I. THE SELECT PANEL HAS THWARTED LIFE-SAVING RESEARCH

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Over the past year, Select Panel Republicans have conducted an end-to-end attack on fetal tissue donation and research. Operating largely out of public view, they have misused congressional authority, with the ultimate goal of driving doctors, clinics, universities, and companies away from fetal tissue work and ending this life-saving research. Tragically, their stealth campaign is working.

Congressional and state-level attacks on fetal tissue donation have reduced the supply of donated tissue. Only two of the six Planned Parenthood affiliates that had been facilitating donation for patients in the past five years still provide this service; three stopped because of threats and controversy caused by the deceptively-edited and discredited videos released by anti-abortion activist David Daleiden.[1] In fact, the threats against one affiliate were so immediate and severe that it stopped its donation program on July 14, 2015 – the day that the first Center for Medical Progress (CMP) video was released.[2]

Tissue procurement organizations have been similarly affected. The Chief Executive Officer of one company received graphic death threats after being identified in CMP's fraudulent videos. That company has now spent hundreds of thousands of dollars increasing its security measures and responding to investigations spawned by the deceptive videos.[3] Another tissue procurement organization informed the Panel that "due in large part to the costs born from having to respond to these congressional inquiries, [the company] is no longer doing business. It has come to the end of the line in terms of resources."[4] A third company – DV Biologics – no longer provides fetal tissue to researchers.[5]

As a result, promising research into conditions and diseases such as Alzheimer's, diabetes, HIV/AIDS, and the Zika virus, which impact millions of Americans has been halted or delayed. Doctors who conduct life-saving research – who have been compared to Nazi war criminals by witnesses and Panel Republicans[6]– fear for their personal and professional well-being and are reluctant to speak publicly about their work.

Despite these risks, some of the nation's leading researchers and research institutions provided compelling evidence demonstrating that fetal tissue research remains critical to the advancement of medical science and deserves continued bipartisan support. Unfortunately, it also confirms how damaging the attacks on fetal tissue donation and research have already been.

A. Fetal Tissue is a Critical Resource

In their July interim update, Select Panel Republicans roundly rejected or ignored statements and testimony by prominent researchers and concluded that this research is "outdated

technology" and "not mainstream science."[7] Deriding Panel Democrats for "exaggerating the importance" of fetal tissue research, Chair Blackburn has also taken the position that sufficient alternatives exist.[8] Similarly, at a September 2016 business meeting of the Panel, Representative Bucshon declared: "[T]here is no evidence that use of fresh fetal tissue has resulted in any scientific research results. . . . It is being used for expediency and for lower cost."[9]

In reality, the Panel has received overwhelming evidence of the indispensable role that fetal tissue research plays in advancing our understanding and treatment of a staggering array of conditions that afflict millions of people in this country and throughout the world.[10] As outlined in the examples below, letters and statements from scientists, researchers, public health authorities, and some of the nation's leading academic medical centers have highlighted its past benefits and confirmed the continued value of fetal tissue for research on a broad range of diseases and conditions from infancy through adulthood.

1. Alzheimer's disease

Alzheimer's disease ("Alzheimer's") is the most common cause of dementia among older adults and the sixth leading cause of death in the United States.[11] A progressive neurological disorder, Alzheimer's impairs memory, thinking, and behavior, resulting in the inability to complete simple daily tasks.[12]

As Dr. Lawrence Goldstein, a neuroscientist at the University of California, San Diego ("UCSD"), told the Panel during its first hearing, "[t]his devastating disease affects 5.3 million Americans and costs us in excess of $200 billion to $300 billion a year."[13]

The only scientist who does fetal tissue research invited to testify during this investigation, Dr. Goldstein discussed how fetal tissue is critical for his study. He informed the Panel that in his lab, "the approach we are taking is to use reprogrammed stem cells to make Alzheimer's-type brain cells…to try and understand what is going wrong and to develop drugs that curtail the problems that happen biochemically."[14] Dr. Goldstein explained that fetal astrocytes, a type of support cell in the brain, is "very valuable" for this work and "proving important to us to make new discoveries."[15] Although it is possible to create cells that are similar to astrocytes without using fetal tissue, Dr. Goldstein clarified that these cells are not identical in capacity, and fetal astrocytes remain the "gold standard."[16]

