

Congress of the United States
Washington, DC 20515

Alex Azar, Secretary of Health and Human Services
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW
Washington, DC 20201

Diane Foley, Deputy Assistant Secretary for Population Affairs
Office of the Assistant Secretary for Health,
Office of Population Affairs
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW
Washington, DC 20201

Valerie Huber, Senior Policy Advisor,
Assistant Secretary for Health
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW
Washington, DC 20201

July 31, 2018

RE: HHS–OS–2018–0008, Proposed Rule for Compliance With Statutory Program Integrity Requirements

Dear Secretary Azar, Senior Advisor Huber, and Deputy Assistant Secretary Foley:

As members of the United States House of Representatives, we submit these comments in response to the Department of Health and Human Services' (the Department's) proposed rule entitled Compliance with Statutory Program Integrity Requirements, which was published in the Federal Register on June 1, 2018.¹ As elected members of Congress, our constituents choose to entrust us to have their best interests in mind when they send us to Washington to craft policies that strengthen our country and help them live better lives. That was the original intent behind the Title X Family Planning Program (Title X) when it was enacted as part of the Public Health Service Act over 40 years ago.

When Congress passed the Title X program, it was strongly supported by a bipartisan majority of the House, passing by a vote of 298 to 32, and passed unanimously in the Senate. Since its enactment, the program has given millions of low-income and otherwise underserved individuals access to comprehensive family planning and related preventative healthcare services, including access to contraception and cancer screenings. It remains the only federal grant program that provides these specific, confidential, medically accurate and evidence-based services for this population.

¹ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 (proposed Jun. 1, 2018) (to be codified at 42 C.F.R. pt. 59).

The proposed rule would significantly and detrimentally alter the Title X program, which has successfully provided vital sexual and reproductive health information and services to people across the country for more than 40 years. For this reason and many others, we support the continuation of this program in its current form, and do not support the changes contained within the proposed rule HHS-OS-2018-008 released on June 1, 2018 by your Administration and therefore urge you to reverse course and not finalize this rule.

Information Exchange Between Providers and Patients

The relationship between medical providers and their patients is based on mutual respect and honesty. The proposed Title X rule is, in effect, a ban on abortion counseling and abortion referrals for patients who use Title X-funded centers for their health care services. This rule asks providers to omit medically and legally permitted medical options from being shared with their patients. Omitting appropriate medical information from being communicated between patients and their providers erodes the trust between patients and providers, which does not bode well for patient health.

The presence of trust in the patient physician relationship is so critical that the executive leadership of the five largest professional societies, the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American College of Physicians, and the American College of Surgeons, who together represent the majority of U.S. physicians who practice in clinical settings, wrote together in the *New England Journal of Medicine* about the importance of this relationship.

According to the physicians, a critical component of the patient-physician relationship "...is respect for the importance of scientific evidence, patient autonomy, and the patient-physician relationship."² The providers were prompted to come together to write this article due to the frequency with which legislators were overstepping what the physicians felt was the "proper limits of their role in the health care of Americans" in order to "dictate the nature and content of patient's interactions with their physicians."³ They continued, noting that "examples of inappropriate legislative interference with this relationship are proliferating, as lawmakers increasingly intrude into the realm of medical practice, often to satisfy political agendas without regard to established, evidence-based guidelines for care."⁴ In other words, doctors were concerned with politics interfering with their ability to practice medicine and give the best possible care to their patients.

We strongly agree with the doctors' assessment, and believe that their words seem even more applicable today. The proposed rule does not just impact trust between patients and physicians, but all clinicians who practice at Title X funded clinics.

