UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE, Plaintiff, *v.* FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants, and SAREPTA THERAPEUTICS, Intervenor-Defendant.	Case No. 1:17-cv-3960 (JMF) May 29, 2018

DECLARATION OF DIANA M. ZUCKERMAN

I, DIANA M. ZUCKERMAN, declare as follows:

1. I am Diana M. Zuckerman, President of the National Center for Health Research, an independent think tank that focuses on health and safety issues. I submit this expert declaration at the request of Charles Seife, who I understand is requesting the unredacted CSRs for Studies 201 and 202 of Exondys 51 from the FDA. The facts in this declaration are true and correct and based on my personal knowledge. The opinions and conclusions are based on my more than thirty years of experience working in government, policy organizations, and academia to enhance the FDA's ability to protect public health, as set forth below. I am accepting no compensation in connection with this declaration.

EXPERIENCE AND QUALIFICATIONS

2. As detailed in my Curriculum Vitae, I have a A.B. in Psychology from Smith College. I received a Ph.D. in Psychology from the Ohio State University in 1977. I was a post-doctoral fellow

in Epidemiology and Public Health at the Yale School of Medicine from 1979 through 1980. I have held faculty positions at Vassar College and Yale University, and was the director of a research project at Harvard University. I shifted to a policy career outside of academia in 1983, although I have continued to be a guest lecturer at college and graduate school courses.

3. In 1983, I was a Fellow in the Congressional Science Fellowship program of the American Association of the Advancement of Science. I then spent more than a dozen years working for the federal government in positions that focused on improving federal health programs and policies for adults and children. I worked as a Congressional staffer in the House and Senate, and was a Director of Policy, Planning, and Legislation at an agency of the U.S. Department of Health and Human Services. I have initiated Congressional hearings on a wide range of health issues, including cancer prevention and treatment and the safety of medical products, and co-authored more than a dozen Congressional hearing and policy reports.

4. In 1995, I served as a senior policy advisor in the White House, working for First Lady Hillary Rodham Clinton and the Office of Science and Technology Policy. Since 1996, I have served in leadership positions in numerous nonprofit organizations. I have been in my current position as president of the National Center for Health Research since 1999.

5. The National Center for Health Research is a nonpartisan, nonprofit research and education organization that works to improve policies and programs that affect the health and safety of adults and children. As President, I conduct research, scrutinize research conducted by others, supervise our scientific and communications staff, and work with Members of Congress and their staff to strengthen patient and consumer safeguards. I have testified about medical products and FDA policies several dozen times before Congress, FDA Advisory Committees, and the FDA Science Board. Our organization also conducts Patient Training Workshops where we train patient partners

on FDA approval standards, scientific evidence for safe and effective treatments, FDA opportunities for patient engagement, and participation in clinical trials.

6. While in my current position, I served as a Fellow at the Center for Bioethics at the School of Medicine of the University of Pennsylvania for several years. I also previously served as the chair of Maryland's Women's Health Promotion Council, appointed by the Governor of Maryland. I serve on the board of directors of the Congressionally mandated Reagan Udall Foundation for the Food and Drug Administration, an independent nonprofit corporation that focuses on enhancing the FDA's ability to protect and promote the health of the American public. I am also on the board of directors of the Alliance for a Stronger FDA, a coalition of industry and non-profit organizations focused on increasing appropriations for the FDA.

7. I am the author of five books, several book chapters, and dozens of articles in medical and academic journals and in newspapers across the country. I currently serve as a peer reviewer for several major medical and public health journals, including New England Journal of Medicine, JAMA Internal Medicine, BMJ, PLOS ONE, and the American Journal of Public Health, and I conduct and publish research studies and invited commentaries in peer-reviewed medical journals, often focused on the FDA and the need for safer and more effective medical products. My recent, peer-reviewed articles include the following:

a. Doamekpor LA, Zuckerman DM. Lack of diversity in cancer drug clinical trials may exacerbate racial disparities in mortality rates. *Cancer Epidemiol* 2014;**38**(5):645-46.

b. Fox DM, Zuckerman DM. Commentary: Regulatory Reticence and Medical Devices. *Milbank Q* 2014;**92**(1):151-59.

c. Zuckerman D, Brown P, Das A. Lack of Publicly Available Scientific Evidence on the Safety and Effectiveness of Implanted Medical Devices. *JAMA Intern Med* 2014;**174**(11):1781-7.

d. Zuckerman D. Screening for Lung Cancer: To be or not to be Covered by Medicare? *Journal of Thoracic Imaging* 2015;**30**(1):24-8.

e. Zuckerman D, Doamekpor LA. More Data are Needed for Essure Hysteroscopic Sterilization Device. *Contraception* 2015;**916**(520).

f. Zuckerman DM, Kennedy CE, Terplan M. Breast Implants, Self-Esteem, Quality of Life, and the Risk of Suicide. *Women's Health Issues* 2016;**26**(4):361-65.

g. Zuckerman, D.M., Jury, N.J. & Silcox, C.E. 21st Century Cures Act and similar policy efforts: at what cost? 2015, *BMJ*, **351**:h6122.

h. Zuckerman D.M. A Major Shortcoming in the Public Health Legacy of the Obama Administration. 2017. *American Journal of Public Health* 2017;**107**(1):29-30.

i. Rupp, T. & Zuckerman, D.M. (2017) Quality of Life, Overall Survival, and Costs of Cancer Drugs Approved Based on Surrogate Endpoints. *JAMA Internal Medicine* **177**(2): 276-277.

j. Zuckerman D.M. (2017) Setting the Record Straight on FDA Approvals in Oncology-Reply. *JAMA Internal Medicine* **177**(8):1222-23.

k. Ronquillo, J.G. & Zuckerman, D. M. (2017) Software-Related Recalls of Health Information Technology and Other Medical Devices: Implications for FDA Regulation of Digital Health. *Milbank Quarterly*. **95**(3): 535-553.

l. Zuckerman, D.M. (2017) Can the FDA Help Reduce Drug Prices or the Cost of Medical Care? *American Journal of Public Health*. **107**(11): 1752-1754.

THE CONTROVERSY OVER EXONDYS 51

8. I am quite familiar with the controversy over the approval of Exondys 51 (eteplirsen) for Duchenne Muscular Dystrophy (DMD), and its implications for the larger field of drug development and regulation. I first became aware of this drug when the mother of one of the clinical trial participants in Study 201/202 attended one of our patient advocate trainings and discussed Exondys 51 with us. My staff reviewed the data made public before the 2016 FDA Advisory Committee meeting regarding Exondys 51. We had a number of concerns based on our review, and one of our staff members was the sole person to testify against approval at the FDA Advisory Committee meeting.

9. The FDA was charged with approving treatments based only on substantial evidence of both safety and efficacy from adequate and well-controlled clinical trials. This is typically established

through randomized, controlled trials. Trials for drug efficacy typically are double-blind and placebo-controlled, with a control group that receives a placebo compared to the treatment group, and with both researchers and patients unaware of who is receiving the study drug.

10. The FDA's requirement of substantial evidence of both safety and efficacy from adequate and well-controlled clinical trials is regarded as the gold standard for approval. Insurance companies rely on the FDA's judgment that a treatment is safe and effective in agreeing to pay for new treatments. Patients rely on the FDA's judgment that the benefits of an approved drug outweigh the risks for most patients—that the drug is both safe and effective for the condition for which it is approved.

