The Union for Affordable Cancer Treatment

1621 Connecticut Avenue NW
Washington, DC 20006
Tel.: +1.202.332.2670
http://cancerunion.org
Contact: committee@cancerunion.org;
manon.ress@cancerunion.org

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Anthony P. Monaco
Office of the President
Tufts University
Ballou Hall, 2nd Floor
Medford, MA 02155
617-627-3300

CC: Michael Baenen, Chief of Staff
Via email: michael.baenen@tufts.edu
CC: Peter Dolan, Chairman of the Board of Trustees

Dear President Monaco,

We are writing on behalf of the Union for Affordable Cancer Treatment (UACT) to express concerns about the recent press conference held by the University in connection with research regarding the cost of drug development. This press conference was held on November 18, 2014, by the Tufts Center for the Study of Drug Development (CSDD) to announce "Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion."[1]

The main point of the press conference was to establish that drug development costs were $2.6 billion for a new drug, a number that was more than a billion higher than a 2012 AstraZeneca funded study by the Office of Health Economics,[2] and 3.2 times higher than an earlier estimate published by the CSDD in 2003.

[1] http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study
[2] Jorge Mestre-Ferrandiz, Jon Sussex And Adrian Towse, The R&D Cost Of A New Medicine, Office Of Health Economics, December 2012

Many observers will undoubtedly read the new “Tufts” study as a justification of high drug prices, including the very high prices for new drugs to treat cancer, a characterization that fits the two previous studies[3] on this topic published by Joseph DiMasi and this co-authors.[4]

Our concern is that Tufts University organized a press conference to announce the results of a study without providing transparency over who funded the study or the press conference, and more importantly, without providing the public the study itself, or even many of the details used to justify the new result.

Following the press conference, Tufts only provided a press release and a few powerpoint slides, and failed to address several questions about the reasonableness or relevance of the results so loudly promoted by the University.

The lack of transparency regarding the data used to make the estimates, and the failure to disclose the study itself, creates a situation where the public is being asked to trust the study authors and Tufts University on an issue that is often used to justify high drug prices.

Since Tufts is soliciting funding from pharmaceutical drug manufacturers, and the authors often are consultants to the pharmaceutical industry, we have ample reason to be skeptical of the balance and objectivity, and also of the manner in which the study will be used by the pharmaceutical industry, including to justify high prices for cancer drugs.

We would like you and the Tufts University Office of the President to respond to the following five points:

1) Funding. Tufts is an academic institution and as such should provide basic information regarding who paid for the press release, press conference and researchers and what amount. Not only are there no details on the data and substance of the study (or even a report!) but we have no details about Tufts financial interests nor do we not know if the peer reviewers for example have any conflict of interest themselves.

2) Secret study data. Tufts should provide information on the data on trials on which the final figures are based. In particular, how many patients were in the trials, how much money was spent on the trials included in the "study," and what were the per patient costs? In the absence of the 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.

[3] DiMasi, J. et al. (1991) Cost of innovation in the pharmaceutical industry. *Journal of Health Economics.* 10(2), 107-152; DiMasi, J. et al. (2003) The price of innovation: New estimates of drug development costs. *Journal of Health Economics*. 22(2), 151-185.

[4] For example, during litigation in India over a compulsory license of patents on the cancer drug Sorafenib, Bayer consistently cited the 2003 DiMasi study to an attempt to rebut actual data from SEC filings on the costs of R&D for Nexavar, the Bayer version of this drug (we could add many more examples).

3) Cancer Drugs. FDA medical reviews for new approvals disclose the number of patients in trials used to support drug registration, and the numbers of cancer drugs are substantially lower than for non-cancer 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?

4) 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. How did the study account for this subsidy, or was it ignored?

5) 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?

We look forward to your responses to these questions and requests for information.

Sincerely,

Ilze Aizsilniece, MD, MSc, Health Projects for Latvia and University of Latvia
Thiru Balasubramaniam, Sri Lanka
Joyce Bichler, ACSW, Deputy Director, Breast Cancer Action, USA
Michael H.Davis, Professor of law, Cleveland State University, Progressive Intellectual Property Law Association, USA
Ophira Ginsburg, MSc, MD FRCP Medical Oncology, Public Health, University of Toronto, Canada
Andy Gray BPharm MSc(Pharm) FPS FFIP, South Africa
Ellen 't Hoen, LLM, The Netherlands
Caroline Izambert, France
Jordan Jarvis, Young Professionals Chronic Disease Network (YP-CDN) & Harvard Medical School, USA
Sandeep P. Kishore, M.D., Ph.D. Young Professionals Chronic Disease Network (YP-CDN) & Yale School of Medicine, USA
Gaelle Krikorian, France
Ruth Lopert MD FAFPHM, Australia
Marcus Low, TAC, South Africa
Kirsten Myhr, Norway
Manon Ress, USA
Judit Rius, Spain
Philippe Rivière, France
Joy Spencer, USA