On the proposed rule, the American Nurses Association (ANA) wrote, "As the most 'honest and ethical' profession, nurses must guard against any erosive policy that hinders patients from making meaningful, informed decisions about their own health, or that blocks access to care."⁵

² Weinberger, S.E., Lawrence, H.C., Henley, D.E., Alden, E.R., & Hoyt, D.B. (2012). Legislative interference with the patient-physician relationship. *The New England Journal of Medicine*, 367, 1557-1559. doi:10.1056/NEJMs1209858

³ Ibid

⁴ Ibid

⁵ American Nurses Association. (2018, May 22). ANA condemns title X funding cuts proposed by the Trump administration. Retrieved from <https://www.nursingworld.org/news/news-releases/2018/ANA-condemns-title-x-funding-cuts--proposed-by-the-trump-administration/>

Furthermore the Title X proposal directly conflicts with clinical recommendations of many professional medical associations regarding the importance of informed consent in healthcare.⁶

The American Medical Association states in its Code of Medical Ethics that providers should “present relevant information accurately and sensitively, in keeping with the patient’s preferences”⁷ and that “withholding information without the patient’s knowledge or consent is ethically unacceptable.”⁸ In addition, the Code of Ethics for Nursing requires that patients are given “accurate, complete, and understandable information in a manner that facilitates an informed decision.” Make no mistake, this is why both the American Medical Association⁹ and the American Nurses Association,¹⁰ among others, released statements strongly condemning the proposed Title X rule.

In their statement on the Title X proposed rule, the ANA went on to cite the Code of Ethics for Nurses, “The Code of Ethics for Nurses outlines that the nurse’s primary commitment is to the patient, whether an individual, family, group, community, or population. This proposed rule interferes with that relationship and violates basic ethics of the profession.”¹¹ The proposed Title X rule would not just interfere with the provider-patient relationship, but it in fact goes out of its way to prevent patients from receiving the complete, fact-based information that they need in order to make informed decisions about their healthcare. What’s worse, these actions were taken solely to advance partisan political agendas with a blatant disregard for the practice of medicine.

It seems difficult, if not impossible for Title X providers to ensure that all patients receive comprehensive, factual information on all pregnancy options under this rule. As such, Congress is concerned that this proposed rule inappropriately directs and stigmatizes family planning services over other health care services (for example, cancer treatment). This stigmatization is not driven by concern for patient health, but by political agenda. Therefore, we ask the Department of Health and Human Services the following questions:

1. Would this type of directive to withhold specific information be given to providers treating cancer or chronic conditions like diabetes?
2. Please explain why the Department made the decision to force providers to provide patients asking for abortion services a list of providers who may not provide the service they asked for?
3. In what other instances would the Department attempt to propose a rule requiring providers to provide patients with a list of providers who do not provide the specific type of care requested by the patient?

⁶ Hasstedt, K. (2018, January 10). *Unbiased information on and referral for all pregnancy options are essential to informed consent in reproductive health care*. Retrieved from <https://www.gutmacher.org/gpr/2018/01/unbiased-information-and-referral-all-pregnancy-options-are-essential-informed-consent>

⁷ American Medical Association. (n.d.). *Informed consent*. Retrieved from <https://www.ama-assn.org/delivering-care/informed-consent>

⁸ American Medical Association. (n.d.). *Withholding information from patients*. Retrieved from <https://www.ama-assn.org/delivering-care/withholding-information-patients>

⁹ Barbe, D.O. (2018, May 23). *AMA response to administration’s attack on family planning services* [Press Release]. Retrieved from <https://www.ama-assn.org/ama-response-administrations-attack-family-planning-services>

¹⁰ American Nurses Association. (2018, May 22). *ANA condemns title X funding cuts proposed by Trump administration* [Press Release]. Retrieved from <https://www.nursingworld.org/news/news-releases/2018/ANA-condemns-title-x-funding-cuts--proposed-by-the-trump-administration/>

¹¹ Ibid

4. Why did the Department decide to allow providers to provide a list of abortion providers (and non-abortion providers) only if specifically asked for by the patient after that patient has stated her decision to have an abortion?
5. Would this practice of providing a list of providers who do and do not offer a requested service be acceptable under medical ethics for patients asking for other services?
6. Under this new rule, how does the Department intend to ensure that providers are giving their patients accurate, medically-appropriate information on reproductive health decisions?
7. How does the Department intend to ensure that patients are given medically-appropriate treatment and counseling on family planning options when it is at the same time requiring providers to omit a medically appropriate treatment all-together?

