

September 17, 2015

Victoria Wachino  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Ms. Wachino,

The undersigned organizations are writing about an important provision in the final regulation on Medicaid Covered Outpatient Drugs (CMS-2345-F) currently under review at the Office of Management and Budget (OMB). We ask that the final regulation implementing Section 1927(c)(1)(D)(i)(IV) of the Social Security Act (42 C.F.R. § 447.508(a)), explicitly state that all non-profit family planning service sites that do not receive 340B qualifying funds,<sup>1</sup> may receive nominally priced drugs without it impacting a pharmaceutical manufacturer's best price and Medicaid rebate calculations. This clarification is needed to assuage manufacturer's concerns and effectuate the intent of the statutory provision – to reinstate access to deeply discounted contraceptives for all family planning clinics.

Section 1927(c)(1)(D)(i)(IV), which became law as part of the Omnibus Appropriations Act of 2009, was designed to correct an unintentional flaw in the Deficit Reduction Act of 2005 (DRA) that immediately cut off many family planning clinics from being able to receive deeply discounted (also called nominally-priced) contraceptives, which they had been able to do for decades prior to the DRA. This flaw in the DRA caused dramatic price increases for contraceptives, making some branded oral contraceptives and long-acting reversible contraceptives (LARCs) – the most effective forms of birth control – unaffordable for many family planning providers and their patients.

Despite congressional history clearly articulating that the provision was intended to capture all nonprofit family planning clinics regardless of their participation in 340B,<sup>2</sup> manufacturers remain reluctant to offer

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<sup>1</sup> In final regulations and guidance implementing the essential community provider (ECP) provision in section 1311(c)(1)(C) of the Affordable Care Act, the U.S. Department of Health and Human Services (HHS) made clear that essential community providers include 340B providers and providers described in section 1927(c)(1)(D)(i)(IV), including "a State-owned family planning service site, or governmental family planning service site, or not-for-profit family planning service site that does not receive Federal funding under special programs [relevant to the 340B program], including under Title X of the PHS Act" 45 CFR 156.235(c); see *Final Rule on Benefit and Payment Parameters*, Centers for Medicare and Medicaid Services, 80 Fed. Reg. 10750, at 10833 and 10835 (Feb. 27, 2015). It is critical that CMS re-assert this interpretation that 1927(c)(1)(D)(i)(IV) includes non-profit family planning service sites that do not receive relevant funding under 340B of the PHS Act for the purposes of a manufacturer's ability to offer these providers nominally-priced drugs in the final Medicaid Covered Outpatient Drug Rule.

<sup>2</sup> Senate Finance Committee Chairman Baucus and Senator Stabenow made clear that providers in section 1927(c)(1)(D)(i)(IV) of the Social Security Act are specifically intended to include "family planning clinics such as Planned Parenthood" that do not receive Title X funds and do not participate in the 340B program. S2817, Congressional Record, March 5, 2009. Chairman Baucus and Senator Stabenow also clarified that "[w]ith



nominal pricing to non-340B family planning providers without a clear indication from the Centers for Medicare and Medicaid Services (CMS) that doing so will not increase a manufacturer's best price and Medicaid rebate liability.

To ensure that the final regulation implementing Section 1927(c)(1)(D)(i)(IV), the nominal price provision of the SSA, carries out the intent of that law, and that patients are better able to access affordable contraceptives including LARCs, we urge CMS to explicitly state in regulation that all non-profit family planning service sites that do not receive 340B-qualifying funds are included Section 1927(c)(1)(D)(i)(IV). We thank you for your consideration.

Sincerely,

Guttmacher Institute  
National Family Planning & Reproductive Health Association  
National Women's Law Center  
Planned Parenthood Federation of America

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enactment of this critical legislation...manufacturers should feel confident that they can extend discounts to family planning clinics such as Planned Parenthood and college and university clinics...." *Id.*





Mr. INOUE. I, too, will work with the Senator to clarify this provision.

