

March 2011

Dear Supporters and Friends:

Recently, you may have heard or read about a new article by Light and Warburton, entitled "Demythologizing the High Costs of Pharmaceutical Research," in which the authors have attempted to critique and discredit CSDD's 2003 study on the cost of new drug development by Joseph DiMasi et.al. Joe DiMasi's peer-reviewed article has received worldwide recognition for its scholarship and scope, and its methodology has been critically examined and validated by the U.S. Office of Technology Assessment and others.

I would like to share with you Tufts CSDD's current response to the Light and Warburton article, prepared by Dr. DiMasi. This response has been forwarded to all media outlets and provided to individual reporters who have called asking for comment.

"In their commentary, Light and Warburton restate arguments about the methods and data used for our R&D cost study that they have had published elsewhere. We have thoroughly rebutted each and every one of their prior claims in two published responses that Light and Warburton do not cite in their current paper (DiMasi et al., 2005a, 2005b). In the current piece, Light and Warburton also attempt to operationalize their criticisms by making adjustments to our published estimates that purport to demonstrate that R&D costs are much lower than we estimated. They make five such adjustments, all of which are erroneous --- they inappropriately mix median values reported for individual drugs with what are mean values for the costs of clinical failures and preclinical fixed costs, and for which the concept of a median has no meaning; they misconstrue the nature of the corporate income tax and incorrectly consider manufacturing tax credits; they use discount rates that are meant for other contexts but that are inappropriate here; they treat line extension approvals as separate and independent units of observation alongside their original approvals; and they grossly misstate the meaning of and misuse figures in our paper on industry-reported data on expenditures on self-originated drugs, licensed-in drugs, and already-approved drugs. Detailed discussions of these issues can be found in our above-mentioned rebuttals. In short, every one of Light and Warburton's adjustments are invalid. Furthermore, two peer-reviewed papers by current and former FTC economists, also not cited by Light and Warburton, validate our work using other methods and public data (Adams and Brantner, 2006, 2010). They find that R&D costs are likely as high or higher than our estimates."

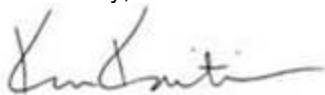
- Joseph DiMasi, Ph.D.

References

- Adams CP, Brantner VV. Estimating the cost of new drug development: is it really \$802 million? *Health Affairs* 2006;25(2):420-428.
- Adams CP, Brantner VV. Spending on new drug development. *Health Economics* 2010;19(2):130-141.
- DiMasi JA, Hansen RW, Grabowski HG. Reply: Extraordinary claims require extraordinary evidence. *Journal of Health Economics* 2005;24(5):1034-1044.
- DiMasi JA, Hansen RW, Grabowski HG. Reply: Setting the record straight on setting the record straight: response to the Light and Warburton rejoinder. *Journal of Health Economics* 2005;24(5):1049-1053.

Make no mistake: While we are more than willing to engage in a productive discussion about research methodology and interpretation, **Tufts CSDD will vigorously defend the scholarship, integrity, and validity of all its published research studies.** As noted above, we have addressed Light and Warburton's criticisms of our cost study in the past. Going forward, we will continue to defend the study against these authors and others who attempt to denigrate the validity of its findings.

Sincerely,



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Director & Research Professor