Targeting Certain Providers and Activities

From the reading of the proposed rule, it is clear that the Department seeks to change Title X requirements in order to make it virtually impossible for some reproductive health providers, including but not limited to Planned Parenthood, to continue to receive Title X funds. Besides requiring separate accounting records, the proposed rule directs HHS to assess program grant applicants for separate office entrances; separate treatment, consultation, examination, and waiting rooms; separate personnel and personnel workstations; and separate medical records systems, among numerous other criteria, that would impose massive expense and redundancy on health care providers.

The economic analysis of this proposed rule suggests that it would cost between \$10,000 and \$30,000 in order to comply with these physical requirements. This cost analysis does not reflect what would be expected in order for clinics to create separate facilities, which would be required to comply with the proposed rule separation requirements. It is very likely that these costs would cause clinics to close or reduce services, resulting in reduced access to health care.

The proposed regulation also includes an extensive prohibition on more than a dozen activities that the Administration considers “related to abortion.” The proposed rule list includes such actions as creating a “favorable attitude” toward abortion, an undefined term that could severely limit providers or health centers to which a patient could be referred. These prohibitions are certain to create confusion among providers and patients and will limit the accessibility of health care services. The lack of clarity within the proposed rule may also lead qualified providers to avoid permissible or medically advisable activities for fear of being found in violation of the law.

Expert providers of family planning services are concerned about how they will comply with these overly broad restrictions in the proposed rule. Consequently, health centers may be forced to forego federal funding rather than risk incidentally running afoul of these proposed standards. This onerous proposed rule design seems to reveal the true purpose of the new regulatory scheme: to discourage specialized reproductive health centers from participating in the program altogether.

By discriminating against clinics unless they agree to unacceptable intrusions on the patient-provider relationship, the proposed rule could force health centers to stop participating in the Title X program or to shut down entirely, both of which would severely limit access to reproductive health care. This is completely contradictory to Congressional intent for the Title X program, which is clear from the statutory and original legislative language that created the Title X program. Further, the closure or limiting of access to reproductive healthcare services at Title X funded

centers would disproportionately impact minorities and low-income women, the very patients who depend on these centers for their healthcare.

In the newly designed proposed rule, a 'four factors' test reverses the Department's longstanding interpretation that, "[i]f a Title X grantee can demonstrate [separation] by its financial records, counseling and service protocols, administrative procedures, and other means . . . , then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for 'physical' separation."¹² A Department notice further explained that Title X service sites could use common waiting rooms, staff, and filing systems for abortion-related activities and Title X project activities.¹³ The proposed additional physical separation of these services are both arduous and demonstratively unnecessary.

It is also important to note that most Title X family planning projects have successfully separated abortion and other family planning activities while operating under the same roof/structure for years without inappropriate commingling of funds, or services. In the rare instances in which commingling of funds was identified, the current system was able to detect and resolve these situations. Therefore, the Department has no valid reason for making such radical, draconian and completely unnecessary changes.

Specifically, on proposed rule separation requirements and repercussions on implementing these new separation requirements, we wish to ask the Department:

1. How does the Department intend to ensure that women who ask for an abortion are given access to clinics that perform the service, especially when travelling to these clinics imposes an undue travel burden on women?
2. Has the Department evaluated how many clinics will likely close or reduce their offered services as a result of these new requirements?
3. Has the Department evaluated the public health impacts of such clinic closures and reduced offerings?
4. Has the Department conducted case studies on the public health consequences of blocking entities like Planned Parenthood from receiving Title X family planning funding?

