

PETE SESSIONS  
32ND DISTRICT, TEXAS

CHAIRMAN  
COMMITTEE ON RULES

COMMITTEE ON  
FINANCIAL SERVICES  
(ON LEAVE)



Congress of the United States  
House of Representatives  
September 7, 2016

- 2233 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-4332  
TELEPHONE: 202.225.2231  
FAX: 202.225.5878
- PARK CENTRAL VII  
12750 MERIT DRIVE  
SUITE 1434  
DALLAS, TEXAS 75251-1229  
TELEPHONE: 972.392.0505  
FAX: 972.392.0615  
sessions.house.gov

Robert M. Califf, M.D.  
Commissioner  
United States Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

We are writing to you today regarding the importance of improving patient participation, enrollment, retention, and equitable access to oncology clinical trials. The study and development of new cancer drugs is an increasingly exciting field. In January, President Obama announced the establishment of a new National Cancer Moonshot Initiative to further accelerate cancer research by enhancing cancer prevention, early detection, and access to treatments.

Despite this excitement, the percentage of cancer patients who participate in oncology clinical trials remains low, especially among minorities and those economically disadvantaged. There are many causes contributing to reduced enrollment and retention rates, one of which is the ancillary financial cost of participating in a cancer clinical trial. In order to attend the multiple, and often extended, visits required for a cancer clinical study, patients must budget for airfare, travel, lodging, gas, and similar costs. At a time when there is a major attempt to include patient involvement in clinical trials, it is concerning that financial disparities are a significant barrier to achieving this goal.

Many clinical sites and sponsors of clinical trials are wary of working with third parties which could provide even ancillary financial support given current guidance for Institutional Review Boards (IRBs) and Clinical Investigators warning against anticipated financial benefits that may create "coercion or undue influence" to research participants, which under 21 CFR 50.20, of which IRBs are supposed to work to minimize this possibility. However, it is our understanding that coercion, as defined in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research's Belmont Report ("Belmont Report"), involves a "threat of physical, psychological, or social harm in order to compel an individual to do something such as participate in a clinical trial." Also, according to the Belmont Report, undue influence "occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance." In the IRB Guidebook, an inducement in clinical research is deemed undue and therefore troublesome if it is so "... attractive that [it can] blind prospective subjects to potential risks or impair their ability to exercise proper judgment."

We argue that the simple payment of ancillary costs by third parties bears no resemblance to forcing people to enroll or undue influence to enroll in any one clinical trial. Moreover, the limited reimbursement of ancillary expenses should not be considered to raise ethical concerns about the validity of consent by distorting the enrollee's perception of risks and benefits when the real issue at hand concerns a person's very health. In order to combat this problem, more precise guidance would be helpful in allowing appropriate stakeholders to provide the ancillary financial support necessary to level the playing field for patients who would like to enroll in a cancer clinical trial.

And, in all cases, we certainly believe the reimbursements should be reviewed by the local IRBs and be in compliance with the laws, regulations, and guidance of the local region where the study is conducted, including the details recorded in the Informed Consent Form.

To these points listed above, we are respectfully submitting to you for your consideration the language below which we feel would be a key component in ultimately improving oncology clinical trial participation. If the FDA would consider embracing and including this language within its own clinical trial research regulations, we believe it could provide a much needed tool for patients in order to gain access to trials and lifesaving drugs. It is our hope this presents a more efficient pathway to market trial participation, all with no additional cost to taxpayers or government.

We submit to you for consideration the following draft clarification language:

*Cancer clinical trials do not cover all of the costs of participation by a patient-subject. There are often significant expenses associated with enrollment in a clinical trial that are not covered by the clinical trial site or the sponsor. These include travel expenses to and from the clinical sites whether by air, car, bus, train, taxi, or public transportation along with the travel associated costs of parking, car rental, gas, tolls, and lodging. Participants in trials may be burdened by additional ancillary costs, such as babysitting /childcare fees incurred during the time period encompassing travel and clinical visits required by trial participation.*

*Also to be considered for reimbursement are the cost of travel and ancillary expenses for needed chaperones such as parents of minors, caretakers of elderly, or a travel companion for a seriously ill patient who participates in a cancer clinical trial. Within the guidelines above, the reimbursement to the chaperone(s) is a necessary expense required for enrolling the patient.*

*If all potential enrollees are informed at the time of the Informed Consent process that: (1) reimbursement for ancillary costs is available to all enrollees based on financial need and (2) that coverage of the costs is to eliminate financial disparities as a barrier to enrollment and in order to retain subjects in the clinical trial, then reimbursement of these ancillary costs is not considered coercive or exerting undue influence to join a trial, but for financially eligible subjects, it is rather a means to create parity in clinical trial access and potentially removes a barrier to participation for financially burdened subjects.*

