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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

MULTNOMAH COUNTY, an existing county government and a body politic and corporate, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary, U.S. Department of Health and Human Services; VALERIE HUBER, in her official capacity as the Senior Policy Advisor for the Office of the Assistant Secretary of Health and the Acting Deputy Assistant Secretary for the Office of Population Affairs; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Defendants.	Case No. 18-cv-01015-YY DECLARATION OF LESLIE M. KANTOR, PHD, MPH

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DECLARATION OF LESLIE M. KANTOR

I, Leslie M. Kantor, declare as follows:

1. I am the Chair of the Department of Urban-Global Public Health at the School of Public Health at Rutgers, The State University of New Jersey, a position I have held since April 2018, after 12 years as an Assistant Professor of Clinical Population and Family Health at the Mailman School of Public Health at Columbia University. I received a Masters of Public Health from the Department of Population & Family Health at Columbia's Mailman School of Public Health in 1992 and a PhD from Columbia's School of Social Work in 2015 with a concentration in Social Policy and Administration.

2. In addition to my faculty appointments, I have also served on the staff of various health care and policy organizations, including SIECUS (Sexuality Information and Education Council of the United States) from 1992 to 1996, Planned Parenthood of New York City from 1996 to 2003, and the Planned Parenthood Federation of America, where I served as the Vice President of Education from 2010 to 2018. In 2017, I was appointed to the Board of Directors of ETR Associates, a national non-profit organization that develops, implements, evaluates, and disseminates science-based resources to advance health and opportunities for youth, adults, and communities. ETR Associates publishes the Tool to Assess the Characteristics of Effective Sex and STD/HIV Education Programs ("TAC"), which is relevant to this litigation.

3. I am a member of the Society for Adolescent Health and Medicine and the American Public Health Association, among other professional associations.

4. I have over three decades of experience in the field of public health, prevention research, and evidence-based health education. My particular specialty is in sex education and adolescent health, including studying and evaluating various approaches to teen pregnancy and

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sexually transmitted disease (STD) prevention. I am the author of more than 15 peer-reviewed, scientific articles as well as numerous book chapters and monographs on topics related to teen pregnancy prevention and effective interventions. Several of my articles outline the policy and funding history for various approaches to teen pregnancy and STD prevention in the United States. I was the co-editor of a special issue of the peer reviewed, scientific journal *Sexuality Research and Social Policy* focused on abstinence-only-until-marriage programs and have studied and written extensively about these programs.

5. I have been a principal investigator/researcher for over $4 million in grants on over a dozen research projects on a number of topics related to teen pregnancy prevention and sex education, including identifying best practices in sex education, conducting preliminary research in order to design technology-based approaches to sex education, and rigorously evaluating teen pregnancy prevention interventions.

6. I have studied and spoken extensively about the U.S. Department of Health and Human Services' (HHS) Teen Pregnancy Prevention Program (TPP Program), which is at issue in this litigation.

7. A copy of my curriculum vitae with a complete listing of my professional background, experience, and publications is attached hereto as Exhibit I. The opinions I express herein are my own and not those of the institutions with which I am affiliated.

8. Based on my years of training and experience in these substantive areas as well as my familiarity with the literature related to teen pregnancy prevention efforts and strategies, including the TPP Program, it is my opinion that (1) the terms used by Congress in funding the TPP Program have settled meanings within the fields of prevention research and sex education that have long been understood as such; (2) the 2018 Tier 1 FOA does not adhere to those

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meanings; (3) the 2018 Tier 1 FOA requires all grantees, regardless of the type of program they seek to run, to deliver untested abstinence-only content; and (4) by requiring the inclusion of this content, the 2018 Tier 1 FOA may actually interfere with the likelihood that a chosen or developed program will be effective. I provide these opinions as an expert in public health, evidence-based health education, teen pregnancy and STD prevention and evaluation, adolescent health, and sexual and reproductive health education.