Limiting Methods of Family Planning

When the Title X family planning program was created, Congress was clear that the program's purpose was "making comprehensive voluntary family planning services readily available to all persons desiring such services."¹⁴ Members of Congress are concerned that the proposed rule undermines patients' contraceptive choice regarding when, where, and what they receive for planning services and methods. The proposed rule eliminates the longstanding requirement that Title X programs provide "medically approved" family planning methods, potentially allowing purveyors of untested, unproven family planning methods or coercive family planning counseling to be eligible for Title X funds.¹⁵

¹² Standards of Compliance for Abortion Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270, 41,276 (Jul. 3, 2000).

¹³ Provision of Abortion-Related Services in Family Planning Projects, 65 Fed. Reg. 41,281, 41,282 (Jul. 3, 2000).

¹⁴ S. Rep. No. 91-1004, pt. 2 at 1504 (1970).

¹⁵ *Compliance with Title X requirements by project recipients in selecting subrecipients*, 81 Fed. Reg. 91852 (December 19, 2016) (to be codified 42 CFR 59). 36 Federal Register

Under current rules, Title X projects must, by statute and regulation, offer a broad range of acceptable and effective family planning methods and services.¹⁶ Further still, the proposed rule removes standing requirements that necessitate that offered family planning methods available to patients at Title X-funded projects be ‘medically approved.’¹⁷ Access to “the full range of FDA-approved contraceptive methods” has also been deemed an essential feature of quality family planning services by the U.S. Office of Population Affairs, which administers Title X, and the Centers for Disease Control and Prevention in its authoritative clinical guidelines for quality care.¹⁸

The proposed rule would also weaken language in current law ensuring that local Title X projects offer access to a broad range of family planning methods. Therefore, this proposed rule would allow Title X projects to purposefully exclude certain family planning methods. In combination, these provisions could permit a non-medical crisis pregnancy center, which promotes a decidedly anti-contraception agenda and employs no trained health care providers, to nonetheless qualify for Title X funds.

The proposed rule reduces the medical standards of information and services required to be provided to patients at Title X funded projects. In effect, the proposed rule would result in some Title X patients receiving substandard and incomplete care based on the location of their Title X provider. In limiting where services can be obtained, what information may be received, and from whom patients receive family planning information, Members of Congress are also concerned that the rule also creates the potential for reproductive coercion.

With these concerns regarding the proposed rule’s limitation of family planning method in mind, we wish to ask the Department the following:

1. Has the Department studied the public health consequences of limiting women’s ability to choose and use the methods of contraception that work best for them?
2. Has the Department studied how implementing policies that limit reproductive choice impact risks and rates of unintended pregnancies?
3. How does the Department intend to avoid and address negative public health consequences, like increased rates of unintended pregnancy, with the changes to the proposed rule?
4. Why does the Department believe that the weakening of medical standards does not violate original Title X Congressional intent and statute?
5. Why does the Department believe that the reduction of information exchanged between patients and providers does not violate original Title X Congressional intent and statute?
6. Why does the Department believe that decreasing womens’ choice of reproductive methods does not violate original Title X Congressional intent and statute?
7. Why would the Department allow a tax-dollar funded program to offer less-effective or non-medically approved family planning methods?
8. Why does the Department think that non-medically approved family planning methods should be acceptable treatments for patients?

¹⁶ 42 U.S.C. § 300(a); 42 C.F.R. § 59.5(a)(1). While the entire project is held to the “broad range” standard under the current rules, each participating entity is not. So “[i]f an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.”

¹⁷ Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 (proposed Jun. 1, 2018) (to be codified at 42 C.F.R. pt. 59).

¹⁸ Centers for Disease Control and Prevention. (2014). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. Retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm>

9. How does the Department intend to deal with issues or negative outcomes arising from the prescription of non-medically approved family planning methods or coercive family planning counseling?
10. What types of non-medically approved family planning methods does the Department intend to allow Title X projects to provide patients under this proposed rule?
11. Has the Department evaluated how often non-medically approved family planning methods lead to unintended pregnancies?
12. Has the Department evaluated the economic and health impact of allowing Title X providers to only offer non-medically approved and less effective family planning methods to communities?