2. Amyotrophic lateral sclerosis (ALS)

Amyotrophic lateral sclerosis ("ALS"), also known as "Lou Gehrig's disease," is a progressive neurological disorder that attacks nerve cells, causing diffuse muscle weakness, disability, and eventually death.[17] Reports suggest that as many as 20,000 Americans have the disease at any given time, and more than 6,000 Americans are diagnosed with the disease annually.[18]

As John Hopkins University informed the Panel, "[a]s the nerve cells degenerate, the muscles they control grow weak and ultimately stop working and ALS patients typically die by suffocation."[19] Johns Hopkins University and other research institutions explained how fetal tissue has already resulted in promising developments with regards to potential ALS treatments.

One research team at Johns Hopkins University found that injecting fetal cells into animal models "appears to protect the existing cells from degenerating."[20] They continued that, "[t]his finding was so promising for a potential ALS treatment that the FDA has approved an investigational new drug application for early stage clinical trials."[21]

Similarly, University of California at Los Angeles ("UCLA") explained that fetal tissue is "of great value for studies of the unique structure of the human brain," including strategies to assist in "determining the underlying causes of neurodegenerative diseases, such as spinal muscular atrophy and amyotrophic lateral sclerosis, and for screening for drugs that could slow disease progression and extend patient lifespan."[22]

3. Diabetes Mellitus

Type 1 diabetes mellitus is an autoimmune disease usually diagnosed in children and young adults.[23] The condition is characterized by the inability to produce insulin, a hormone needed for the body to ensure that glucose moves from the bloodstream into cells. The hallmark of treatment is lifelong insulin therapy.[24] In the United States, type 1 diabetes is responsible for an estimated $14 billion in healthcare costs each year.[25] Over one million Americans currently live with this condition, including approximately 200,000 young adults, and 40,000 new cases are diagnosed annually.[26]

Harvard explained to the Panel that its researchers depend on fetal tissue because it enables them to "model and better understand the auto-immune attack that leads to type 1 diabetes, among other diseases."[27] Harvard also described its efforts to ameliorate the suffering of children with type 1 diabetes by seeking to "make human pancreatic beta cells for transplantation into diabetics, thereby relieving them of the daily finger pricks and insulin injections they need to stay alive."[28]

Fetal tissue is also used in research focused on complications of type 1 diabetes, such as diabetic retinopathy. This disease is characterized by damage to the blood vessels in the back of the eye resulting in vision loss.[29] Diabetic retinopathy is the leading cause of blindness among people with diabetes mellitus, and according to the American Academy of Ophthalmology, eighty percent of patients with type 1 diabetes will develop diabetic retinopathy over the course of their lives.[30] Johns Hopkins University informed the Panel: "Using fetal eye tissue, our researchers were the first to show the location of two forms of the VEGF protein, which are responsible for the growth and disappearance of these blood vessels . . . This discovery can be used to learn more about how tumors and diabetic retinopathy progress."[31]

4. HIV/AIDS

The human immunodeficiency virus attacks the body's immune system, specifically the cells that fight off infection.[32] If left untreated, HIV can lead to AIDS, or acquired immunodeficiency syndrome.[33] Recent reports suggest that more than 1.2 million Americans currently live with HIV; one in eight don't even know they have the condition.[34] In 2014 alone, nearly 21,000 people in the U.S. were estimated to have been diagnosed with AIDS.[35]

The University of Minnesota informed the Panel that fetal tissue research is a critical part of efforts to "develop an intervention to prevent mother-to-child transmission of HIV."[36] As the University of Minnesota further explained: "[t]hat research alone has saved over 1 million infants in the last 10 years, while also reducing elective abortion in HIV positive women by more than half in this country."[37] Other preeminent research institutions informed the Panel that fetal tissue has been vital to enhancing our understanding of and identifying treatments for HIV/AIDS.