9. I am not being compensated for my testimony in this matter.

The History of Congressional Funding for Teen Pregnancy Prevention Initiatives

10. Until 2009, the United States government's support for teen pregnancy prevention initiatives was mainly for abstinence-only-until-marriage programs. Abstinence-only-until-marriage programs are those that exclusively promote no sex until marriage.[1]

11. Because advocates of these abstinence-only-until-marriage programs view sex education that includes information about birth control and condoms as sending "mixed messages" that inhibited the communication of abstinence-only messages, abstinence-only programs historically limited the provision of information about condoms and other forms of contraception to discussion about failure rates.[2] For youth who are already sexually active, these programs sought to return them to a state of abstinence, or what abstinence-only advocates referred to as "secondary virginity."[3]

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[1] Santelli, J. S., Kantor, L. M., Grilo, S. A., Speizer, I. S., Lindberg, L. D., Heitel, J. & Heck, C. J. (2017). Abstinence-only-until-marriage: An updated review of US policies and programs and their impact. *Journal of Adolescent Health, 61*(3), pp. 274–275.

[2] *Id.* at 274–75.

[3] Medical Inst. for Sexual Health, *What is Secondary Virginity?* (June 2012), https://www.medinstitute.org/faqs/what-is-secondary-virginity/.

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12. Congress's funding for abstinence-only-until-marriage programs included support for evaluations of these programs.[4] Those evaluations and others showed no effects of these programs on altering teen behavior,[5] including no impact of these programs on helping teens abstain from sexual activity and no differences in rates of birth control and condom use.[6]

Congress Shifts to an Evidence-Based Model through the Teen Pregnancy Prevention Program

13. In response to the growing body of literature showing no effects of abstinence-only-until-marriage programs on behavior, Congress in 2009 shifted most of the federal dollars for teen pregnancy prevention and sex education away from abstinence-only-until-marriage programs and toward a new funding stream focused on evidence-based approaches to teen pregnancy prevention, the TPP Program.[7]

14. The terms that Congress chose in funding the so-called Tier 1 grants in the TPP Program—"replicating programs that have been proven effective through rigorous evaluation"—

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[4] Santelli, *supra* note 1, at 276.

[5] *Id.* at 276.

[6] *Id.* at 276.

[7] Congress appropriated $110,000,000 for grants to fund "medically accurate and age appropriate programs to reduce teen pregnancy," with not less than $75,000,000 directed to "replicating programs that have been proven effective through rigorous evaluation to reduce teenage pregnancy, behavioral risk factors underlying teenage pregnancy, or other associated risk factors," which was implemented as "Tier 1." Congress directed that a smaller portion of funds, not less than $25,000,000, go to "research and demonstration grants to develop, replicate, refine and test additional models and innovative strategies for preventing teenage pregnancy," which was implemented as "Tier 2." Consolidated Appropriations Act, 2010, Pub. L. No 111-117, 123 Stat. 3034, 3253 (2009). On an annual basis, Congress has reauthorized this program on the same terms in amounts ranging from $98,000,000 to $110,000,000. Adrienne L. Fernandes-Alcantara, Cong. Research Serv., R45183, *Teen Pregnancy: Federal Prevention Programs* 6 (2018).

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have well-established and longstanding meanings within public health and evidence-based policymaking, and more broadly in the scientific and research community and literature.

15. For example, the Society for Prevention Research (SPR) is a leading multi-disciplinary organization within the public health field of prevention research.[8] In 2004, SPR appointed a task force of researchers from institutions including Columbia University, University of Pennsylvania, Duke University, and the National Institute of Mental Health at the National Institutes of Health to determine the "most appropriate criteria for prevention programs and policies to be judged efficacious, effective, or ready for dissemination."[9] The task force generated guidelines intended to define the most effective ways to evaluate public health prevention programs, including criteria for describing and replicating programs as well as criteria for evaluating their efficacy.[10] These guidelines are widely followed and generally recognized as objective and authoritative.

