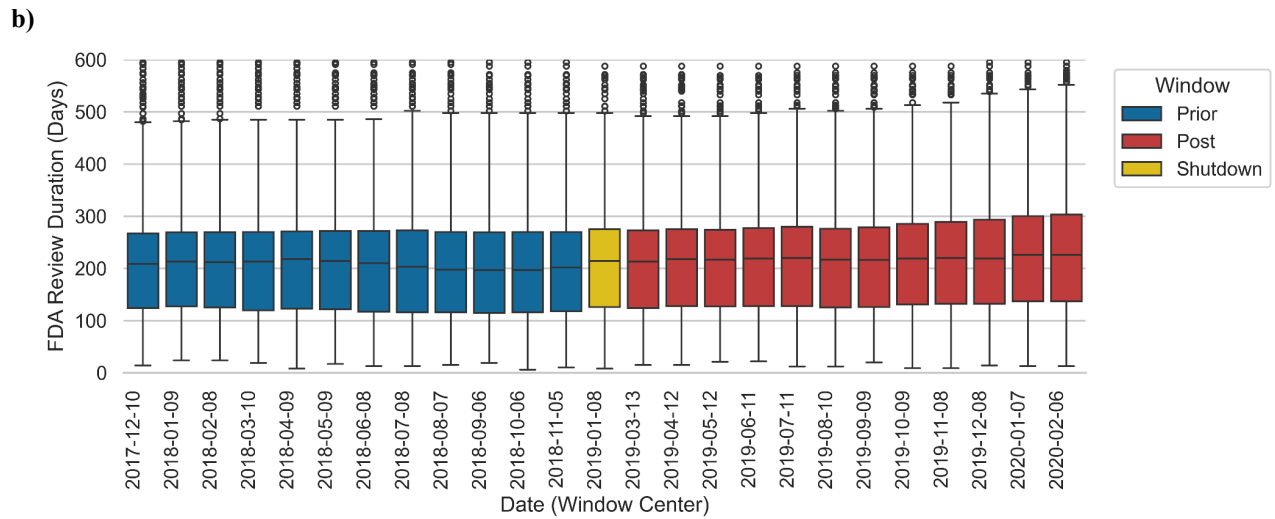
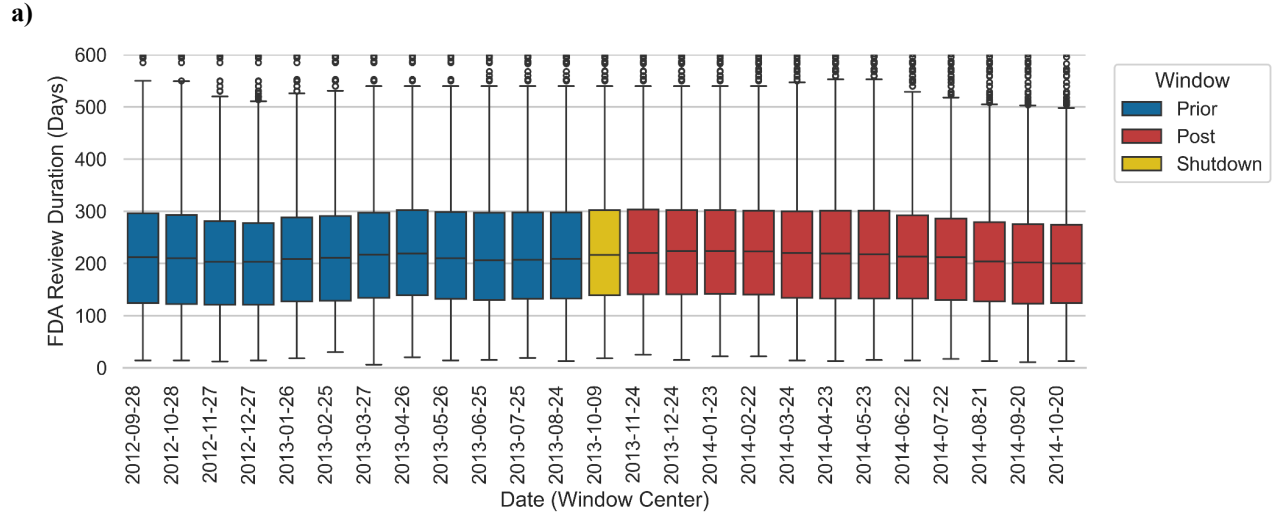
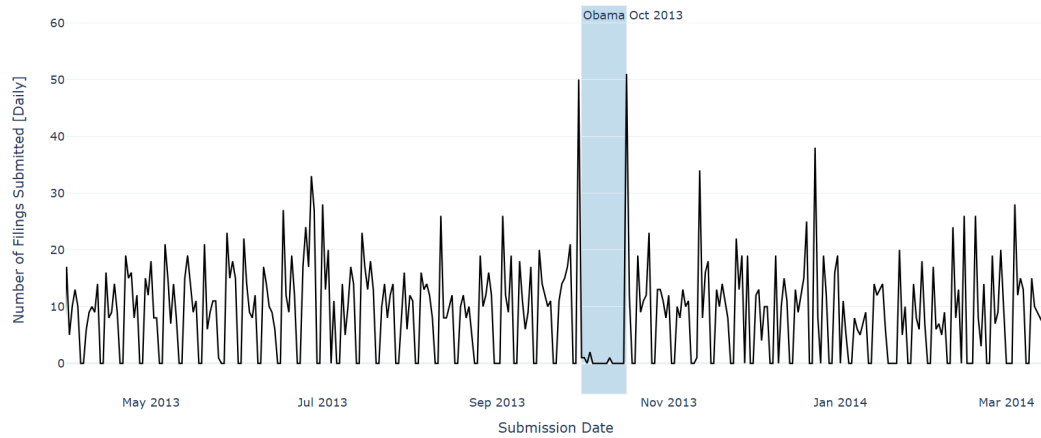