Oregon Health & Science University told the Panel that "in HIV/AIDS research, the use of fetal tissue has been critical to advancing animal models that can mimic the human immune system," which "is crucial to developing much needed vaccines for this terrible disease and others…"[38]

The International Society for Stem Cell Research similarly stated that fetal tissue research has "[a]llowed the development of novel approaches to HIV prevention that could not have been studied in other systems" and "[a]llowed for the testing of drugs in human cells in vivo in a way that could not have been done in other preclinical systems."[39]

5. Infant and Childhood Leukemia

Leukemia is a cancer that starts in early blood-forming cells.[40] It is the most common type of cancer affecting children and teens, with reports suggesting that about 2,700 children in the United States are diagnosed with leukemia each year.[41] According to UCLA, "[a]lthough the survival rate of these patients has improved dramatically, approximately 15% of pediatric patients with the most aggressive forms of the leukemia continue to die."[42]

As UCLA explained to the Panel, their researchers rely on fetal tissue in a project focused on improving treatments for a form of lymphocyte leukemia in young children: "A growing body of evidence suggests that these fatal leukemias may be unusually aggressive because they emerged from a unique type of B cell progenitor (B cells are white blood cells that secrete antibodies) generated only during fetal development" and that, through ongoing fetal tissue research, they seek "to identify genes expressed only in fetal B-cell progenitors that contribute to the development of the aggressive forms of leukemia observed in young children."[43]

The Children's Hospital of Pennsylvania ("CHOP") also confirmed the value of fetal tissue research in their efforts to study treatments for infant leukemia. As CHOP explained,

scientists using fetal tissue to prevent and treat infant leukemia can make "faster progress because disease-causing mutations target fetal cells specifically."[44]

6. Macular degeneration

Age-related macular degeneration ("AMD") is characterized by deterioration of the eye's macula, the part of the retina that is responsible for central and high-acuity vision.[45] It is a common cause of visual impairment in older adults, and while it does not lead to complete blindness by itself, those affected have difficulty performing simple everyday activities, such as recognizing faces, driving, and reading.[46]

Harvard told the Panel that it relies on fetal tissue to study AMD because the macula develops during gestation and does not exist in most mammals or other experimental models; therefore "human fetal tissue provides the required starting point for such studies."[47] Similarly, the University of Michigan stressed that animal models, cellular derivatives, and other alternatives are limited when searching for treatments of AMD. They explained that "therapies exist for only ten to fifteen percent of patients and animal models are not very good,"[48] while fetal tissue "behaves more like the type of tissue that researchers are attempting to model."[49]

7. Preterm Birth

Preterm or premature birth of a baby before thirty-seven weeks of pregnancy affects approximately one out of every ten infants born in the United States, with higher rates among communities of color.[50] Babies born prematurely face a higher risk of serious disability, developmental delay, or even death.[51]

The University of Illinois at Chicago explained to the Panel that fetal tissue research is essential for studying "the impact of premature birth on infant health and development,"[52] and the "development of therapies to prevent or reduce the morbidity and mortality from birth defects and developmental disorders."[53]

The Department of Health and Human Services ("HHS") also confirmed that scientists using fetal tissue can "study the immune systems of the fetus and mother, and any incompatibilities arising due to infection or inflammation that may lead to rejection, miscarriage, or preterm birth."[54]

8. Spinal Cord Injury

Spinal cord injury refers to damage to any part of the spinal cord or nerves at the end of the spinal canal, which can lead to partial or complete paralysis.[55] The most common cause of spinal cord injury is trauma, either due to a motor vehicle accident or fall.[56] More than 250,000 Americans currently live with spinal cord injuries, and there are an estimated 12,000 new spinal cord injuries in the U.S. each year.[57]

In his testimony at the Panel's first hearing, Dr. Lawrence Goldstein discussed how research trials involving fetal tissue at the center he directs "are vital to pushing medical science forward and to helping to rescue people who are afflicted with spinal cord injuries, which is a terrible affliction."[58]

Dr. Goldstein explained how researchers have now initiated an FDA-approved phase 1 clinical trial to test the ability for fetal cells "to develop and positively impact the paralysis" for individuals suffering from spinal cord injuries.[59] As associations representing leading research institutions confirmed, fetal tissue research enhances our understanding of methods to improve "recovery from spinal cord injury."[60]