Mr. CRAPO. Mr. President, I appreciate the fact that there is consensus that section 626 goes too far and that it is not the intention of the chairman of the Banking Committee and the chairman of the Appropriations Committee to provide the Federal Trade Commission authority in its rulemaking over mortgage loans overseen by the Federal banking and credit union regulators. However, if the intention is merely to expedite the FTC rulemaking process over nonbanks then the language should be clear on that account. Unfortunately, that is not the case.

It is important to remember that once this legislation is signed into law, the FTC is directed to initiate rulemaking within 90 days. Rather than agreeing to clarify this issue at a later point, it is my strong preference that the Senate would have deleted this section and agreed to working out compromise language at a later point. That is what my amendment would have accomplished by striking the section.

Per the colloquy of Senators DODD, INOUE, and DORGAN, I will follow up with the FTC that it is the clear intent of the Senate that the provision does not expand the FTC's regulatory jurisdiction and that the required FTC rulemaking will not attempt to include insured depository institutions. I will also note that there is a bi-partisan agreement that the Senate will shortly take up legislation to clarify the scope of the legislation to that effect. Additionally, in light of the focus by the Federal Reserve Board on mortgage lending, the FTC should be required to consult with the Federal Reserve Board in developing their rule. I would encourage my colleagues to send similar letters to the FTC.

If the initial FTC proposed rule attempts to go beyond this scope, it is my understanding that there is agreement that the Senate would immediately take up legislation and stop that from occurring. It would be a terrible mistake to add another patchwork of conflicting authorities and interpretations of Federal laws for insured depository institutions as it relates to home loans and other types of consumer finance transactions. This type of regulatory uncertainty and complexity will only further complicate the resurrection of our mortgage market, harming consumers who are having a difficult enough time obtaining appropriate mortgage loans.

I intend to closely monitor how the FTC proceeds and work with my colleagues to craft a narrow legislative clarification. If we cannot shortly come to agreement on this front, then I will push for a vote to eliminate this authority in the next appropriate vehicle before the Senate.

With that clarification and explanation, the FTC rulemaking that will be able to proceed under this legislation will not seek to extend to the FDIC depository institutions and credit union regulated institutions, then

I—and our agreement that we would on an expeditious basis statutorily seek to correct that and make that clear in the CONGRESSIONAL RECORD, I ask unanimous consent that the amendment be withdrawn.

The PRESIDING OFFICER. Without objection, the amendment is withdrawn.

#### RESTORING NOMINAL DRUG PRICES

Ms. STABENOW. I would like to engage in a colloquy with the chairman of the Committee on Finance, Senator MAX BAUCUS. Senator BAUCUS, I am very pleased to see that the fiscal year 2009 Omnibus appropriations bill corrects an unintended consequence of a provision in the Deficit Reduction Act of 2005, DRA. Section 6001(d) of the DRA, which is Public Law 109-171, caused family planning clinics that do not receive Federal funding and university-based clinics to sustain increases in the price of oral contraceptives as much as tenfold over the past 2 years. This is because drug manufacturers stopped offering discounts to these clinics in response to changes to the Medicaid drug rebate program made by the DRA. While discounts remained perfectly legal, drug companies were concerned about the impact of their Medicaid rebate liability for the continued offering of discounts to certain family planning and college- or university-based clinics. The price increases have put a terrible strain on our country's first line of defense against unintended pregnancies. We have the highest unintended pregnancy rate of any advanced industrial country.

With enactment of this critical legislation, these clinics will once again have access to nominally priced drugs, should private sector manufacturers choose to provide these discounts. This access should begin immediately upon enactment, and manufacturers should feel confident that they can extend discounts to family planning clinics such as Planned Parenthood and college and university clinics without it affecting the rebates they must provide under Federal law to State Medicaid programs.