Figure S3a-b: Offset Window Analysis Including a Year of 30-Day Spaced Windows Prior and Post the Oct 2013 and Dec 2018 Shutdowns. Distributions of FDA Review Durations for 510(k) filings which overlap 25 sampling windows spaced 30 days apart around the median day of each subject shutdown showing longer term changes in filing review duration throughout the year before and after the subject shutdown. Sampling windows are the same width as the duration of each subject shutdown. S3a) indicates the Oct 2013 shutdown and S3b) indicates the Dec 2018 shutdown.

a)



b)

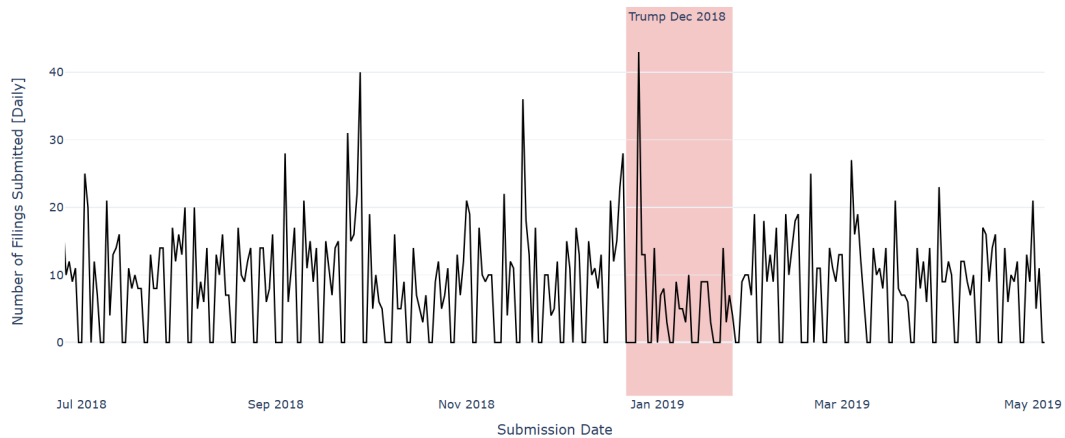


Figure S4a-b: FDA medical device daily submission frequency. S4a) The submission frequency around the Obama Oct 2013 shutdown shows a near complete halt of medical device filing submissions exclusively during the shutdown period, with clear compensatory peaks of >50 submissions on the days immediately before and after the shutdown. S4b) The submission frequency around the Trump Dec 2018 shutdown shows some decrease in overall submission volume during the shutdown period, with a notable local peak of >40 submissions corresponding with Wed Dec 26th within the shutdown period