9. Vaccine Research

Thanks to vaccinations, many common and devastating diseases can now be prevented in the United States and across the world.[61] The Centers for Disease Control and Prevention ("CDC") estimates that for children born from 1994 through 2013, routine immunization has prevented more than 700,000 deaths and 21 million hospitalizations.[62]

As Harvard University told the Panel, "[t]he field of vaccine R&D is probably the best known example of how fetal material provides an invaluable resource to scientific and medical progress; most recently in work seeking to better understand and combat the spread of Zika virus, just as it did chicken pox and polio, among others."[63] Other leading research and government institutions confirmed the role that fetal tissue has and continues to play in vaccine-related research.

Yale School of Medicine told the Panel that the vaccines for rubella and varicella, "effectively eradicated a major source of child mortality and mental retardation."[64] HHS also explained that "cell lines derived from fetal tissue have also played an essential role in the creation of new vaccines and remain valuable in important efforts such as the pursuit of a vaccine for Ebola."[65]

Notably, Panel Republicans acknowledge that the development of the polio vaccine relied on fetal tissue research but claim that it could have been done without using fetal tissue. Dr. Goldstein rejected this claim at the Panel's first hearing, explaining that "[t]he fact is, that is how those vaccines were developed," and that "it is so easy to look in the rearview mirror at research and say well, now that we know everything we know, it would have been so much easier to do it a different way."[66] The University of Wisconsin also confirmed that "the development of the human polio vaccine would not have been possible without cells of fetal origin."[67]

Other testimony and documents obtained by the Panel confirmed the unique and critical role that fetal tissue continues to play in research on vaccine development. As explained by one witness interviewed by the Panel, her Planned Parenthood affiliate was asked by a nearby medical college to facilitate donation of tissue for researchers working on vaccines for infectious diseases including "HIV, Hepatitis, Malaria, and Dengue" fever.[68]

As the researcher explained to the Planned Parenthood affiliate, "because we have been limited to human peripheral blood samples for our studies, it has been very difficult to develop successful therapies to prevent or treat these diseases."[69] Unlike these samples, fetal tissue would allow these researchers "to perform necessary experiments for the development and validation of vaccines and immune correlates for the treatment and prevention of lethal infectious diseases."[70]

Unfortunately, the Planned Parenthood affiliate ultimately decided not to move forward with this project because of the controversy surrounding the fraudulent Daleiden/CMP videos.[71]

10. Zika Virus

The current Zika virus epidemic in the Americas is one of the most serious public health emergencies since the Ebola outbreak in West Africa in 2014.[72] While often benign in adults, the Zika virus can have "devastating effects on the developing human fetus," resulting in microcephaly and other conditions.[73]

Dr. Lawrence Goldstein told the Panel during the first hearing: "I think that if you want to understand the Zika virus, the most efficient place to start is with fetal tissue that is infected."[74] Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases, agreed that fetal tissue is most needed in circumstances such as the Zika virus:

> I think the argument of the need to have fetal tissue research in a disease in which the virus is affecting fetal tissue, is about as strong a justification as you can get for using fetal tissue in research in this case.[75]

As the International Society for Stem Cell Research (ISSCR) confirmed, insights from fetal tissue research "are already guiding the development of drugs that may protect the unborn baby from the ravages of the Zika virus."[76]

B. Fetal Tissue Plays a Unique and Irreplaceable Role

The alternatives to fetal tissue posited by the Republicans – primarily induced pluripotent stem cells (iPSCs), as well as animal and human adult tissue and cell lines – have been successfully used by researchers. However, scientists and research institutions have repeatedly advised the Panel that tools and technologies are not interchangeable and fetal tissue is still needed for certain research that requires its distinct properties.