Worsening Health Disparities

The Title X program is intended to provide affordable, high-quality family planning services to low-income individuals, adolescents, communities of color, and other marginalized communities.

This proposed rule would worsen health disparities by imposing substandard care on those who rely on publicly funded services and providers and by jeopardizing Title X patients' access to vital family planning and basic healthcare. Further, Title X patients are more likely to be low-income, young and otherwise underserved¹⁹. These populations already face multiple barriers to accessing affordable care. The proposed rule will further exacerbate existing health disparities and barriers to care. It would effectively deny low-income and underserved populations access to the best possible care – including experienced providers and all methods of contraception.

The proposed rule would undermine Congressional intent for the Title X program. According to a recent *New England Journal of Medicine* article on the proposed Title X rule, “These proposed regulations go farther by restricting providers’ ability to deliver sound patient care and essentially dismantling the well-established, well-functioning Title X care system, disregarding local community care systems and policy preferences.”²⁰ Of the proposed rule, the *New England Journal of Medicine* article concludes that, “the consequent changes in the Title X system are likely to increase unintended-pregnancy rates in the most vulnerable segments of the population and are thus more likely to increase than to reduce the incidence of abortions.”²¹

In addition, the strong confidentiality protections in the current Title X regulations and in the underlying statute are vital to ensuring that adolescents and young adults seek the health care they need. The proposed rule would require rather than encourage family involvement unless providers can meet a strict documentation requirement. This new requirement which may not be appropriate for all patients, and would undermine the provider-patient relationship, could cause adolescents to avoid seeking health care at all.²²

With these public health and underserved population concerns in mind, we would like to ask the Department the following questions:

¹⁹ RTI International. (2017). Family planning annual report: 2016 national summary. Retrieved from <https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf>

²⁰ Bronstein, J.M. (2018). Radical changes for reproductive health care—Proposed regulations for title X. *New England Journal of Medicine*, 1-3. doi:10.1056/NEJMp1807125

²¹ Ibid

²² English, A., & Ford, C.A. (2004). The HIPPA privacy rule and adolescents: Legal questions and clinical challenges. *Perspectives on Sexual And Reproductive Health*, 36(2), 80-86. doi: <https://doi.org/10.1363/3608004>

1. Has the Department examined how the proposed rule will negatively impact public health outcomes in underserved populations?
2. How does the Department intend to mitigate further harm to communities most in need and low-income populations caused by the proposed rule?
3. How does the Department intend to ensure that communities do not experience service disruption both during and after the transition period from the current rule to the proposed rule, and under the provisions of the proposed rule?
4. How does the Department intend to ensure that linguistically appropriate and culturally sensitive services are provided at future Title X-funded sites that do not have familiarity with the communities they propose to serve under the new rule?
5. Has the Department evaluated the repercussions of requiring more family involvement in family planning as contained in the proposed rule?
6. Has the Department examined how strict reporting requirements included in the proposed rule, especially those pertaining to minors, could negatively impact underserved populations?

The proposed rule would gravely harm the people that we were elected to serve and would exacerbate existing public health issues and health disparities. Further, the proposed rule completely ignores the goal and intent of Congress in establishing a nationwide family planning program. While we look forward to your answers to our questions, we strongly urge you to withdraw the proposed rule as it will cause unmitigated harm to many of our constituents.

