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April 4, 2019

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To the Division of Dockets Management:

We hereby withdraw our petition to the Food and Drugs Administration to require a moratorium on new opioid approvals, currently posted at Docket No. FDA-2019-P-1364-0001 at www.regulations.gov.

We will be submitting a revised petition requesting the same agency actions that includes the certification statement required under section 505(q) of the Food, Drug, and Cosmetic Act.

Thank you for your attention to this matter.

Sincerely,

Sidney Wolfe, M.D.
Founder, Senior Adviser
Public Citizen's Health Research Group

Raeford E. Brown, Jr, M.D., FAAP
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The University of Kentucky/Kentucky Children's Hospital
Chair, FDA Anesthetic and Analgesic Drug Products Advisory Committee