11. Since 1992, the FDA has had an accelerated approval pathway for drugs to treat serious conditions that provide a meaningful advantage over existing therapy. This pathway and other FDA expedited pathways allow the FDA to approve a drug more quickly and based on less impressive scientific evidence, often with additional confirmatory clinical trials to be conducted after the drug is allowed on the market. Many of the drugs that are eligible for expedited review are for rare diseases.

12. In traditional clinical trials, efficacy is typically shown by clinical outcomes such as the drug's effect on morbidity or mortality. The FDA is allowed, in the context of expedited approval pathways, to use surrogate endpoints in place of clinical outcomes. Confirmatory studies often are required as a condition of approval to prove that the surrogate endpoint is related to the clinical endpoint for which it is substituted. One example of a surrogate endpoint, in the case of cardiovascular disease, is cholesterol level as a surrogate for the clinical endpoints of heart attack or death.

13. Recently, the FDA has been pressured to approve drugs based on less evidence than is scientifically sound. During the Obama administration, there were a number of Congressional hearings where the FDA Commissioner faced hostile questioning, suggesting that the agency's

standards for drug approval were interfering with innovation and with the health of the U.S. pharmaceutical industry. The 21st Century Cures Act contains direction to the FDA to accept less stringent evidence for drug approval, as described below. Along with many others who work in the area of FDA research and policy, I have been concerned that this will result in lowered standards and increased risk to patients and the public health. Companies will have little incentive to do the best possible research if drugs can be approved based on shorter-term studies with little evidence of safety or efficacy.

14. Since approval on an expedited pathway is sometimes permitted based on questionable surrogate endpoints or poorly controlled studies, this has pressured FDA to approve drugs based on less stringent evidence of efficacy and safety. Our organization therefore has paid close attention to FDA decision-making around approval of drugs, including those for rare diseases.

15. In particular, I was gravely concerned about the recent FDA approval of Exondys 51 for DMD based on the skimpiest evidence I have ever seen in the approval of a drug.

16. I am aware of the difficulties faced by patients and families with DMD. In particular, I have heard from parents of patients with DMD who are very frightened about their children's future. Prior to the approval of Exondys 51, patients relied on symptomatic treatment, which consists primarily of long-term steroid treatment and medications to treat cardiac and pulmonary difficulties. Without an effective medication to interrupt the progressive loss of physical function, patients lose the ability to walk, and eventually cannot breathe without a ventilator. Once the heart muscles stop functioning, death is inevitable.

17. Before Exondys 51, another antisense oligonucleotide was submitted to the FDA for DMD, Kyndrisa (drisapersen). Made by BioMarin, Kyndrisa was also intended for mutations amenable to skipping exon 51. The FDA denied approval in January 2016. A large placebo-controlled trial of Kyndrisa failed to show effectiveness, and the drug was not proven safe—it caused severe toxicity

across many organ systems. BioMarin then abandoned its plans to conduct further drug trials for DMD. One of our staff members, Dr. Tracy Rupp, had reviewed the data made available about Kyndrisa, and testified against approval at the FDA Advisory Committee meeting held on November 24, 2015.

18. Sarepta had sought FDA approval for Exondys 51, another antisense oligonucleotide intended for mutations amenable to skipping exon 51, and a decision was pending in 2016.

19. Members of my staff reviewed the publicly available information posted on the FDA website prior to the Peripheral and Central Nervous System Drugs Advisory Committee meeting, which was held on April 25, 2016. This is the same information that the Advisory Committee reviews prior to the meeting. We had significant concerns regarding the adequacy of the clinical trials conducted by Sarepta, including the extremely small sample size (12 participants) in Study 201/202, the failure of the trial to have a control group throughout the trial, the poor 6-minute walk test results, and the failure of the study to establish a statistically significant increase in dystrophin (the biomarker) in participants. Two of the boys in the study quickly lost the ability to walk, leaving only ten boys whose data were analyzed for many of the statistical tests. There were also issues regarding the historical controls used as a comparison. The data presented by Sarepta did not meet FDA standards for approval. This trial was much smaller than the typical trial for drug approval, and much smaller than the failed trial for Kyndrisa, which was intended for the same rare disease. With only eight participants in the Exondys 51 treatment group, and four in the placebo group, it is not possible to generalize results to the larger population of patients for whom the drug was intended.

20. We were aware that Sarepta was already conducting an additional long-term trial, Study 301, the PROMOVI study, which was designed to enroll 160 participants, of which eighty would receive Exondys 51, and eighty would serve as a control group. The study was ongoing, was better designed, and was more likely to present scientifically useful information about whether Exondys 51

was efficacious than Study 201/202. Yet at the Advisory Committee meeting, Sarepta presented only limited data from this larger trial, which had not been vetted by the FDA. It seemed odd that the company didn't provide the data to the FDA prior to the meeting, or discuss efficacy data at the meeting for this larger sample. This raised my concerns further regarding the adequacy of the proof that Exondys 51 had any benefit for boys with the condition.

21. As a result of the dire circumstances associated with DMD, patients and caregivers were willing to accept greater risks in connection with the possible benefit promised by Sarepta and lobbied strongly in favor of approval. I know from discussions with a parent of a child with DMD that the company told families that if they did not receive FDA approval shortly, the company would stop manufacturing the drug. This created a tremendous incentive for parents to pressure the FDA to approve the drug quickly based on limited information, rather than to urge Sarepta to prove the efficacy and safety of the drug through better research prior to approval. I also read the information from patient advocacy groups, such as the Race to Yes, https://theracetoyes.org, being circulated prior to the meeting, which indicated a carefully coordinated effort to gain approval.

22. One of our staff members, Dr. Laura Gottschalk, was the sole person testifying at the Advisory Committee meeting against the approval of Exondys 51. Dr. Gottschalk, who received her PhD in Cellular and Molecular Biology from the Johns Hopkins School of Medicine, questioned why Sarepta had not offered preliminary results from Study 301 to the FDA. Our organization took the position that the drug should not be approved based on such scanty evidence from the 201/202 study. Dr. Gottschalk testified that the trial was too small, with only twelve participants, that two patients of the eight on the drug lost the ability to walk quickly after joining the trial, that there was an inadequate control group (with the four patients in the control group switched to the drug after twenty-four weeks), that the Exondys 51 Western blot results showed levels below that thought to be clinically significant, and that the 6-minute walk test was fraught with problems.

23. I am also familiar with the dispute within the FDA over approval of Exondys 51. Dr. Ellis Unger, Director of the FDA's Office of Drug Evaluation-I; the members of the review team within the Division of Neurology Products, in the Office of Drug Evaluation-I, the Office of Biometrics; and the Office of Clinical Pharmacology were unanimous in recommending that Exondys 51 not be approved. Dr. Unger's direct supervisor, Dr. John Jenkins, then Director of the Office of New Drugs, also agreed that Exondys 51 should not be approved. Dr. Janet Woodcock, the head of the Center for Drug Evaluation and Research, overruled the unanimous scientific review team. After an appeal by the scientific staff, the FDA Commissioner, Dr. Robert Califf, declined to overrule Dr. Woodcock's decision, but made many of the internal dissenting documents public. To my knowledge, a voluntary public revelation of this type of internal scientific dispute within the FDA is unprecedented.