16. The 2005 SPR guidelines, and other literature both in the general fields of public health and prevention research and specific to the teen pregnancy context, define the terms used by Congress in creating the TPP Program as follows:

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[8] SPR publishes the peer-reviewed scientific journal *Prevention Science* and is committed to promoting the highest quality science needed to effectively scale up evidence-based programs, practices and policies to combat public health problems. Society for Prevention Research, *About SPR*, https://www.preventionresearch.org/about-spr/ (last visited July 26, 2018); Society for Prevention Research, *Mission Statement and Strategic Plan,* http://www.preventionresearch.org/about-spr/mission-statement/ (last visited July 26, 2018).

[9] Flay, B. R., Biglan, A., Boruch, R. F., Castro, F. G., Gottfredson, D., Kellam, S. & Ji, P. (2005). Standards of evidence: Criteria for efficacy, effectiveness and dissemination. *Prevention science*, *6*(3), pp. 152.

[10] *See generally id.* at 151–75.

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a. *Program*: A program is a planned, coordinated group of activities, processes, and procedures designed to achieve a specific purpose. A program should have specified goals, objectives, and structured components (e.g., a defined curriculum, an explicit number of treatment or service hours, and an optimal length of treatment) to ensure the program is implemented with fidelity to its model.[11] The SPR guidelines note that a program should be "described at a level that would allow others to implement/replicate it" and "that manuals and appropriate training and technical support are readily available."[12]

b. *Replication*: Replication of a program means providing the program the way it was conducted when it was researched and found to be effective.[13] Replication with fidelity means adhering very closely to the way the program was conducted when it was researched and found to be effective.[14] SPR notes that "scientific replication" means delivering the same intervention on a new, similar population

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[11] Substance Abuse and Mental Health Servs. Admin., *Glossary*, https://nrepp-learning.samhsa.gov/glossary#P (last visited July 26, 2018); *see also* Douglas Kirby, *Emergency Answers 2007 Research Findings on Programs to Reduce Teen Pregnancy and Sexually Transmitted Diseases*, at 13 (2007), https://powertodecide.org/sites/default/files/resources/primary-download/emerging-answers.pdf; Douglas Kirby et al., *Tool to Assess the Characteristics of Effective Sex and STD/HIV Education Programs*, 65 (2007), http://recapp.etr.org/recapp/documents/programs/tac.pdf ("A program is a set of activities packaged in a purposeful way with the goal of preventing a problem, treating a problem, and/or supporting an individual or a group.").

[12] Flay, *supra* note 9, at 170.

[13] *Id.* at 162.

[14] *Id.* at 162.

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and ensuring that the intervention is delivered in the same way with the same training as in the original study.[15]

c. *Rigorous Evaluation*: There are well-established standards of evidence that guide the research methods that must be used to demonstrate whether a prevention program has been responsible for the outcomes that were measured.[16] The SPR guidelines include a number of research characteristics that must be in place in order to be able to say that a program worked. For example, rigorous evaluation requires that there be one group that receives the program and another group that does not receive the program (e.g., a control group). The most rigorous design includes randomly assigning individual participants to either the program/intervention group or the control group—a randomized control trial or RCT.[17]

d. *Proven Effective*: In general, if there is a rigorous research design and a statistically significant difference is found on the outcome or outcomes of interest between the program/intervention group and the control group, the program would be considered to be effective. There must be findings on the main outcomes of interest (e.g., for prevention programs, those are usually behavioral

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[15] *Id.* at 162.

[16] *See generally* Flay, *supra* note 9, at 151–75.

[17] *Id.* at 170.

