March 27, 2017

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Comments from the Cross-Industry Quality Metrics Collaboration Group regarding Docket FDA-2015-D-2537: Submission of Quality Metrics Data.

The undersigned trade and technical organizations, representing a broad, informal group, stand together on behalf of the vast majority of the U.S. pharmaceutical industry as the Cross Industry Quality Metrics Collaboration Group (the "Collaboration Group") to provide feedback on FDA's Revised Draft Guidance on Quality Metrics.

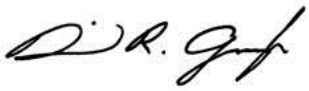
After careful deliberation and analysis, the Collaboration Group believes that FDA's metrics collection proposal should be paused and there needs to be further public dialogue between industry and the Agency before FDA's metrics collection efforts proceed further by guidance, rule-making, metrics collection notice or other means. The full burden and benefit for industry, FDA and patients must be considered and defined to achieve a positive benefit-burden balance.

We believe that the burden of FDA metrics collection far outweighs the benefits, at least as currently proposed. As we have continued to learn in depth about what it would take to operationalize a metrics program of the kind proposed by FDA, we have concluded that such a program would require substantial resources, present significant operational challenges and complexities, and draw resources and management attention away from other programs that drive continual quality improvement. In our organizations' individual comments, you will find details of the potential legal and practical issues raised by the agency's proposal, and detailed suggestions for improvements.

We believe there is an opportunity to discuss ways to operationalize a gated, multi-phased approach, which considers all perspectives of a complex supply chain, connectivity to other regulatory initiatives, and insights that industry has gained by working toward operationalizing FDA's proposed program. We look forward to continuing this important dialogue with you and commit to working with you to try to find a reasonable path forward.

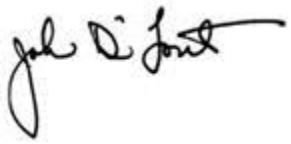
cc: Office of Management and Budget
Attn: FDA Desk Officer
725 17th Street, NW
Washington, DC 20503
oira_submission@omb.eop.gov
https://www.regulations.gov

Sincerely,

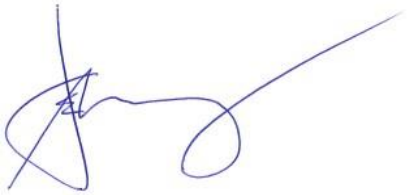


David R. Gaugh, R.Ph.
Senior Vice President for Sciences and Regulatory Affairs
Association for Accessible Medicines (AAM)

Luisa Paulo
Compliance Senior Director
Hovione
Vice-chair of the Active Pharmaceutical Ingredients Committee Quality Working Group



John DiLoreto
Executive Director
Bulk Pharmaceuticals Task Force



John Bournas
President and CEO
International Society for Pharmaceutical Engineering

Gil Roth
Founder, President
Pharma & Biopharma Outsourcing Association

William W. Chin, M.D.
Executive Vice President, Science and Regulatory Advocacy
Pharmaceutical Research and Manufacturers of America (PhRMA)