

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In July 2014, FDA issued a draft guidance entitled, "Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors," which provides recommendations on informed consent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

united as a watch-care member from Mt. Calvary Missionary Baptist Church under the pastorate of Reverend Jeffery Stegall. Again, she relocated to Louisville, KY where she united with Community Baptist Church under the pastorate of Reverend William T. Shoemaker.

Mrs. Smith-Owens lived a long industrious, hard working life. For many years, she labored as an agriculturalist and a cook at Double Quick Store No. 19 in Lexington, MS for 16 years and she gave true light to the phrase "Be the job large or small do it well or not at all." She retired from public work in 1989 and enjoyed traveling throughout the United States with her children.

Mrs. Smith-Owens was preceded in death by: her beloved mother, Ruby Walker; father, Johnny Winston; spouses: Fred Smith and Jerry L. Owens; two daughters: Mildred Smith, and Patsie Williams; two sons: Andrew Smith and John Smith; two granddaughters: Jacqueline Campbell-Jones and Racine Smith; one step-son, Lathan Jefferson; three brothers: Louis Stuart, Jesse Castel and Melvin; seven sisters: Ora, Eliza, Ida, Vivian, Lottie, Lela Mae, and Cora; and two son-in-laws: Charles Smith and Roy Williams.

Mrs. Smith-Owens leaves to rejoice her legacy and cherish her memories: four children: Richard (Burnette) Smith, Myron Smith, Dorothy Williams of Jackson, MS and Regina Commodore of Louisville, KY; two step-daughters: Geraldine Owens and Debbie Horton of Chicago, IL; three sisters: Julie (Jack) Greer of Lexington, MS, Thelma (Samuel) Greene, and Gertrude (Charles) Green of Chicago, IL; twenty six (26) grandchildren; a host of great-grandchildren, great-great grandchildren, nieces, nephews, a multitude of cousins and a legion of friends.

Mr. Speaker, I ask my colleagues to join me in recognizing the legacy of Mrs. Juanita Winston Smith-Owens for her life and works to be remembered.

MAJOR GENERAL H. MICHAEL
EDWARDS

HON. ED PERLMUTTER

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

Monday, April 3, 2017

Mr. PERLMUTTER. Mr. Speaker, I rise today to recognize Major General H. Michael Edwards, The Adjutant General of the State of Colorado, for his combined service of more than 44 years in the United States Air Force and the Colorado National Guard.

Major General Edwards' remarkable service to our state and our nation is much appreciated. His leadership skills were evident even as a cadet attending the United States Air Force Academy; transitioning to Student pilot while attending Undergraduate Pilot Training. He continued to hone his flying skills, serving a distinguished career flying various aircraft from the T-38 to the F-4s. Major General Edwards' command expertise was showcased as he rose through the ranks, becoming commander of the 140th Wing, Buckley Air Force Base, Colorado, and as the Director of the Combined Air Operations Center, Al Udeid Air Base, State of Qatar. His honorable military career is significant, culminating in the selection and service as The Adjutant General, Colorado National Guard.

Major General Edwards has also advised my office on military and National Guard matters and assisted in a number of medal and service recognition ceremonies. His congenial manner, yet focused approach to his command has led to admiration and respect by all Coloradans.

I extend my deepest congratulations to Major General H. Michael Edwards for his dedication, commitment and service to our community, state and nation.

QUESTIONING THE RUSSIAN
CONNECTION

SPEECH OF

HON. BARBARA LEE

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, March 29, 2017

Ms. LEE. Mr. Speaker, first let me thank Congresswoman JAYAPAL and Congressman RASKIN for their tireless work to protect our democracy.

I also want to thank the fearless leaders of the CPC, Congressman KEITH ELLISON and Congressman RAUL GRIJALVA for organizing this Special Order Hour and for leading the fight for the integrity of our republic.

Mr. Speaker, we're here today to shine a light on the deceit and corruption taking place at the White House. For months, we've known that Russia meddled in our election to benefit Donald Trump's campaign.