24. In the materials posted on the FDA website about the scientific dispute, concerns were raised by Dr. Ellis Unger, then Director of the FDA's Office of Drug Evaluation-I, whose office was responsible for reviewing the drug, that Dr. Woodcock's decision was based not on the scientific evidence, but rather upon sympathy for patients, and concerns that Sarepta Therapeutics would go out of business if Exondys 51 were not immediately approved. Participants in the clinical trials were receiving Exondys 51 free of charge in an extension of the clinical trial while the company awaited an FDA decision. The company would no longer supply the drug if it went out of business.

25. I am aware that children with DMD and their family members directly contacted Dr. Woodcock and others at the FDA to press for approval of Exondys 51. I saw a social media post on Facebook, in which a parent described her son's conversation with Dr. Woodcock at the FDA Advisory Committee Meeting and included their photograph together at the FDA meeting.[1] Dr. Woodcock's high level of participation during the FDA Advisory Committee Meeting was unusual

[1] *Redacted Facebook Post,* Facebook (April 26, 2016) (Kenney Decl., Ex. GG).

for her and inconsistent with typical FDA practice, and the fact that it was out of the ordinary was noted in the information posted on the FDA website about the scientific dispute.

26. The FDA's decision-making regarding Exondys 51 has been questioned by many in the research and policy community. Review of the complete Clinical Study Reports and appendices by researchers would shed light on the FDA's decision-making, could provide more information about Sarepta's decision to remove the two patients who lost the ability to ambulate from their modified Intent to Treat (*m*ITT) statistical analyses, and could provide needed information about the side effects experienced by participants during the clinical trial.

27. The FDA's decision to approve Exondys 51 on scant evidence has meant that families are having difficulty obtaining insurance approval. Although Medicare and Medicaid pay for most approved drugs, private insurers decide which approved drugs to cover, based in part on the level of evidence showing that the drugs are effective and safe. Drugs that are considered experimental or investigational are not usually covered. For that reason, some insurers have refused to cover Exondys 51 or are willing to provide coverage only for patients who are still able to walk. I put out a statement in October 2016 when Anthem, a large insurer, refused to cover Exondys 51 due to the lack of evidence to support effectiveness. In my statement, I indicated that the drug should not have been approved until effectiveness had been proven, and that Sarepta and the FDA jointly bore responsibility for the tragic financial situation faced by these patients and their families. At that time, reports indicated that the cost per year for Exondys 51 was $300,000.

28. I am now aware that $300,000 is actually a low estimated cost per year for Exondys 51, based on publicly available information. Since Exondys 51 dosage is calculated in milligrams per kilogram, the cost of Exondys 51 increases proportionately based on patient weight. The cost for larger patients is reportedly as high as $750,000 per year, and I cited this high cost in an editorial published in the American Journal of Public Health (AJPH) in November 2017. A *New York Times*

article written by Katie Thomas quoted the chief clinical officer of a pharmaceutical benefit management company stating that the actual cost can even amount to $1.5 million a year.[2] Because the FDA approved the drug in a highly unusual process based on scant evidence, families are struggling to gain insurance approval.

29. The FDA's decision-making about the safety of Exondys 51 would provide important information to help patients and families make informed decisions about the drug. This would be possible if complete safety information in the Clinical Study Reports was released. In the materials posted on the FDA website about the scientific dispute, concerns were raised by Dr. Ellis Unger about the health risks for patients taking Exondys 51, since it is administered intravenously, which poses a risk of infection. I am aware that patients with DMD can have inadequate veins due to both disease progression and the side effects of corticosteroid treatment, and that an indwelling central venous access device, such as a port-a-cath, is often implanted surgically to allow for treatment with Exondys 51. One of my staff members, Dr. Megan Polanin, testified in May 2017 at an FDA hearing in favor of allowing port-a-cath implantation in clinical trial participants with DMD in the context of a study evaluating a treatment's safety and effectiveness. In the FDA's adverse events database, FAERS, there are reported cases of serious infections, including one death associated with septic shock, in patients prescribed Exondys 51, along with a case of infusion site hemorrhage. If Exondys 51 is not effective, patients with DMD who are not enrolled in scientifically valid clinical trials will be exposed to the risk of serious infection without an accompanying benefit to them or to future patients.

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[2] Katie Thomas, *Insurers Battle Families Over Costly Drug for Fatal Disease*, New York Times (June 22, 2017), https://www.nytimes.com/2017/06/22/health/duchenne-muscular-dystrophy-drug-exondys-51.html. (Kenney Decl., Ex. GG)

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 29th day of May 2018, in 2018 in Washington, D.C.

Diana M. Zuckerman

CURRICULUM VITAE (Short Version)

Name: **Diana M. Zuckerman**

Address: National Center for Health Research
1001 Connecticut Ave, NW, Suite 1100
Washington, DC 20036

[redacted]

Telephone and Fax: Office: [redacted] Fax: [redacted]

Educational Background:

Smith College, Northampton, Massachusetts, 1968-72.
Psychology, B.A. 1972.

Ohio State University, Columbus, Ohio, 1972-77.
Clinical Psychology, M.A. 1975; Ph.D. 1977.

Yale Medical School, New Haven, Connecticut.
Post-doctoral fellow in epidemiology/public health, 1979-80.

Clinical Internship: Worcester State Hospital, MA, 1976-77.

Areas of Expertise: Epidemiology, public health, biostatistics, research methodology, clinical trial design, comparative effectiveness research, psychology and mental health, federal health policies, bioethics, health education for patients and consumers

Fellowships, Grants, Honors:

Smith College Scholarship, 1968-72.

Elected to Sigma Xi (Honorary Research Society), 1972.

Mershon Center, Research Assistant on communications and public policy, Ohio State University, 1972-73.

National Institute of Mental Health Public Health Trainee: 1973-74; 1974-75; 1975-76.

State of Ohio Clinical Psychology Trainee: 1974, 1975.

Ohio State University, Psychology Department Teaching Assistant, 1976.

National Institute of Mental Health Internship, 1976-77.

National Institute of Mental Health Post-doctoral Fellowship in epidemiology, 1979-80.

American Association for the Advancement of Science, Congressional Science Fellowship, sponsored by the American Psychological Association, 1983-84.
Grant #1R03 MH38060-01, National Institute of Mental Health, research on college students' eating disorders, 1983-84.

APA Media Award as co-author of Big World, Small Screen: The Role of Television in American Society, 1992.

Listed in Who's Who of American Women, 1995-96.

Inducted into the International Women In Medicine Hall of Fame, 2010

Principal Investigator for 22 grants, including research grants from Robert Wood Johnson Foundation, Pew Charitable Trust, and Verizon Foundation; conference grants from Agency for Healthcare Research and Quality; U.S. Food and Drug Administration, U.S. Department of Health and Human Services Office for Disability; U.S. Department of Health and Human Services Office for Women's Health, and patient education grants from DC Cancer Consortium and Susan G. Komen Foundation, 2000-present.

Boards, Committees, and Commissions

American Psychological Association: Fellow of the APA since 1992; Board of Professional Affairs 1990-1992; Committee on Legal Issues 1990-1992; Task Force on Television and Society, 1986-88.

Society for the Psychological Study of Social Issues (Division 9): Council 1990-92; Co-Chair, Public Policy Fellow Committee, 1992-94; member of the selection committee for the James Marshall Post-doctoral Public Policy Fellow, 1992-94; Fellowship consultant 2001-2004.