Mr. BAUCUS. I thank the Senator. I share the Senator's views on this matter. It has taken too long to correct what all parties agree was an unintended outcome of the DRA. I had asked the previous administration to use the discretion provided in the DRA to designate additional health providers as entities to whom the sale of nominally priced drugs is appropriate. The Bush administration chose not to make these designations when it promulgated final regulations on July 17, 2007, and so Congress is acting now to correct this error. The Senate included this provision in last year's Iraq supplemental appropriations bill, but the administration objected to its inclusion so it did not become law.

It is my understanding that, once this provision is enacted into law, drug manufacturers will immediately be able to restore the nominal drug prices they provided to these types of clinics—family planning clinics and college

and university health centers—for decades.

This provision simply restores the original policy in place since the enactment of the Medicaid rebate program in the Omnibus Reconciliation Act of 1990. Then, as now, no administrative action is necessary for manufacturers to commence offering deep discounts to the entities described in this provision.

Ms. STABENOW. I thank the Senator. I hope that the manufacturers will do this and that women will have access to affordable birth control and other critical health services.

#### TRANSPORTATION FUNDING

Mr. KOHL. Mr. President, I wish today to engage in a colloquy with my colleague, the Senator from Washington and the chairman of the Transportation Appropriations Subcommittee. As the chairman is aware, language was included in the explanatory statement accompanying the bill before us to help address an issue that has plagued the Milwaukee area for several years.

Due to a longstanding dispute between city and county officials, unobligated transportation dollars have lost value with each passing year. In an effort to spend down those funds on much needed transit projects, the report resolves this dispute by dividing the funding. I have spoken with Congressman OBEY, the chairman of the House Appropriations Committee, to confirm the intent of the language included in the explanatory statement. I would ask the Senator from Washington, is it your understanding that it is the expectation of both the House and Senate committees that 60 percent of the funding in question should be made available to the city of Milwaukee for a downtown fixed-rail corridor while 40 percent of the funding should be made available to the county of Milwaukee for energy efficient buses?

Mrs. MURRAY. To the Senator from Wisconsin I would say, yes, that is our expectation.

Mr. KOHL. I thank the chairman of the Transportation Appropriations Subcommittee for her help and for engaging in this colloquy.

Mrs. MURRAY. Mr. President, as chairman of the Appropriations Subcommittee on Transportation, Housing and Urban Development, and Related Agencies, I rise to clarify an error that we have found in the explanatory materials accompanying H.R. 1105, the Omnibus Appropriations Act. Included within the Transportation-Housing Division of the bill is an appropriation of \$570,000 within the TCSP program for transportation improvement in the Antelope Valley in Lincoln, NE. The attribution table that accompanies the explanatory statement to the bill inadvertently omits the name of the Senate sponsor of that appropriation. Mr. President, the Senate sponsor of the project is my colleague, Senator BEN NELSON.





# United States Senate

WASHINGTON, DC 20510

August 10, 2012

Marilyn Tavenner  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Acting Administrator Tavenner:

We are writing to comment on an important provision that will help promote women's access to family planning services contained in the regulation your agency proposed related to Medicaid's coverage of outpatient drugs (CMS-2345-P). We appreciate your efforts to expand access to affordable basic healthcare for women, and we hope that the final regulation can clarify that all family planning clinics and women's health centers are able to purchase contraceptives at discounted prices.

A flaw in the Deficit Reduction Act of 2005 resulted in fewer family planning clinics, and other women's health centers, receiving discounted contraceptives than Congress intended. The flaw allowed only certain entities to receive discounted prices on contraceptives without triggering "best price" concerns for drug manufacturers under section 1927(c)(1)(C) of the Social Security Act (Act). In order to resolve the flaw and any ambiguity in the proposed rule, we ask that the final regulation make clear that section 1927(c)(1)(D)(i)(IV) of the Act, which is referenced in the proposed regulation, includes family planning clinics and other women's health centers as entities to which sales may be classified as "nominal," and, therefore, excluded from drug manufacturers' best price calculations.