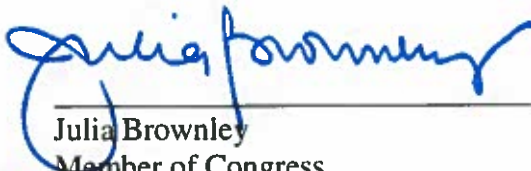
Sincerely,



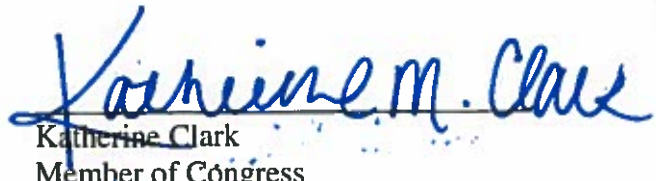
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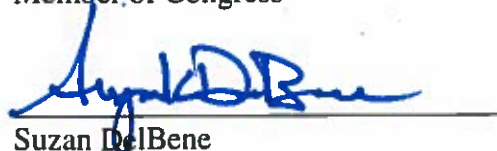
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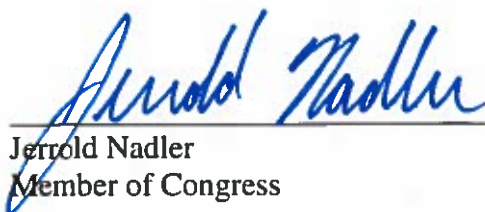
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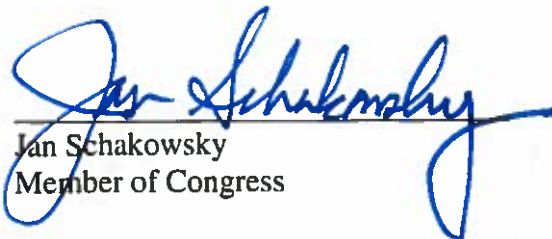
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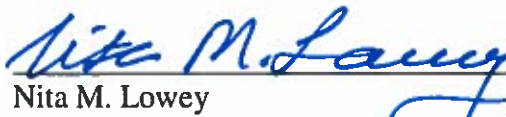


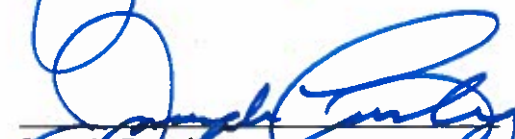
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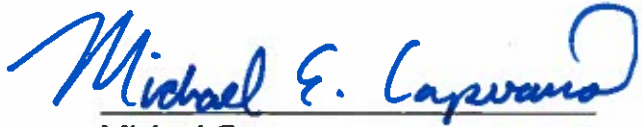

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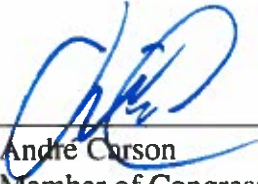
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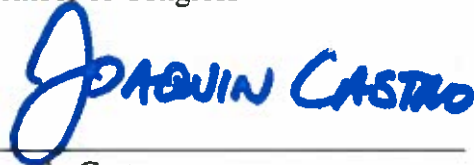
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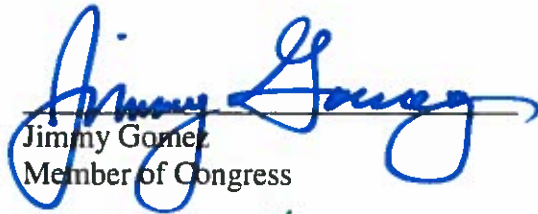
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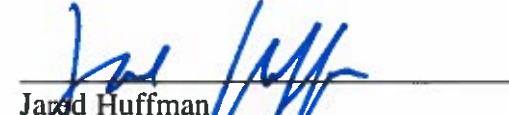
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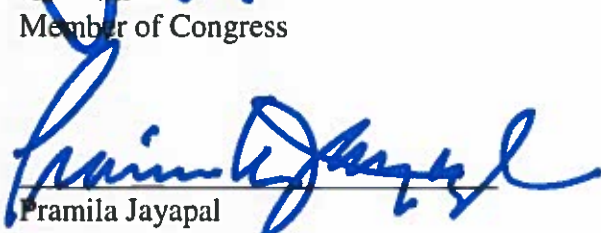
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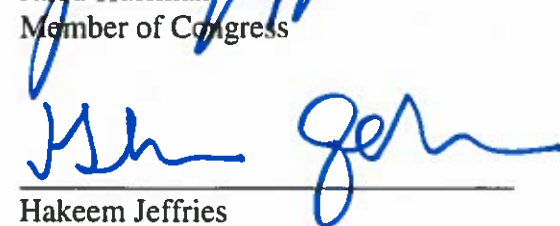
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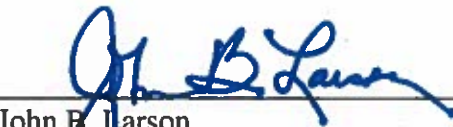
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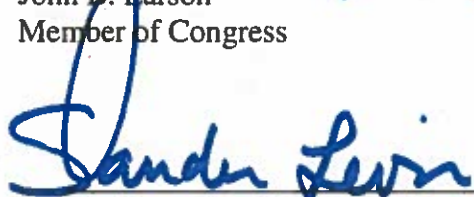
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Brenda L. Lawrence
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Sander M. Levin
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Ted W. Lieu
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Sean Patrick Maloney
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Doris Matsui
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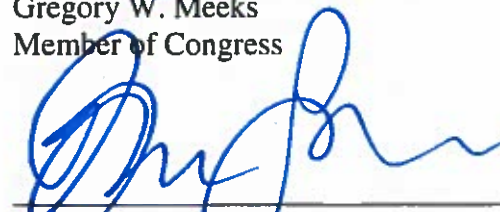