Congressional Science Fellowship: Member of the post-doctoral fellowship selection committee for the American Association for the Advancement of Science, 1995 and 1996, and for the American Psychological Association, 1985 and 1986.

American Association for the Advancement of Science (AAAS): Member of the NIH Fellowship Selection Committee, 2001; Member of the AAAS Media Awards Selection Committee for TV reporting on health issues, 2001 and 2007.

National Women's Health Network: Vice Chair of the Board of Directors 1996-2000.

TMJ Association: (a patient advocacy organization) Board of Directors 1997-2004.

Commission for Women, Montgomery County, MD: Co-chair of Legislative Task Force, 1998-2001.

National Cancer Institute Scientific Advisory Committee: Advisory Committee for NCI studies on implants, 1999- present.

Girl Neighborhood Power: (a project of the U.S. Public Health Service) Member of the Steering Committee 1998-2001.

National Cancer Institute Consumer Advocates in Research and Related Activities: Founding member and designated mentor to new members, 2001-2005.

State of Maryland Work-Life Alliance: Appointed by Lt. Governor Kathleen Kennedy Townsend, 2001-2003
State of Maryland Governor's Council on Women's Health Promotion: Co-chair, 2002-2005.

Alliance for a Stronger FDA: Board of Directors, 2006-present

Reagan-Udall Foundation: Board of Directors of Congressionally mandated foundation to strengthen the FDA, 2007-present

Medical Device Epidemiology Network (MDEpiNe)t: Stakeholder Council, 2012-present

Medicare Evidence Development Coverage Advisory Committee (MEDCAC), CMS, Member, 2014-present

Editorial Responsibilities:

Member of the editorial board of the *Journal of Social Issues* 1997-2000; guest editor of *Journal of Social Issues* special issue on welfare reform, 2001; 1980-present occasional peer reviewer for text books and journal articles in psychology, public policy, and medicine.

Health Policy Experience:

1999-present **President, National Center for Health Research** (formerly National Research Center for Women & Families)
Manage and direct an independent, non-profit research-based think tank that analyzes, synthesizes, and widely disseminates research data on policy-relevant issues that affect the health and safety of adults and children. Responsibilities include obtaining initial grant and contract support and creating and building the organization; representing the organization in meetings with Congress, the White House, and federal agencies; serving as a spokesperson with the media. Current projects include directing the Center's Cancer Prevention and Treatment Fund, improving quality of care for cancer patients; improving safety of medical products, toys, and children's products;

improving strategies to prevent cancer; improving programs and policies to reduce obesity; reducing environmental exposures that harm health, assisting working mothers and military families.

1997-98 **Director of Research and Policy Analysis, Institute for Women's Policy Research**
Manage and direct Research Department and policy efforts of an independent, non-profit scientific research organization that conducts research on the full spectrum of issues affecting women and families. Co-chair for the National Council of Women's Organizations' (a coalition of 140 national organizations) Task Force on Women and Economic Security, which conducts monthly briefings for Congressional staff and policy analysts.

1995-96 **Senior Policy Analyst, The White House**
Advised White House officials and staff regarding a range of programs and issues, particularly health care and research programs related to Persian Gulf War veterans' illnesses. Briefed President and First Lady, wrote speeches and position papers, and served as a member of White House working groups to develop policy activities and to plan and appoint a Presidential Advisory Committee, while serving in this one-year position.

1993-95 **Director, Health Policy Staff, Senate Committee on Veterans' Affairs**
Initiated and managed all Senate legislation and hearings on health and mental health research and services of the Department of Veterans' Affairs, which runs the largest medical system in the U.S. Advised Chairman Jay Rockefeller (D-WV) on health care reform, Gulf War illnesses, and other issues; wrote speeches, articles, and Congressional reports. Managed Committee health staff, initiated and monitored General Accounting Office (GAO) reports requested by the Chairman. Represented Sen. Rockefeller at meetings with White House officials, staff of Federal agencies, members of Congress and their staff, university deans and faculty, advocacy organizations, and constituents.

1993 **Director of Policy, Planning and Legislation, Center for Mental Health Services**
Responsible for fiscal planning and program priorities for this $385 million mental health services agency of the U.S. Department of Health and Human Services. Established new office; hired and managed staff; and worked with Congress, other Federal agencies, experts in the field, and advocates to improve services to prevent and treat mental illness.

1985-93 **Committee Professional Staff, U.S. House of Representatives**
Managed several high-visibility public policy reviews for a subcommittee of the Government Operations Committee, including access to health care, safety of silicone medical devices, and quality of government research programs and demonstration projects. Reviewed policies and programs of the Departments of Health and Human Services, Education, and Veterans Affairs, National Science Foundation, and the D.C. government; initiated and managed Congressional hearings; developed legislation; wrote speeches, reports, and press releases;

managed the media; and represented the Chairman (Rep. Ted Weiss) at meetings with Congress and staff, Administration officials, lobbyists, and experts in health, mental health, and social policy.

1983-84 **Congressional Science Fellow, U.S. House of Representatives**
Legislative Assistant to Rep. Pat Williams in the areas of health, social services, women's issues, and the elderly: developed and evaluated legislation; wrote speeches and position papers; and represented Rep. Williams at meetings with Congress, Congressional staff, advocates, and policy-related experts.

Academic Experience

2006-2012 **University of Pennsylvania Center for Bioethics**
Fellow

2005-present **Johns Hopkins, University of California, University of Maryland, American University, George Washington University, University of Illinois**
Guest Lecturer in several graduate and undergraduate courses

1980-83 **Harvard University, Director, Seven College Study**
Developed, analyzed, and published results of a longitudinal study of the life goals and well-being of 9,000 undergraduates from Barnard, Bryn Mawr, Mount Holyoke, Radcliffe and Harvard, Smith, Vassar, and Wellesley. Hired and managed staff; supervised data collection on seven campuses; developed the budget; designed surveys; wrote articles; gave speeches; and coordinated and chaired planning meetings of faculty and administrators representing the seven colleges.

1979-80 **Yale Medical School, Departments of Psychiatry and Epidemiology**
Post-doctoral Fellow in epidemiology. Designed research, analyzed data, and wrote articles on the results of three research projects: social factors influencing the mortality of the elderly poor, treatment for depression, and medical care for battered women.

1978-79 **Yale University, Psychology Department, Research Psychologist (faculty)**
Director of a nationally recognized research project that evaluated and modified the impact of television on children. Designed research, trained teachers, supervised staff, analyzed data, developed lesson plans, and co-authored two books and several articles for professional journals.

1977-78 **Vassar College, Psychology Department, Assistant Professor**
Taught Abnormal Psychology, Current Psychotherapies, Personality, and Psychopathology Seminar, and supervised field work and research projects.

1974-76 **Ohio State University, Psychology Department, Teaching Associate**

Taught Abnormal Psychology, Research Methods, and Seminar on Research on the Psychology of Women.

Clinical Experience

1979 **Yale University**, Depression Research Unit and Connecticut Mental Health Center. Therapist for depressed outpatients.

1976-77 **Worcester State Hospital**, Worcester, MA. Pre-doctoral intern. Inpatient case management and psychological assessment; outpatient individual, couples, family, and group therapy; and training of professionals and paraprofessionals at mental health clinics.