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outcomes rather than only knowledge or attitude outcomes) and the measures and statistical procedures used must adhere to scientific standards.[18]

17. The creation of the TPP Program as an evidence-based model coincided with a larger movement across the federal government to engage in evidence-based policymaking, which sought to ensure that public funds were appropriated for approaches backed by evidence and that investments were made in evaluations to help build out the evidence base related to solving particular problems.[19] In shifting the balance of teen pregnancy prevention funding to an evidence-based model, Congress likewise dedicated federal funds to those programs that had demonstrated evidence of success, rather than those that were unproven.[20]

18. A critical goal of prevention research and evidence-based policymaking is to expand the evidence portfolio to determine which programs work, for which populations, and under which circumstances, and equally important, for replication studies in particular, to report on null or negative findings, as each such study adds to the development of the body of evidence in important ways.[21] The TPP Program embodied this goal by providing for both the development and evaluation of previously unevaluated programs (Tier 2) and the replication of programs that had been proven effective in at least one rigorous evaluation (Tier 1) to determine

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[18] *Id.* at 154–66.

[19] Kappeler, E. M., & Farb, A. F. (2014). Historical context for the creation of the Office of Adolescent Health and the Teen Pregnancy Prevention Program. *Journal of Adolescent Health*, *54*(3), S3–S4; Commission on Evidence-Based Policymaking, The Promise of Evidence-Based Policymaking 15–16 (Sept. 2017), *available at* https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf.

[20] *Id.* at S3–S6; Commission on Evidence-Based Policymaking, *supra* note 19, at 94; Ron Haskins & Greg Margolis, Show Me the Evidence: Obama's Fight for Rigor and Results in Social Policy 67-101, Brookings Institution Press, Washington, DC, 2014.

[21] Flay, *supra* note 9, at 151–175.

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their effectiveness among other populations and in other settings. In 2010 and 2015, HHS funded two waves of five-year grants through the program for Tier 1 and Tier 2 grantees whose work has led to a valuable expansion of the evidence base for teen pregnancy prevention initiatives.[22]

The 2018 Tier 1 Funding Opportunity Announcement

19. Despite the rigorous work and all of the public funding that has gone into developing and updating the teen pregnancy prevention evidence base, the current 2018 Tier 1 Funding Opportunity Announcement (Funding Opportunity Number: AH-TP1-18-001 CFDA NUMBER: 93) now requires applicants to "replicate a risk avoidance model or a risk reduction model that incorporates the common characteristics outlined in one of the two programs": the Systematic Method for Assessing Risk-avoidance Tool (SMARTool) or the Tool to Assess the Characteristics of Effective Sex and STD/HIV Education Programs (TAC).[23]

20. In my opinion, neither the SMARTool nor the TAC is a "program" as that term is used within the teen pregnancy prevention field and literature or more broadly within public health and evidence-based policymaking. Rather, these are tools designed to help adults who are trying to assess and select programs for teen pregnancy prevention, sex education, or abstinence education for youth in their schools, communities, or other settings.

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[22] See, for example, the special issue of the *American Journal of Public Health*, September, 2016, which features a set of articles based on the Teen Pregnancy Prevention Program. Available at https://ajph.aphapublications.org/toc/ajph/106/S1.

[23] Dep't of Health & Human Servs., *Announcement of Availability of Funds for Phase I Replicating Programs (Tier 1) Effective in the Promotion of Healthy Adolescence and the Reduction of Teenage Pregnancy and Associated Risk Behaviors*, at 4 (updated May 9, 2018), https://www.grantsolutions.gov/gs/preaward/previewPublicAnnouncement.do?id=61741.

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21. The TAC, which articulates 17 characteristics of programs that have demonstrated efficacy, was developed more than a decade ago by conducting a systematic review of 83 programs, identifying which had positive behavioral outcomes, and analyzing the characteristics that were common across those effective programs.[24] In my opinion, these "characteristics" in and of themselves are not "programs" and, taken together, do not add up to being a "program."

22. The SMARTool includes a number of suggestions for choosing or developing programs culled from various sources.[25] The SMARTool states: "Nine protective factors have been identified through research as appropriate targets for sexual risk avoidance curricula."[26] Similarly, in my opinion, these "protective factors" also do not add up to a "program."