As Dr. Goldstein testified, "fetal tissues and cells cannot be easily replaced by embryonic stem cells, reprogrammed stem cells, or adult stem cells."[77] He went on to say that cell lines "are simply not interchangeable,"[78] and that "we need all different types of cells to do research because we don't know what is best."[79]

Dr. Goldstein's testimony was reinforced by the Association of American Medical Colleges:

> The cell lines themselves have limitations, and access to fresh fetal tissue remains critically important. '[O]ff-the-shelf fetal cell lines are of limited use for scientists because they do not faithfully mimic native tissue and represent only a subset of cell types: WI-38 and MRC-5, for example, were derived from fetal lungs. The lines can also accumulate mutations after replicating in vitro over time…For all of these reasons, researchers turn to fresh tissue.'[80]

Johns Hopkins University also advised the Panel that the unique nature of fetal tissue cannot be replicated by iPSCs or other models:

> Our researchers have shown that human fetal cells hold unique properties that are not shared even with human iPSCs: human fetal cells survive, mature and migrate more reliably.[81]

Columbia University recognized that, while "IPS cells may hold the key to unlocking the mysteries on many diseases" it remains true that "there are many instances where FTR [fetal tissue research] are still very much irreplaceable" and remain the "gold standard for the field for now."[82]

The Yale School of Medicine explained that, while sufficient in some instances, animal and adult human tissue cannot completely replace fetal tissue because "the differences are so profound, with so many genes that are expressed differently, that the fetal brain at the molecular level is almost a different organ from the adult brain, making adult brain cells a poor proxy for fetal brain cells."[83]

UCLA provided the Panel with seven representative examples of current research projects that are dependent on "the continued availability of fetal tissue."[84] UCLA explained that "human fetal tissues exhibit biological properties that are distinct from those of tissues derived from children and adults."[85] UCLA further explained the unique role that fetal tissue plays in medical research:

> [T]he direct study of human fetal tissues is essential for an understanding of human development. This understanding is necessary for the advancement of fundamental biology, for the pursuit of therapies for the treatment of developmental diseases, such as Down syndrome and the microcephaly associated with Zika virus infection, and for the pursuit of therapies for the treatment of many other diseases that have been linked to developmental defects, including several cancers.[86]

The University of Minnesota similarly reported to the Panel: "There is currently no substitute for the use of human fetal tissue in some areas of research. Where possible, researchers have looked for alternatives, such as using adult cells that have been reprogrammed to their earlier forms. But those techniques are still being refined and some fields, such as the study of fetal development, are likely to remain reliant on fetal tissue."[87]

The University of Washington ("UW"), which operates the Birth Defects Research Laboratory, also explained the unique role of fetal tissue research.[88] UW provided the Panel with a list of thirty eight diseases and conditions, including ALS, Alzheimer's, multiple sclerosis and the Zika virus for which researchers had requested fetal tissue from UW from 2014-2016.[89] UW explained:

> These research projects investigate human developmental biology which cannot be done using various animal and other cellular systems. The use of human fetal tissue is a vital way to confirm human development because it is a specimen that has developed in its native habitat.[90]

Another university further reinforced to the Panel that fetal tissue has distinct properties that cannot be replicated in research by any available substitute:

> Neither adult stem cells, nor reprogrammed somatic cells approach the versatility and quality of the natural stem cells derived from the fetus which remains the best resource for regenerative medicine…. We are aware of how many times promising solutions for diabetes, cancer, and neurodegenerative diseases have been shown to cure the mouse or rat but fail when tested in humans….There is no comparable substitute for fetal tissue for the accurate understanding of human development.[91]

The approach taken by Panel Republicans discounts the views of the scientific community regarding the value and need for fetal tissue research and ignores the reality of how science works. As HHS advised the Panel:

> It is impossible to predict what types of cells or systems will be necessary for answering particular research questions or developing new treatments and cures. Thus, human fetal tissue is likely to remain a unique and invaluable resource for studying both typical and atypical processes early in development, elucidating the pathogenesis of infectious disease, advancing our understanding of a wide range of conditions, and developing new treatments and cures.[92]

The Association of American Medical Colleges echoed HHS's reasoning:

> By closing the door on one type of research, we may never know what advances we might have attained. For every bit of knowledge

> or advance that has resulted from research using fetal tissue, alone or in combination with other research, there may be other questions and potential lines of inquiry that merit further exploration, using all available methods.[93]

C. Life-saving Research is at Risk

At the Panel's first hearing, Dr. Lawrence Goldstein highlighted the real-world consequences of Republican attacks on fetal tissue research. As he explained, one of the projects he was working on involving research on multiple sclerosis ("MS") "is basically seeing a supply of fetal material dry up completely and it was a very promising therapy for MS."[94]