1975-76 **Ohio State University**, Psychological Counseling Center, Columbus, Ohio. Assertive Training and self-relaxation workshops.

1974-75 **Community Mental Health Centers**, Columbus, Ohio. Individual therapy with adults and children, couples therapy, group therapy, psychological assessment, intake interviews, and consultation with schools and day care centers.

Selected Testimony and Invited Presentations 1997-present

Health and Public Policy

Zuckerman, D.M. The Role of Social Scientists in Public Policy. Invited speaker for the City University of New York Social-Personality Psychology Colloquium Series, New York City, 1997.

Zuckerman, D.M. Research on Women's Health for the 21st Century. Presented testimony at conference sponsored by the National Institute of Health's Office of Research on Women, Sante Fe, 1997.

Zuckerman, D.M. Women and Pensions. Moderated a Congressional briefing sponsored by the Council of Presidents' Economic Security Task Force and the Congressional Office on Women's Issues, Washington, D.C., 1997.

Zuckerman, D.M. The Importance of Child Care to Working Women. Invited speaker at a Congressional briefing entitled *Child Care: The Key to Economic Survival for Families* sponsored by the Council of Presidents' Economic Security Task Force and the Congressional Caucus on Women's Issues, Washington, D.C., 1997.

Zuckerman, D.M. Eating Disorders and Federal Policies. Invited speaker at a Congressional briefing sponsored by the Society for the Psychological Study of Social Issues and the American Psychological Association, Washington, D.C., 1997.

Zuckerman, D.M. How Much Does Domestic Violence Cost the U.S. Taxpayer? Speaker at a Congressional briefing sponsored by the Council of Presidents' Task Force on Economic Security and the Congressional Caucus on Women's Issues, Washington, D.C., 1997.

Zuckerman, D.M. Social Science and Social Policy: Research That Influences Policies Affecting Women. Presented paper and moderated a panel on *Social Policy* at the National Women's Studies Association's Mid-Atlantic Regional Conference, Arnold, Maryland, 1997.

Zuckerman, D.M. Measuring Progress: The Status of Women in the United States. Moderated a panel at the National Women's Conference's 20th Anniversary Celebration of the Houston National Women's Conference, Washington, D.C., 1997.

Zuckerman, D.M. The Messages We Give Girls About What Women Can Be. Invited speaker on a panel at a roundtable meeting entitled *The Culture of Girlhood and Passage to Womanhood: Implications for Teen Pregnancy*, sponsored by the Family Impact Seminar, Washington, D.C., 1997.

Zuckerman, D.M. Reproductive Health and Economic Security. Moderated a Congressional briefing sponsored by the Council of Presidents' Economic Security Task Force and the Congressional Caucus on Women's Issues, Washington, D.C., 1997.

Zuckerman, D.M. , Women in Public Policy Careers. Invited speaker for panel on gender policy at the Columbia University Career Conference, Washington, D.C., 1997.

Zuckerman, D.M. The Role of Social Scientists in Public Policy. Invited speaker for the City University of New York Social-Personality Psychology Colloquium Series, New York City, 1997.

Zuckerman, D.M. Faces of Poverty. Invited plenary speech at the New York State conference *Does Work End Poverty?: People, Policies and Strategies in Reforming Welfare*, Albany, 1998.

Zuckerman, D.M. Measuring the Impact of Welfare Reform. Invited workshop presentation at the New York State conference *Does Work End Poverty?: People, Policies and Strategies in Reforming Welfare*, Albany, 1998.

Zuckerman, D.M. Advancing Women's Educational Opportunities in the Higher Educational Act. Moderated a Congressional briefing sponsored by the Council of Presidents' Economic Security Task Force and the Congressional Caucus on Women's Issues, Washington, D.C., 1998.

Zuckerman, D.M. Avoiding an Old-Age Crisis in the 21st Century. Invited speaker at roundtable sponsored by the American Association for University Women, Third Millennium, Girls Incorporated, and Financial Women International, Washington, D.C., 1998.

Zuckerman, D.M. Women and Social Security. Moderated a Congressional briefing sponsored by the Council of Presidents' Economic Security Task Force and the Congressional Caucus on Women's Issues, Washington, D.C., 1998.

Zuckerman, D.M. The Continuum of Care: Addressing the Needs of America's Working Families: From Child Care to Elder Care. Moderated a Congressional briefing sponsored by the Council of Presidents' Economic Security Task Force and the Congressional Caucus on Women's Issues, Washington, D.C., 1998.

Zuckerman, D.M. Drug Safety and Pregnancy. Invited speaker at workshop co-sponsored by the National Institute of Child Health and Human Development and the FDA, Bethesda, 2000.

Zuckerman, D.M. The Need for Research: The Benefits of H.R. 1961. Testimony before the Subcommittee on Health of the Committee on Energy and Commerce, U.S. House of Representatives, Washington, D.C., 2001.

Zuckerman, D.M. We Need to Know More: The importance of studying medical products that are already approved. Invited speaker at FDA's Public Meeting on the Prescription Drug User Fee Act (PDUFA), Washington, D.C., 2001.

Zuckerman, D.M. Methylmercury in Fish: Risks for Pregnant Women and Children. Invited speaker at FDA's Advisory Panel meeting on a Public Advisory on Methylmercury in Fish, 2002.

Zuckerman, D.M. How the Federal Budget Affects Programs for Women, Children, and Families. Invited speaker, Clearinghouse for Women's Issues Luncheon, Washington, 2003.

Zuckerman, D.M. Challenges Facing Blind Adults in America. Invited speaker, Annual Program Managers Conference for Independent Living Services for Older Individuals, Bethesda, Maryland, 2003.

Zuckerman, D.M. Poverty and Families. Speaker at Congressional briefing in the U.S. House of Representatives, 2003.

Zuckerman, D.M. Cancer, Prevention, and Federal Policies. Speaker at Congressional briefing in the U.S. Senate, 2003.

Zuckerman, D.M. Blind Adults in America: Their Lives and Challenges. Speaker at Congressional briefing in U.S. House of Representatives, 2004.

Zuckerman, D.M. When Little Girls Become Women: Early Puberty and Risk Behaviors in Girls. Invited keynote speaker at annual spring training meeting of State of Pennsylvania's teen pregnancy program staff, Harrisburg, 2004.

Zuckerman, D.M. Psychologists as Advocates. Invited speaker for the biennial conference of the Society for the Psychological Study of Social Issues, Washington, DC, 2004.

Zuckerman, D.M. The Need for Diversity in Clinical Trials of New Medical Products. Invited speaker for the annual conference of the American Medical Women's Association, Washington, DC, 2004.

Zuckerman, D.M. Conflicts of Interest and the Integrity of NIH Research. Meeting of the NIH Advisory Committee on Conflicts of Interest, Bethesda, 2004.

Zuckerman, D.M. Scientific Integrity and Women's Health. Panel presentation at the annual meeting on scientific integrity of the Center for Science in the Public Interest, Washington, D.C., 2004

Zuckerman, D.M. Politics, Science, and Health. Invited speaker at Princeton University roundtable on science and politics, 2004.

Zuckerman, D.M. Politics and Health. Invited speaker at George Washington University roundtable, 2004.

Zuckerman, D.M. Working on and off Capitol Hill. Invited speaker for the Women's Research and Education Institute Congressional Fellowship Program, U.S. House of Representatives, Washington, DC, 2005.