23. To understand the difference between these two tools and a "program," as that term is used in public health terminology, an analogy may be helpful. Both the TAC and SMARTool are guidelines for choosing a program, much like a school district might consider certain guidelines in choosing a new math textbook. The guidelines might talk about what should be included in a good textbook but would not include the actual text for students or the math problems. Similarly, these two resources do not include lesson plans and are not the manuals or curricula that are needed to actually implement a program. Thus, they are not programs and cannot be used as programs any more than the school district's guidelines are a textbook which can be used to teach math to students.

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[24] Douglas Kirby et al., *Tool to Assess the Characteristics of Effective Sex and STD/HIV Education Programs* 2 (2007), http://recapp.etr.org/recapp/documents/programs/tac.pdf.

[25] Center for Relationship Education, *SMARTool: Assessing Potential Effectiveness for Sexual Risk Avoidance Curricula and Programs* (2010), https://www.myrelationshipcenter.org/getmedia/dbed93af-9424-4009-8f1f-8495b4aba8b4/SMARTool-Curricula.pdf.aspx.

[26] *Id.* at 14.

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24. In my opinion, the TAC and the SMARTool also cannot be used to "replicate" an evidence-based teen pregnancy prevention program as that term is used within the teen pregnancy prevention field and scientific literature. As I explained above, "replication" of a program means providing the program the way it was conducted when it was researched and found to be effective. Since the TAC and the SMARTool are not themselves "programs," and have not been "rigorously evaluated" as such for effectiveness, requiring grantees to use these tools to choose existing programs or to develop new programs is not the same as requiring that funds be used to replicate already evaluated evidence-based programs. In fact, programs developed based on either of the tools will not necessarily result in programs that work.

25. In my opinion, the 2018 Tier 1 FOA, as presently constructed, also would permit prospective grantees to use the TAC and the SMARTool to select programs that have no evidence at all of "effectiveness" and have never been "rigorously evaluated," or even those that have had negative findings.

"Public Health Priorities" in the 2018 Tier 1 FOA

26. The 2018 Tier 1 FOA on its face requires that *all* recipients choose either a "risk avoidance" or a "risk reduction" model.[27]

27. The terms "risk avoidance" and "sexual risk avoidance" are synonymous with "abstinence-only." The former terms have been adopted by proponents of abstinence-only programs to describe programs that focus exclusively on promoting abstinence.[28]

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[27] Dep't of Health & Human Servs., *supra* note 23, at 4.

[28] Lindberg, L. D., Maddow-Zimet, I., & Boonstra, H. (2016). Changes in adolescents' receipt of sex education, 2006–2013. *Journal of Adolescent Health*, *58*(6), p. 625; Santelli, *supra* note 1, at 274–75; Fam. Res. Council, *Abstinence and Sexual Health*, https://www.frc.org/abstinence-and-sexual-health (last visited July 26, 2018).

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28. Regardless of which model grantees use, risk avoidance or risk reduction, the 2018 Tier 1 FOA requires that each grantee "implement" certain "public health priorities"—"weaving the goal of optimal health into every component of the project," "clearly communicate risk," "providing skills to avoid sexual risk," and "providing cessation support"—in the programs they choose.[29]

29. In my opinion, these "public health priorities" mean that *all* grantees will be required to deliver abstinence-only messages.

30. For example, in explaining that all projects should "clearly communicate risk," the FOA notes: "Both risk avoidance and risk reduction approaches can and should include skills associated with helping youth *delay sex* as well as skills to *help those youth already engaged in sexual risk to return toward risk-free choices in the future*."[30] Also, the FOA states: "Projects will clearly communicate that teen sex is a risk behavior for both the physical consequences of pregnancy and sexually transmitted diseases; as well as sociological, economic, and other related risks."[31] The concept of "sexual risk" as used in this manner here and throughout the FOA is, in my experience and familiarity with abstinence-only literature and concepts, consistent with how it has long been used by proponents of an abstinence-only approach to communicate that any and all sex before marriage is inherently risky.