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Jerry McNerney
Member of Congress

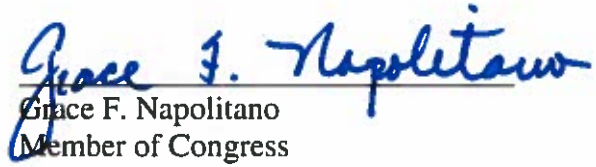

Gregory W. Meeks
Member of Congress


Grace Meng
Member of Congress


Gwen Moore
Member of Congress



Seth Moulton
Member of Congress



Grace F. Napolitano
Member of Congress



Richard M. Nolan
Member of Congress



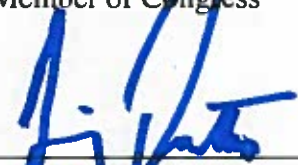
Donald Norcross
Member of Congress



Eleanor Holmes Norton
Member of Congress



Tom O'Halleran
Member of Congress



Jimmy Panetta
Member of Congress



Donald M. Payne, Jr.
Member of Congress



Ed Perlmutter
Member of Congress



Scott H. Peters
Member of Congress



Chellie Pingree
Member of Congress



Mark Pocan
Member of Congress



Jared Polis
Member of Congress



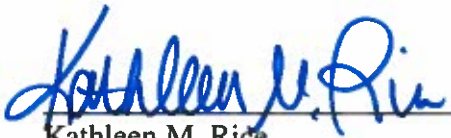
David E. Price
Member of Congress



Mike Quigley
Member of Congress



Jamie Raskin
Member of Congress



Kathleen M. Rice
Member of Congress



Cedric L. Richmond
Member of Congress



Jacky Rosen
Member of Congress



Lucille Roybal-Allard
Member of Congress



Raul Ruiz
Member of Congress



C.A. Dutch Ruppberger
Member of Congress



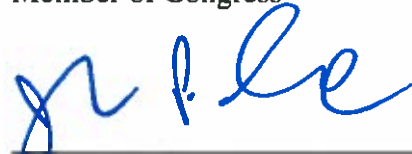
Bobby L. Rush
Member of Congress



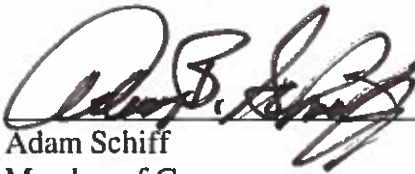
Tim Ryan
Member of Congress




Linda T. Sánchez
Member of Congress



John Sarbanes
Member of Congress



Adam Schiff
Member of Congress



Bradley S. Schneider
Member of Congress



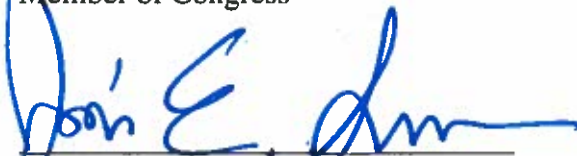
Kurt Schrader
Member of Congress



David Scott
Member of Congress



Robert C. Scott
Member of Congress



José E. Serrano
Member of Congress

Carol Shea-Porter

Carol Shea-Porter
Member of Congress

Brad Sherman

