



February 3, 2015

Joseph DiMasi
Center for the Study of Drug Development
Tufts University
75 Kneeland Street
Suite 1100
Boston, MA 02111
Tel.: 1.617.636.2170

cc: Anthony Monaco, President, Tufts University; Kenneth Kaitin, Director of CSDD; Henry Grabowski, Duke University; Ronald Hansen, University of Rochester

Dear Dr. DiMasi:

At the suggestion of Tufts University President Anthony Monaco, the Union for Affordable Cancer Treatment (UACT)¹ would like to obtain from you some clarifications regarding the recent “Tufts Drug Development Cost Study” and the November 18, 2014 press conference during which the conclusions of that study were presented.²

We wrote to Dr. Monaco to ask who funded the study and the press conference that announced the results of a study, without providing the public the study itself, nor many of the details used to justify the new result.

Many observers will undoubtedly read the new study as a justification of high drug prices, including the very high prices for new drugs to treat cancer, an outcome that occurred following the release of the previous two iterations of the study. Indeed, the \$2.6 billion study number was cited by John Castellani, the CEO of PhRMA, in a January 26, 2015 letter to the New York Times where he specifically defended high prices for cancer drugs.

¹ More information about UACT is available on our web site at <http://cancerunion.org>

² http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study

As per President Monaco's suggestion, we are asking you to provide information on five points:

Funding. The press release and the social media described this as the "Tufts Cost Study." Tufts is an academic institution. Can you tell us who paid for the press release, the press conference and the researchers, and what amount? Can you also let us know whether the peer reviewers of the study include persons whose research is paid for by drug companies?

Undisclosed study data. Tufts University should provide information on the data on trials on which the final figures are based. Can you tell UACT the number of patients in each of the trials in the database, and in particular, the number of patients associated with the trials for each drug in the study? Can you tell us how much money was spent on the trials included in the study, and what the per patient costs were? In the absence of these details it is impossible to evaluate the reasonableness or relevance of the study sample to the R&D costs for drugs that are the center of pricing disputes.

Cancer Drugs. The FDA medical reviews for new drug approvals disclose the number of patients in trials used to support drug registration. For at least the past ten years, the number of patients in trials for new cancer drugs are substantially lower than for non-cancer new drugs. How does the study data relate to the facts for drugs for cancer? How does the Tufts study deal with these differences, and should we consider the study even relevant to products for cancer?

Orphan Drug Tax Credit. A majority of new cancer drugs qualify for the orphan drug tax credit, which subsidizes 50 percent of the costs of clinical trials. In 2014, 9 of 10 new cancer drugs were approved as orphan products. How did the study account for this subsidy, or was it ignored?

Public funding of research. The annual budget for the NIH National Cancer Institution is nearly \$5 billion per year, and governments and charities around the world fund cancer research. How does the study take this into account? When the NIH provides funding for grants and contracts for work on the development of a particular drug, does the dataset show lower pre-clinical expenses from the private companies?

Since Tufts University highly publicized the results of the study, and PhRMA and others are already using the study to defend high cancer drug prices, we ask that the study itself be made available now, so it can be evaluated by third parties for relevance, context, balance and accuracy.

We look forward to your response to these questions about the study and to our concerns regarding the press conference, which you can send to Manon Ress at info@cancerunion.org.

Sincerely,
(In alphabetical order)

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