31. Similarly, the provision of "cessation support," another of the 2018 Tier 1 FOA's "priorities," further demonstrates that these priorities are aligned with an abstinence-only

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[29] Dep't of Health & Human Servs., *supra* note 23, at 14–16.

[30] *Id.* at 15 (emphasis added).

[31] *Id.* at 15.

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approach. The FOA defines "cessation support" as providing "affirming and practical skills for those engaged in sexual risk to make healthier and risk-free choices in the future, thereby improving the chances for achieving optimal health outcomes."[32] The only "risk-free" approach to sex is abstinence. Further, the term cessation support, which appears to be borrowed from interventions to assist quitting smokers in the "cessation" of tobacco use,[33] is being used here to refer to a return to a state of abstinence among teens that have previously engaged in sexual behavior. It is a repackaging of the concept of "secondary virginity" used in abstinence-only-until-marriage curricula in the 1980s, '90s and early 2000s.[34] The new FOA explains that the sexual risk *reduction* approach is the "natural approach for an emphasis on cessation support,"[35] meaning once again that *all* grantees, even those attempting to pursue a risk reduction path rather than a sexual risk avoidance path, need to include this abstinence-only content.

32. Taken together, the 2018 Tier 1 FOA asserts that "optimal health" for adolescents is to abstain from any sex before marriage or return to a sex-free status—and the FOA requires the recipient to "weave" that abstinence-only message into every component of its program.[36] Conversely, the FOA assumes that teens who have chosen to become sexually active have not achieved "optimal health" and therefore, must be provided with "cessation" instruction to get

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[32] *Id.* at 16.

[33] See, for example, descriptions of tobacco control program best practices from the Centers for Disease Control and Prevention at https://www.cdc.gov/tobacco/stateandcommunity/best_practices/pdfs/2014/sectionA-III.pdf.

[34] McGuire, J. K., Walsh, M., & LeCroy, C. W. (2005). Content analyses of Title V abstinence-only education programs: Links between program topics and participant responses. *Sexuality Research & Social Policy*, *2*(4), 35.

[35] Dep't of Health & Human Servs., *supra* note 23, at 15.

[36] *Id.* at 14.

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them to return to an abstinent state. Under this meaning of "optimal health," there is no appropriate risk reduction approach for unmarried teens; rather, all premarital sex is unhealthy.

33. Importantly, the priorities required by the new FOA are also untested and are lacking in scientific basis. In my opinion, including these messages might shift programs away from being evidence-based. Even an applicant seeking to apply under this FOA to conduct an evidence-based program would need to graft this new and untested content onto the selected program. Further, the FOA requires this untested content to be inserted throughout the program by "weaving the goal of optimal health into *every component* of the project."[37] But once a program is changed with this new content, there cannot, by definition, be a replication. Likewise, adherence to these additional priorities from the FOA may actually interfere with the likelihood that a chosen or developed program will be effective. Without evaluation, the degree to which these "priorities" might change the programs and shift the outcomes is simply unknown.

34. In my opinion, by no longer requiring that Tier 1 programs be replications of programs that have previously been rigorously evaluated and found to work, the FOA has actually become a different effort altogether. The Tier 2 funding is designed to support new and innovative approaches to teen pregnancy prevention programs which do not have previous rigorous research demonstrating their effectiveness. By shifting to an approach that allows applicants to create or choose a program with no previous rigorous evidence of effectiveness, the Tier 1 program has essentially been discontinued in favor of a Tier 2 approach, something that does not adhere to the stated purposes of the program, and which discontinues an important effort to build on the evidence that has been developed in the field of teen pregnancy prevention.

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[37] *Id.* (emphasis added).

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

Executed July 27 2018 in Newark, New Jersey

Leslie M. Kantor, PhD, MPH

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