Brad Sherman
Member of Congress

Krysten Sinema

Krysten Sinema
Member of Congress

Albio Sires

Albio Sires
Member of Congress

Adam Smith

Adam Smith
Member of Congress

Darren Soto

Darren Soto
Member of Congress

Thomas R. Suozzi

Thomas R. Suozzi
Member of Congress

Eric Swalwell

Eric Swalwell
Member of Congress

Mark Takano

Mark Takano
Member of Congress

Mike Thompson

Mike Thompson
Member of Congress

Bennie Thompson

Bennie Thompson
Member of Congress

Dina Titus

Dina Titus
Member of Congress

Paul D. Tonko

Paul Tonko
Member of Congress

Niki Tsongas

Niki Tsongas
Member of Congress

Juan Vargas

Juan Vargas
Member of Congress

Marc A. Veasy

Marc A. Veasy
Member of Congress




Nydia Velazquez
Member of Congress



Pete Visclosky
Member of Congress



Timothy Walz
Member of Congress



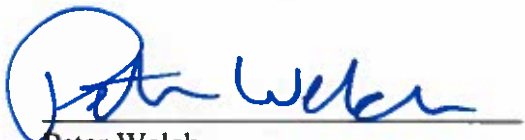
Debbie Wasserman Schultz
Member of Congress



Maxine Waters
Member of Congress



Bonnie Watson Coleman
Member of Congress



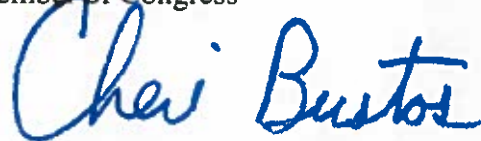
Peter Welch
Member of Congress



Frederica S. Wilson
Member of Congress



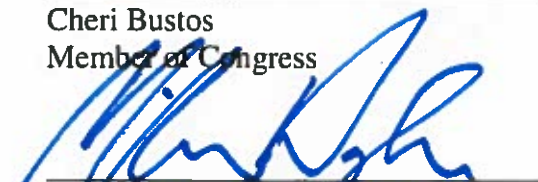
John Yarmuth
Member of Congress



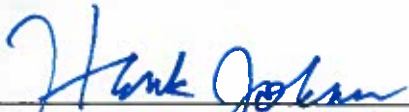
Cheri Bustos
Member of Congress



Michelle Lujan Grisham
Member of Congress



Mike Doyle
Member of Congress



Henry C. "Hank" Johnson
Member of Congress



Donald Norcross
Member of Congress



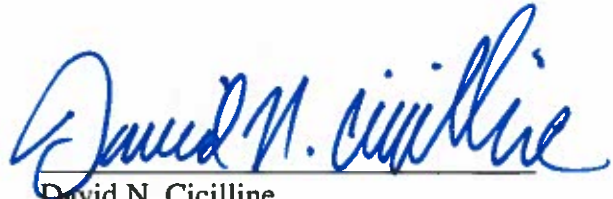
Charlie Crist
Member of Congress



Josh Gottheimer
Member of Congress



Beto O'Rourke
Member of Congress



David N. Cicilline
Member of Congress



Sheila Jackson Lee
Member of Congress



Val Butler Demings
Member of Congress



Jim Costa
Member of Congress