Zuckerman, D.M. A Psychologist on Capitol Hill. Invited speaker for the American Psychological Association Congressional Science Fellowship Program, Washington, DC, 2005.

Zuckerman, D.M. Children and Obesity. Keynote speaker at the Delta Kappa Gamma biennial conference for women educators, March 19, 2006.

Zuckerman, D.M. Everything you Need to know about Women's Health. Keynote speaker at Temple Sinai Sisterhood dinner, Washington, DC, May 18, 2006.

Zuckerman, D.M. Myths and Realities of Plastic Surgery. Invited speaker at the Women's Health Conference sponsored by Women's Health Virginia, June 9, 2006.

Zuckerman, D.M. Life after a Congressional Fellowship. Invited speaker for the Women's Research and Education Institute Congressional Fellowship Program, U.S. House of Representatives, Washington, DC, 2006.

Zuckerman, D.M. Improving the Safety of Medical Products. Invited speaker at Capitol Hill Briefing of the Patient and Consumer Coalition, 2007.

Zuckerman, D.M. Health Policy Issues and the National Research Center for Women & Families. Invited speaker for the Women's Research and Education Institute Congressional Fellowship Program, U.S. House of Representatives, Washington, DC, 2007.

Zuckerman, D.M. Political Science: How Federal Priorities Affect Health Research and Policy. Invited speaker for Health Policy Fellowship Program, Philadelphia College of Osteopathic Medicine, 2007.

Zuckerman, D.M. Politics v. Science v. Anecdote on Capitol Hill, presentation to faculty and students at the University of Pennsylvania Center for Bioethics, Philadelphia, 2007.

Zuckerman, D.M. The FDA and Women's Health, presentation at the annual meeting of the American Public Health Association, Washington, D.C., 2007.

Zuckerman, D.M. Medical Devices and User Fees, Testimony before the Health Subcommittee of the Energy and Commerce Committee, U.S. House of Representatives, 2007.

Zuckerman, D.M. Are Medical Devices Safe? Shortcomings of the Approval Process, Testimony before the Health Subcommittee of the Energy and Commerce Committee, U.S. House of Representatives, 2007.

Zuckerman, D.M. Clinical Trials to Ensure Public Health, Invited speaker at the Food and Drug Law Institute, 2009.

Zuckerman, D.M. Improving Cancer Treatment and Prevention, keynote speaker for the Cancer Awareness Program of the Blacks in Government and The Wellness Program, Department of Energy, 2009.

Zuckerman, D.M. Improving Safety for Cardiac Patients, invited speaker, Transcatheter Cardiovascular Treatment (TCT) annual conference, 2010.

Zuckerman, D.M. Public Health Implications of the Device Approval Process, Invited speaker at FDA Forum on the 510(k) Approval Process, 2010.

Zuckerman, D.M. Surgical Mesh and The Need for Patient-Centered Outcome Data, Invited speaker at Congressional briefing, U.S. House of Representatives, 2011.

Zuckerman, D.M. Medical Devices and Public Health, Testimony before the Aging Committee of the U.S. Senate, 2011.

Zuckerman, D.M. The Sentinel Initiative: Consumer Perspective, invited panel speaker at Brookings Institution conference, 2012.

Zuckerman, D.M. Changes you can make to Prevent Cancer, Department of Energy Blacks in Government annual meeting, 2012

Zuckerman, D.M. Consumer Perspective on Medical Device Approval Criteria, invited speaker on panel with FDA officials at Food Drug Law Institute conference, 2012

Zuckerman, D.M. Safety, Effectiveness, and Public Health, invited speaker at annual meeting of Consumers United for Evidence-based Healthcare/Cochrane Collaborative, 2012.

Zuckerman, D.M. What Seniors Need to Know about Medications, invited speaker at meeting of IBM's Rusty Blues (retirees), 2012.

Zuckerman, D.M. Compounding Pharmacies and Public Health, invited speaker at Congressional press conference hosted by Rep. Ed Markey, 2012.

Zuckerman, D.M. FDA Regulatory Standards for Medical Devices, speaker at Briefing in U.S. House of Representative and U.S. Senate, 2012.

Zuckerman, D.M. Medical Device Recalls, speaker at Congressional Briefing hosted by George Mason University Law School, 2013.

Zuckerman, D.M. Standards for FDA Approval: Drugs v. Devices, speaker at Georgetown Medical School conference on Medical Behavior in a Commercial World, 2013.

Zuckerman, D.M. The FDA Approval Process: Implications for Public Health, speaker at Congressional Briefings, U.S. House of Representative and U.S. Senate, 2013

Zuckerman, D.M. FDA Approval Process: What Physicians Need to Know, speaker at the annual meeting of the National Physicians Alliance, 2013

Zuckerman, D.M. Medical Device Approval Criteria, speaker at Leadership Conference for the American Medical Students Association, 2013.

Zuckerman, D.M. The Impact of FDA Approval Standards on Patient Health, speaker at briefing at the U.S. Senate, 2014

Zuckerman, D.M. Safety and Effectiveness of Drugs and Devices, speaker at Conference sponsored by Harvard Medical School, American Association for the Advancement of Science, and National Center for Health Research, 2014.

Zuckerman, D.M. Expedited Reviews of Drugs and Devices, speaker at annual meeting of Consumers United for Evidence-Based Medicine (CUE), 2014.

Zuckerman, D.M. Is a Medical Device Safe if it Isn't Proven Safe?, speaker at the annual meeting of the National Physicians Alliance, 2014.

Zuckerman, D.M. The Impact of FDASIA on Medical Devices, invited speaker at Senate HELP Committee briefing, U.S. Senate, 2014

Zuckerman, D.M. How FDA Approval Policies Affect Medicaid, meeting of the Drug Effectiveness Review Project, Oregon Health and Science University, 2014.

Zuckerman, D.M. The Impact of Changing FDA Approval Standards, invited speaker at Senate HELP Committee briefing, U.S. Senate, 2015

Zuckerman, D.M. The Challenge of Well-Funded Medical Lobbying, speaker at the annual meeting of the National Physicians Alliance, 2015.

Zuckerman, D.M. FDA and Your Patients' Health: What Does Safe and Effective Actually Mean?, Grand Rounds, University of Maryland Medical School, 2014.

Zuckerman, D.M. Shortcuts for Getting Medical Products to Market, invited speaker at annual meeting of Consumers United for Evidence-based Healthcare/Cochrane Collaborative, 2014

Zuckerman, D.M. Standards for Safe and Effective Medical Treatments, invited speaker at Conference of Consumer Reports Safe Patient Project, 2015.

Zuckerman, D.M. The Role of Patients and the Public in FDA Approval Decisions, Invited speaker at Harvard Medical School Bioethics Seminar Series, 2016

Zuckerman, D.M. Public Health Considerations, FDA, and Opioids, invited speaker at meeting regarding Opioid Addiction of the National Academies of Sciences, Engineering, and Medicine, 2016.

Zuckerman, D.M. How Changes to the Affordable Care Act Would Affect the Health of Women with Disabilities, presentation at Cerebral Palsy Foundation Workshop supported by CPF PCORI Engagement Award, 2016.