In fact, even before the election, 17 intelligence agencies all concluded that the influence came from the highest levels of the Kremlin. The reality of this unprecedented interference is outrageous and appalling.

But even more disturbing than the fact of foreign actors meddling, has been the response of our Commander-in-Chief. President Trump stacked his campaign, and then his Administration, with officials who benefited both financially and personally from Russian ties.

Now, instead of calling for a bipartisan independent investigation into Russia's influence, President Trump has heaped praise on Vladimir Putin and undermined the ongoing investigations.

Amid all of the evidence pointing to Russian interference to benefit President Trump, one question remains.

Why has the President not taken this national security issue seriously? Over the past 60 days we have learned the answer to that question. A steady stream of revelations has shown what we've suspected all along. President Trump's cozy relationship with Russia warrants a bipartisan independent investigation. Nearly every week, the ties and lies that exist between President Trump and the Russians have led the news cycle.

Former Trump campaign manager Paul Manafort stepped down during the campaign after reports of his murky financial dealings with Russia became public. Michael Flynn was forced to resign after news reports confirmed he lied about contacts with the Russians during and after the campaign.

Attorney General Jeff Sessions lied under oath to conceal meetings he had with Russian officials while on the campaign. And, just this week, we learned that President Trump's son-in-law Jared Kushner had questionable financial links to Russia that warrant a Senate investigation.

The web of ties and lies gets murkier by the day. As these improprieties come to light, President Trump peddles increasingly desperate conspiracy theories in an attempt to distract from the truth.

Mr. Speaker, enough is enough. The American people are demanding that the truth about this Administration be exposed.

They deserve to know every last detail concerning Putin's involvement in our election; ties that exist between Trump allies and Putin officials; and exactly what knowledge President Trump had of Russian actions during the campaign.

Clearly, Republicans have proved that they are incapable of leading such an investigation. Just this week, we've watched the Chairman of the Intelligence Committee be caught up in this cloud of corruption. Congressman DEVIN NUNES, a former executive board member on Trump's transition team, is too compromised by the Trump Administration to lead this investigation. Congressman NUNES' conflicts of interest clearly demonstrate he cannot be trusted to conduct the investigation.

Mr. Speaker, the list is endless. He has withheld information from Members of the Intel Committee; shared critical information with the President, the subject of the investigation, without alerting his counterparts on the committee, including the Ranking Member, ADAM SCHIFF. Mislead the American people with scant details of his sources. Not to mention, he helped develop President Trump's national security plan on the campaign.

Mr. Speaker, Congressman DEVIN NUNES has lost the confidence of the American people. He needs to step down immediately from Chair of the Intelligence Committee.

Mr. Speaker, the corruption shrouding this Administration undermines our national security and makes us less safe. So the only solution here is an independent investigation to reveal the extent of President Trump's personal, political and financial ties to Russia.

I urge my colleagues to support this commission. This has gone far beyond partisan politics. This is about the character of our nation and the independence of our democracy. The American people deserve to know the truth about the troubling links that exist between President Trump and Putin's Russia.

IN RECOGNITION OF THE FRESNO
COUNTY FARM BUREAU

HON. DAVID G. VALADAO

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Monday, April 3, 2017

Mr. VALADAO. Mr. Speaker, I rise today to recognize the Fresno County Farm Bureau in celebration of its 100 year anniversary of advocating for agriculture on behalf of the Central Valley.

The Fresno County Farm Bureau has been dedicated to bringing farmers and ranchers together to promote agriculture in the Central Valley since 1917. The organization was started by George Feaver, J.A. Poytress, Sam Heisinger, H.W. Wrightson, Charles Parlier, and Leroy Smith. Leroy Smith was the first Extension Service farm advisor assigned to Fresno County, which spurred his desire to initiate the Fresno County Branch.

The Fresno County Farm Bureau is one of fifty-three county Farm Bureaus, and represents over four thousand members. The