Subsequent reporting confirmed that another MS research trial planned for this year, which focuses on regenerating myelin (the insulation around nerve fibers) in late stage MS patients, was pushed back to 2019 because researchers lacked the fetal tissue that they needed to proceed.[95] As a neurologist leading the research team explained: "This kind of delay . . . results in the additional deaths of people who could have been rescued."[96]

Leading institutions also told the Panel about the chilling impact on life-saving research. UCLA wrote that "recent national events have increased the challenge of obtaining the fetal tissues" needed for ongoing research projects. UCLA went on to explain:

> One reputable company was forced to close due to legal expenses associated with challenges to its operations. This has delayed important studies and has forced laboratories to spend a considerable amount of time and resources searching for alternative suppliers. One laboratory has identified a reliable source of fetal tissues in Germany. Another laboratory has reduced their effort on studies that require fetal tissues, despite the importance of this research, due to concerns about personal safety.[97]

Another university reported "a paucity of sources from which to obtain human fetal tissue, creating roadblocks to the conduct of important biomedical research. Entities that previously provided the sources of human fetal tissue have either closed, due to external pressure, or currently offer more limited options than previously proffered."[98] That institution further explained that "[o]ver the past year, the supply of fetal tissue has dwindled… to the point where we can no longer depend on this important resource for our studies."[99]

The University of Illinois at Chicago explained that "because of difficulty in obtaining fetal tissues and concerns about their continued availability . . . [a] researcher [studying early life exposure to certain toxicants and risk for prostate cancer] opted to use a less satisfactory alternative, human prostate organoids grown in vitro."[100]

Johns Hopkins University told the Panel that a private funder asked one of its research teams to "alter their research approach" to avoid using fetal tissue because of the recent "adverse publicity" around this research.[101] The University expressed its concern that "changes in the availability of human fetal tissue will result in major setbacks in the understanding of devastating diseases and development of future treatments and cures for patients."[102] It further explained the chilling impact on its research faculty:

> [D]ue to the sensational nature of linking fetal tissue research to broader concerns about abortion, faculty will be discouraged from pursuing important scientific questions due to difficulty in acquiring needed material or out of fear of personal reprisal.[103]

A May 2016 article in the scientific journal *Nature Biotechnology* demonstrates that safety concerns and threats are common throughout the scientific community. According to the *Nature* article:

> One cancer researcher received hate mail after a conservative media website linked the investigator's name to fetal tissue research. In response, the floors of some researchers' laboratories are now permanently locked and de-identified, constraining the scholarly exchange of students, visitors, and ideas.[104]

As a professor of medicine at the University of California, San Francisco who uses fetal tissue to develop therapies that might save babies with lethal congenital disorders further explained:

> We read news of deaths and attacks on abortion clinics, so one has to fear that someone misguided might put something in your mailbox, or do something to your children, and that has really caused a significant amount of anxiety.[105]

This researcher was "one of the rare researchers who uses fetal tissue and agreed to speak on the record," but "twenty others did not reply or declined to comment."[106]

ENDNOTES

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[59] *Id.*
[60] Letter from the Ass'n of American Medical Colleges et al., to Hon. Marsha Blackburn, Chair, Select Investigative Panel (Oct. 7, 2016), at 1-2.

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[64] Letter from Yale School of Medicine to Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (May 9, 2016).
[65] Letter from Jim Esquea, Assistant Sec'y for Legislation, Dep't of Health and Human Services to Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (Apr. 6, 2016), at 2.
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[81] Letter from Johns Hopkins University to Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (Sept. 20, 2016), at 3.
[82] Letter from Columbia University to Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (Nov. 10, 2016), at 2-3.
[83] Letter from Yale School of Medicine to Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (May 9, 2016), at 3.
[84] Letter from University of California, Los Angeles to Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (Sept. 19, 2016).
[85] *Id.* at 3.
[86] *Id.*
[87] Letter from University of Minnesota to Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (Mar. 22, 2016), at 2.
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[91] Letter to Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (Sept. 21, 2016).

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