

21 U.S. Code § 360g-2

Third party data transparency

(a) In general

To the extent the Secretary relies on any data, analysis, or other information or findings provided by entities that has been funded in whole or in part by, or otherwise performed under contract with, the Food and Drug Administration, in regulatory decision-making with respect to devices, the Secretary shall—

- (1) request access to the datasets, inputs, clinical or other assumptions, methods, analytical code, results, and other components underlying or comprising the analysis, conclusions, or other findings upon which the Secretary seeks to rely; and

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