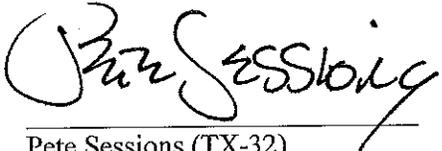
*Assistance in covering these ancillary expenses may proceed through a number of avenues. Depending upon the institution conducting the trial and the sponsorship of research, contributors to funds supporting these ancillary costs could be grants from government, industry, public and private foundations, corporations, and individuals. These stakeholders could offer these contributions through their support of third party nonprofit corporations and public charities that seek to increase enrollment, retention, and minority participation in cancer clinical trials.*

Commissioner Califf  
September 7, 2016  
Page Three

*Reimbursement programs must be reviewed and approved by the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) in conjunction with their review of the proposed clinical trial. IRBs/IECs must consider whether the reimbursed patients are recruited fairly, informed adequately, and paid appropriately. The nature of the ancillary support and general guidelines on financial eligibility must be disclosed in the Informed Consent process and the reimbursement process itself must conform to state and federal laws and guidance.*

If you need any assistance, please contact Jennifer Lackey in Congressman Pete Sessions' office at [Jennifer.Lackey@mail.house.gov](mailto:Jennifer.Lackey@mail.house.gov) or Zac Commins in Congressman Swalwell's office at [Zac.Commins@mail.house.gov](mailto:Zac.Commins@mail.house.gov). We look forward to working with you to help improve access to oncology clinical trials. Thank you for your consideration of our request.

Sincerely,



Pete Sessions (TX-32)  
Member of Congress



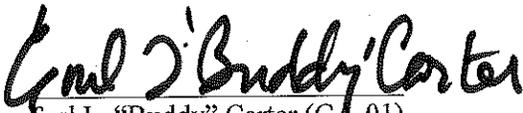
Eric Swalwell (CA-15)  
Member of Congress



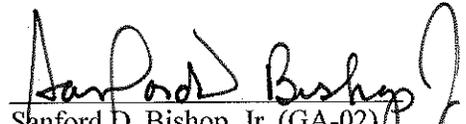
Martha McSally (AZ-02)  
Member of Congress



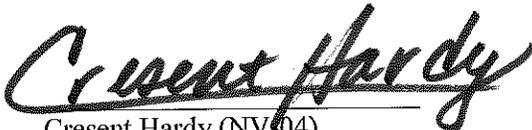
Brenda L. Lawrence (MI-14)  
Member of Congress



Earl L. "Buddy" Carter (GA-01)  
Member of Congress



Sanford D. Bishop, Jr. (GA-02)  
Member of Congress



Crescent Hardy (NV-04)  
Member of Congress



Ted Lieu (CA-33)  
Member of Congress



Gwen Moore (WI-04)  
Member of Congress



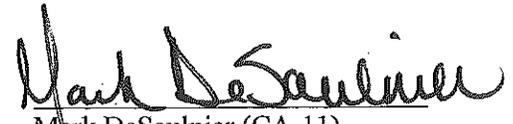
Donald M. Payne, Jr. (NJ-10)  
Member of Congress

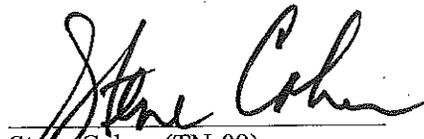
Commissioner Califf  
September 7, 2016  
Page Four

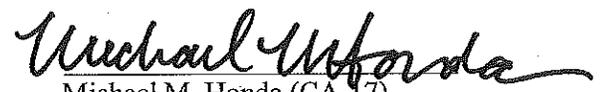
  
Collin Peterson (MN-07)  
Member of Congress

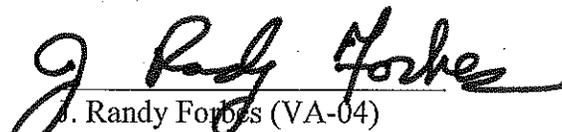
  
Alan Grayson (FL-09)  
Member of Congress

  
Hakeem Jeffries (NY-08)  
Member of Congress

  
Mark DeSaulnier (CA-11)  
Member of Congress

  
Steve Cohen (TN-09)  
Member of Congress

  
Michael M. Honda (CA-17)  
Member of Congress

  
J. Randy Forbes (VA-04)  
Member of Congress

cc: Dr. Peter Marks, FDA, Center for Biologics Evaluation and Research  
Dr. Janet Woodcock, FDA, Center for Drug Evaluation & Research  
Dr. Richard Pazdur, FDA  
Greg Simon, Director, White House Cancer Moonshot Initiative