

Joined by over a dozen of our colleagues from both sides of the aisle, we sent a letter to the FDA regarding possible misperceptions surrounding the regulatory meaning of inducement and coercion and asked for its assistance in providing clarity.

The FDA's letter in response we include in the RECORD today, helps provide this needed clarity, explaining that reimbursement is neither inducement, coercion, nor even a so-called "benefit" but rather fair compensation creating parity and equality in cancer trial access. The letter also states the FDA's commitment to further addressing our concerns when it finalizes guidance on this issue.

Accordingly, we, along with our colleagues, will continue our dialogue with national stakeholders, patient advocacy organizations, the pharmaceutical industry, and the Administration to continue to improve patient enrollment, retention, minority participation and equitable access in cancer clinical trials, especially among underserved and underrepresented patients.

U.S. FOOD & DRUG ADMINISTRATION,
Silver Spring, MD, March 22, 2017.

Hon. PETE SESSIONS,
House of Representatives,
Washington, DC.

DEAR MR. SESSIONS: Thank you for the discussion on September 21, 2016, with Dr. Robert Califf, the former Commissioner of the U.S. Food and Drug Administration (FDA or the Agency) and Dr. Richard Pazdur, regarding the improvement of patient participation, enrollment, retention, and equitable access to oncology clinical trials. In a follow-up letter dated October 6, 2016, you asked the Agency to confirm that it views reimbursement for travel expenses to and from clinical trial sites, including reimbursement for travel costs such as parking and lodging, as permissible and suggested that such reimbursement should not be construed as coercion or inducement.

As discussed with you on September 21, 2016, FDA generally would not consider reimbursement for such expenses to be undue influence or coercion intended to induce participation in a clinical trial. FDA has stated in the past that it is not uncommon for subjects to be paid for their participation in research, and has provided guidance on how those payments should be addressed during Institutional Review Board (IRB) review of a proposed clinical trial. When appropriate, the informed consent would identify any additional costs to the participant that may result from participation in the research and whether such expenses would be reimbursed.

In July 2014, FDA issued a draft guidance entitled, "Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors," which provides recommendations on informed consent content and the informed consent process. In this draft guidance, the issue of additional cost and payment to research participants is briefly addressed. For example, we recommend that, beyond the costs directly related to participation in the research, it may be appropriate to identify additional costs that the subject may incur. Additional costs may include the loss of income when the subject takes time off from work to participate in the clinical investigation and transportation costs. The consent form would also make clear whether and, if so, how funds for reimbursement will be made available to subjects, or the form would provide direction to subjects regarding how to obtain further information. The draft guidance also states that FDA considers payment to subjects for participation in clinical investigations to be

compensation for expenses and inconveniences, not a benefit of participation in research and that if payments are provided, the consent process should not identify them as benefits. Further guidance on when payments to research participants may be considered coercive or an exercise of undue influence is available on FDA's webpage "Payment to Research Subjects—Information Sheet."

As we finalize the draft guidance, we will look for ways to address your concerns about reimbursement of these types of expenses so that the final guidance will be more useful to patients and our stakeholders. We will also take advantage of our educational outreach activities to clarify this issue with the research community.

Thank you again for bringing this important issue to our attention. Please let us know if you have any further questions.

Sincerely,

STEPHEN M. OSTROFF, M.D.,
Acting Commissioner of Food and Drugs.

RECOGNIZING ARNOLD SMEENK

HON. TOM REED

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Monday, April 3, 2017

Mr. REED. Mr. Speaker, I rise today to congratulate Arnold Smeenk on his retirement and recognize his distinguished career in the field of mortgage banking.

Mr. Smeenk joined First Maryland Mortgage Corp. in December 1993. He built an impressive portfolio of clients and projects, which directly contributed to the company's successful merger with M&T Realty Capital Corp. In recognition of his excellent work, Mr. Smeenk earned the prestigious President's Council Award in three consecutive years. In 2007, he was promoted to National Production Manager and Group Vice President. In these positions, Mr. Smeenk was responsible for managing the company's origination platform and supervising employees in nine states. Under his leadership, the sales team originated almost \$16 billion in deals. Mr. Smeenk will retire on April 3, after more than 23 years of service to M&T Realty Capital Corp.

Even more impressive than Mr. Smeenk's professional resumé is his commitment to serving his community. Arnold and his wife, Anne, have opened their home and their hearts to those in need. From taking in foster children and providing assistance to troubled youths, to repairing inner-city homes and building a school for deaf children in Mexico, Arnold and Anne have worked tirelessly to help people overcome difficult circumstances. Through the Smeenk Family Foundation, they have financially supported countless Christian ministries and charitable organizations, including the Charles Finney School and the new Pregnancy Resource Center in Corning, New York.

I ask my colleagues to join me in congratulating Arnold Smeenk on an impressive career and wishing him all the best in his well-deserved retirement.

KENDALL WILLS EARNS BOY SCOUT EAGLE RANK AWARD

HON. PETE OLSON

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Monday, April 3, 2017

Mr. OLSON. Mr. Speaker, I rise today to congratulate Kendall Camilo Wills of Sugar Land, TX, for earning his Boy Scout Eagle Rank Award.

Eagle Rank is the highest achievement a Boy Scout can earn. To earn this distinguished award, Kendall had to achieve the Life Scout rank, earn a total of 21 merit badges, and develop and provide leadership to others in a service project. The Boy Scouts of America will also award Kendall with the Catholic religious award, Ad Altare Dei. Kendall is also a member of the Order of the Arrow, the Boy Scouts national honor society.

On behalf of the Twenty-Second Congressional District of Texas, congratulations again to Kendall Camilo Wills for earning his Boy Scout Eagle Rank Award. We are confident he will have continued success in his future endeavors. We are very proud.

HONORING JUANITA WINSTON SMITH-OWENS

HON. BENNIE G. THOMPSON

OF MISSISSIPPI

IN THE HOUSE OF REPRESENTATIVES

Monday, April 3, 2017

Mr. THOMPSON of Mississippi. Mr. Speaker, I rise today to honor the legacy of a dedicated servant, Mrs. Juanita Winston Smith-Owens.

Mrs. Smith-Owens, who was the seventh child of sixteen children, was born to the late Johnnie and Ruby Winston on December 6, 1917 in Pickens, MS. After aging and a short period of illness, Juanita completed her earthly journey while at Westminster Terrace Healthcare Center on August 4, 2016. It was a peaceful passing when she took her Savior's hand and transcended into eternity.

Mrs. Smith-Owens received her early childhood education from the Little Red Schoolhouse formerly known as Richland High School in Pickens, MS.

Mrs. Smith-Owens was married to the late Fred Smith, and this union was blessed with eight children. After the death of her husband, she later married Jerry Lee Owens and to this union no children were born, but she gave her wisdom and love to three stepchildren.

Mrs. Smith-Owens confessed a hope in Christ at an early age and was baptized at Crossroad Missionary Baptist Church, currently known as Mt. Sinai Missionary Baptist Church in Pickens, MS under the pastorate of Reverend Don Sutton. In later years, she joined and united with Newport Missionary Baptist Church under the pastorate of Reverend J.L. Cross where she served in several capacities: Mother's Board, Church Secretary, Sunday School Teacher, President of the Usher Board, and a member of the Choir. She also served for many years as the Treasurer of the Lebanon District Association and Vice President of the District Rose Hill Convention. Mrs. Smith-Owens served faithfully. She later moved to Jackson, MS with her children and