Zuckerman, D.M. What Patients Need to Know About the FDA, presentations at 4 Patient Training Workshops supported through NCHR's PCORI Engagement Award, 2015-2017

Zuckerman, D.M. The Importance of Patient-Centered Research, invited speaker at PCORI annual conference, 2017.

Zuckerman, D.M. Legislation Affecting the Health of Women and Children, invited speaker at annual meeting of Delta Kappa Gamma International (women educators), 2018.

Zuckerman, D.M. What the FDA Can Do to Reduce the Opioid Epidemic, invited speaker at FDA public forum on opiods, 2018.

Zuckerman, D.M. Priorities for the Consumer Product Safety Commission in 2018-2019. Speaker at annual public meeting of the Consumer Product Safety Commission, 2018.

Zuckerman, D.M. Science, Regulations, and Human Health, invited speaker at the ABA Administrative Law and Regulatory Practice Institute, 2018.

Recent Articles, Monographs, and Book Chapters (2000-present)

Zuckerman, D.M. (2000) The Need to Improve Informed Consent for Breast Cancer Patients. Journal of the American Medical Women's Association, 55, 285-89.

Zuckerman, D.M.& Kalil, A. (2001) Introduction: Welfare Reform: Preliminary Research and Unanswered Questions. Journal of Social Issues, 56, 579-586.

Zuckerman, D.M. (2001) Welfare Reform in America: A Clash of Politics and Research. Journal of Social Issues, 56, 587-600.

Zuckerman, D.M. (2001) The Evolution of Welfare Reform: Policy Changes and Current Knowledge. Journal of Social Issues, 56, 811-820.

Zuckerman, D.M. (2002) Helping Cancer Patients Consider the Pros and Cons of Breast Reconstruction. RN Magazine

Zuckerman, D.M. (2004) Blind Adults in America: Their Lives and Challenges. National Center for Policy Research for Women & Families.

Zuckerman, D. (2005) Treat Your Body Well, in M. Burk (Ed.) 50 Ways to Improve Women's Lives, Inner Ocean Publishing.

Zuckerman, D. M. and Dubowitz, N. (2005) Clash of Cultures: Women and Girls on TV and in Real Life. In Featuring Females, E. Cole and J. H. Daniel, (eds), American Psychological Association Press.

Zuckerman, D.M. (2006) Breast Implants: Making an Informed Decision, Johns Hopkins Advanced Studies in Medicine.

Dudley, S. and Zuckerman, D.M. (2006) Unnecessary Mastectomies? American Breast Cancer Guide.

Zuckerman, D.M. (2006) Decisions in the Dark. National Research Center for Women & Families.

Zuckerman, D.M. (2006) FDA Advisory Committees: Does Approval Mean Safety? National Research Center for Women & Families.

Zuckerman, D.M. (2007). A Consumer Advocate's Perspective on Medical Device Safety. In Medical Device Epidemiology and Surveillance, S. L. Brown, R.A. Bright, and D. Tavris (ed.). John Wiley & Sons.

Zuckerman, D. and Abraham, A. (2008). Teenagers and Cosmetic Surgery, Journal of Adolescent Health, 43, 318-324.

Zuckerman, D. (2008) Do Conflicts of Interest Undermine FDA Approval Decisions? Regulatory Affairs Journal, 16, 309-310.

Zuckerman, D. (2009) The Ethics of Inclusion and Exclusion in Clinical Trials: Race, Sex, and Age, In The Penn Center Guide to Bioethics, Vardit Ravitsky, Autumn Fiester, and Art Caplan (eds.), Springer.

Zuckerman, D.M. (2010) Reasonably safe? Breast Implants and Informed Consent, Reproductive Health Matters, 18, 94-1-2.

Zuckerman, D.M., Brown, P, and Nissen, S.E. (2011) Medical Device Recalls and the FDA Approval Process, Archives of Internal Medicine, 117, 1006-11.

Zuckerman D.M., Brown P., Nissen S.E. (2011). In Reply, Archives of Internal Medicine, 171(11), 1045

Zuckerman D.M., Brown P., Nissen S.E. (2011). In Reply, Archives of Internal Medicine, 171(21), 1963.

Abraham, A. and Zuckerman, D. (2011) Adolescents, Celebrity Worship, and Cosmetic Surgery, Journal of Adolescent Health, 49, 453-4.

Zuckerman, D., Booker, N, and Nagda, S. (2012) Public Health Implications of Difference in US and European Union Regulatory Policies for Breast Implants, Reproductive Health Matters, 20 (40),102-111.

Terplan M. and Zuckerman D. (2013) Comment on 'Statement on combined hormonal contraceptives containing third- or fourth-generation progestogens or cyproterone acetate, and the associated risk of thromboembolism'. Journal of Family Planning and Reproductive Health Care, **39**(4):304.

Zuckerman, D. (2013) Hip Implant Failure for Men and Women: What and When We Need to Know Comment on "Sex and Risk of Hip Implant Failure" JAMA Internal Medicine, 173(6): 442-443.

Yttri J. and Zuckerman D. (2013) Addressing the need for new antibacterials". The Lancet Infectious Diseases, **13**(10):834.

Fox, D.M. & Zuckerman, D.M. (2014) Regulatory Reticence and Medical Devices, Milbank Quarterly, 92(1): 151-159.

Zuckerman D.M., Brown P. & Das A. (2014) Lack of Publicly Available Scientific Evidence on the Safety and Effectiveness of Implanted Medical Devices, JAMA Internal Medicine, 174(11): 1781-1787.

Doamekpor L.A. and Zuckerman D.M. (2014) Lack of diversity in cancer drug clinical trials may exacerbate racial disparities in mortality rates. Cancer Epidemiology, **38**(5):645-46.

Zuckerman D.M. and Brown P. (2015) Sufficiency of Information in 510(k) Summaries-Reply. JAMA Internal Medicine, **175**(5):864.

Zuckerman, D.M.. (2015) Screening for Lung Cancer, To Be or Not To Be Covered by Medicare? J Thoracic Imaging, 30(1): 24-28.

Gonsalves, G. & Zuckerman, D.M. (2015) Will 20th Century Patient Safeguards Be Reversed in the 21st Century? BMJ, 350 h1500.

Zuckerman, D.M. & Doamekpor L.A. (2015) More Data Are Needed for Essure Hysteroscopic Sterilization Device. Contraception 91 (6): 520

Zuckerman, D.M. (2015) Understanding the Controversies Over a Groundbreaking New Health Care Law. http://www.milbank.org/the-milbank-quarterly/the-op-eds/understanding-the-controversies-over-a-groundbreaking-new-health-care-law

Zuckerman, D.M., Jury, N.J. & Silcox, C.E. (2015) 21st Century Cures Act and similar policy efforts: at what cost? BMJ, 351:h6122.

Zuckerman, D.M. & Silcox, C.E. (2016) The Challenges of Informed Consent When Information and Time are Limited. In Informed Consent: Procedures, Ethics and Best Practices, Winston Hammond (ed.), Nova Science.

Zuckerman D. (2016). When Will Presidential Candidates Ask, "What Do Women Want in Health Care?" American Journal of Public Health, **106**(5):790-1.

Zuckerman D.M., Kennedy C.E., Terplan M. (2016) Breast Implants, Self-Esteem, Quality of Life, and the Risk of Suicide. Women's Health Issues, **26**(4):361-65.

Zuckerman D.M. (2017) A Major Shortcoming in the Public Health Legacy of the Obama Administration. Am J Public Health 2017;**107**(1):29-30.

Zuckerman, D. (2017). How to Kill Obamacare: Death by 1,000 Cuts? The BMJ Opinion, BMJ.

Zuckerman, D. (2017). "What Does It Mean to March for Women in 2017?" The BMJ Opinion, BMJ.

Rupp, T. & Zuckerman, D.M. (2017) Quality of Life, Overall Survival, and Costs of Cancer Drugs Approved Based on Surrogate Endpoints. JAMA Internal Medicine, 177(2): 276-277.

Zuckerman D.M. (2017) Setting the Record Straight on FDA Approvals in Oncology-Reply. JAMA Internal Medicine **177**(8):1222-23.

Ronquillo, J.G. & Zuckerman, D. M. (2017) Software-Related Recalls of Health Information Technology and Other Medical Devices: Implications for FDA Regulation of Digital Health. Milbank Quarterly. 95(3): 535-553.

Ronquillo J.G., Zuckerman D.M. (2017) Electronic Health Records. Annals of Internal Medicine, **166**(7):536-36.

Zuckerman, D., Tomes, M & Murphy, A. (2017) Are Gummy Bear Breast Implants the Safer Implants? In Breast Implants, Rene Simon (ed), Nova Science.

Zuckerman, D.M. (2017) Can the FDA Help Reduce Drug Prices or the Cost of Medical Care? American Journal of Public Health, 107(11): 1752-1754.

Testimony

Cavitt v. Bayer Corp., No. CJ-2014-195 (Okla. Civ. App. Dist. Ct. Carter Cty. 2016). Zuckerman Videotape Dep. 2016 WL 9229325, Feb. 5, 2016.

Additional Publications in Past 10 Years Not Listed on Curriculum Vitae

Blog Posts

Zuckerman, D. (2012). Death By Medicine. Huff Post Blog. **2018**.

Zuckerman, D. (2012). The Other Health Care Bill. Huff Post Blog. **2018**.

Zuckerman, D. (2012). What the Health Care Decision Means to Us. HuffPost Blog.

Zuckerman, D. (2013). Angelina Jolie's Decision. Huff Post Blog. **2018**.

Zuckerman, D. (2013). October Surprise. Huff Post Blog, Huff Post. **2018**.

Zuckerman, D. (2013). Perfecting Bodies Through Chemistry? Fem2.0. **2018**.

Zuckerman, D. (2013). Warning: This Birth Control Product May Be Hazardous to Your Health. Huff Post Blog, Huff Post. **2018**.

Zuckerman, D. (2013). What Would Wendy Davis Do? The REAL Threat to Women's Health. Huff Post Blog, Huff Post. **2018**.

Zuckerman, D. (2014). Antibiotic Resistance: Will Policymakers Resist Effective Strategies? Capitol Connection, American Association for the Advancement of Science. **2018**.

Zuckerman, D. (2014). Can the War on Cancer Be Won? A Surprising Answer. Huff Post Blog, Huff Post. **2018**.

Zuckerman, D. (2014). Ebola Outbreak: A Teachable Moment for Scientists. Sci on the Fly, AAAS S&T Policy Fellows Central. **2018**.

Zuckerman, D. (2014). Health Care Advice That Can Save Your Life. Huff Post Blog, Huff Post. **2018**.

Zuckerman, D. (2014). No More Pap Smears? Huff Post Blog, Huff Post. **2018**.

Zuckerman, D. (2014). Shooting Stars, Hot Flashes and Feeling Sexy. Huff Post, Huff Post. **2018**.

Zuckerman, D. (2014). Which Cancer Drugs Actually Work? Many Unanswered Questions Threaten Patients and Families. Maria's Farm Country Kitchen. **2018**.

Zuckerman, D. (2014). The Worst New Drug of 2014? Huff Post Blog, Huff Post.

Zuckerman, D. (2015). Are We Asking the Wrong Questions about Campus Sexual Assault? Maria's Farm Country Kitchen. **2018**.

Zuckerman, D. (2015). Congress Is Up to Something. Huff Post Blog, Huff Post. **2018**.

Zuckerman, D. (2015). The Facts About Addyi, its Side Effects and Women's Sex Drive. Our Bodies, Our Blog, Our Bodies, Ourselves. **2018**.

Zuckerman, D. (2015). Letters to Annie: Why Did This Healthy Young Woman Die in Her Sleep? Maria's Farm Country Kitchen. **2018**.

Zuckerman, D. (2016). Abortion Clinics vs. Cosmetic Surgery Centers: Which are Safer for Women? Our Bodies, Our Blog, Our Bodies, Ourselves. **2018**.

Zuckerman, D. (2016). Congress Shouldn't Pass FDA Reform Bills Without Addressing Patient Safety and Drug Prices. The Health Care Blog. **2018**.

Zuckerman, D. (2017). In the News: Breast Implants Linked to Rare Cancer. Our Bodies, Our Blog, Our Bodies, Ourselves. **2017**.

Zuckerman, D. (2017). Why Are So Many American Women Having Masectomies? Our Bodies, Our Blog, Our Bodies, Ourselves. **2018**.

Zuckerman, D. Y., Jennifer (2013). Antibiotics: When Science and Wishful Thinking Collide. Health Affairs Blog. **2018**.

Newspaper Articles

Wood, S. F. and D. Zuckerman (2015). The 21st Century Cures Act could be a harmful step backward: Congress should fund patient research that includes both sexes and a wide range of age groups. The Washington Post. Washington, DC.

Wood, S. F. and D. Zuckerman (2015). The Dangers in a Medical Cures Bill. The Washington Post. Washington, DC**:** A.23.

Zuckerman, D. (2011). Playing With the Band. New York Times. New York, NY**:** A23.

Zuckerman, D. (2013). Eat, Drink and Be Merrily Healthy. GRAND.

Zuckerman, D. (2013). Still Working to Understand Cancer. The Washington Post. Washington, DC.

Zuckerman, D. (2015). Patients Shouldn't Be Used as Guinea Pigs. Sun Sentinel. Deerfield Beach, Florida, Tronc.

Zuckerman, D. (2016). 21st Century Cures Act: Yes or No? No: Act's Promise of Quick Cures Is a Brew of Ultra-Hype Mixed with Snake Oil. Syndicated to U.S. newspapers including Chicago Tribune. Chicago, IL, Tribune News Service.

Zuckerman, D. (2016). Pro&Con: Experience Well-suits Her to Deliver Affordable Care to All. Syndicated to U.S. newspapers including Southcoast Today. New Bedford, MA.

Zuckerman, D. (2016). Why the 21st Century Cures Act Could Be Disastrous for Medicine. Spectrum.

Zuckerman, D. (2017). Right to Try Laws Allow Big Pharma to Exploit Patients' Hope. Syndicated to U.S. newspapers including Chicago Tribune. Chicago, IL**:** 15.

Zuckerman, D. (2017). Right to Try? Or Right to be Exploited Before You Die? Our Bodies, Our Blog, Our Bodies, Ourselves. **2018**.

Press Releases

Mazzucco, A. Z., Diana (2013). Response to CDC Study on Camp Lejeune Drinking Water Health Hazards, National Center for Health Research.

Zuckerman, D. (2017). Statement of Dr. Diana Zuckerman in Honor of Dr. Vivian Pinn, National Center for Health Research.