Section 1927(c)(1)(D)(i)(IV) is based on the bipartisan "Prevention Through Affordable Access Act," which was introduced by then-Senator Obama on November 13, 2007, and was intended to correct the flaw in the Deficit Reduction Act. Ultimately, the provision became law as part of the Omnibus Appropriations Act of 2009 on March 11, 2009.

Congress clearly intended section 1927(c)(1)(D)(i)(IV) to allow *all* family planning clinics to purchase discounted contraceptives. During a unanimous consent request to pass the Prevention Through Affordable Access Act on December 19, 2007, Senator Stabenow noted that the bill was meant "to ensure that family planning services and birth control pricing are restored." Furthermore, a colloquy between Senate Finance Committee Chairman Baucus and Senator Stabenow on March 5, 2009, clarified that the legislation was intended to include family planning clinics that do not participate in the 340B program among the women's health centers allowed to purchase discounted contraceptives. That colloquy said "[t]his access should begin immediately upon enactment, and manufacturers should feel confident that they can extend discounts to family planning clinics such as Planned Parenthood."

To ensure that the implementing regulation carries out the intent of the law, and that patients are better able to access affordable contraceptives, your agency should be explicit that section 1927(c)(1)(D)(i)(IV) includes all non-340B family planning clinics and other women's health





centers in its final rulemaking. This will ensure their eligibility to purchase contraceptives at discounted prices.

We appreciate the opportunity to comment. We look forward to working with you to improve the health of our nation and to ensure that all women have access to recommended preventive services.

Sincerely,

Debbie Stabenow My Barnes

Tom Harkin Barack Obama

Richard Blumenthal Jennifer Levinson

Charles Schumer Janet Shalens

Jon Tester Al Franken

John F. Kerry Jeffrey A. Merkley

Mark Warner Kirsten E. Gillibrand

Maria Cantwell



**Congress of the United States**  
**Washington, DC 20515**

August 10, 2012

The Honorable Marilyn Tavenner  
Centers for Medicare and Medicaid Services  
PO Box 8016  
Baltimore, MD 21244-8016

Dear Acting Administrator Tavenner,

Thank you for this opportunity to comment on the proposed regulation on Medicaid's coverage of outpatient drugs (CMS-2345-P). We are concerned with a critical provision that will affect access to family planning services and ask that the final regulation make explicitly clear that Section 1927(c)(1)(D)(i)(IV) of the Social Security Act includes family planning clinics, as well as university and college health centers and other women's health centers.

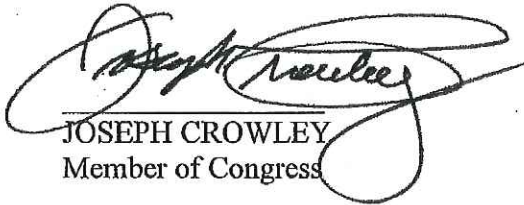
Section 1927(c)(1)(D)(i)(IV) is based on the bipartisan *Prevention Through Affordable Access Act*, led by Representative Joseph Crowley and supported by a bipartisan coalition. The Act's purpose was to correct a flaw in the *2005 Deficit Reduction Act*, which unintentionally prevented many family planning clinics and other women's health centers from being able to access discounted contraceptives. Ultimately, this language became law as part of the 2009 omnibus appropriations bill (Public Law 111-8).

The intent of Congress was very clear: this provision was supposed to create a way to capture *all* family planning clinics, especially those family planning clinics that do not qualify for the 340B Drug Pricing Program. The congressional debate and the legislative correspondence surrounding the *Prevention Through Affordable Access Act* clearly demonstrate the goals of this legislation that is now in law.

During the 110<sup>th</sup> Congress, a bipartisan coalition of Representatives contacted House leadership on three separate occasions urging the passage of the *Prevention Through Affordable Access Act* specifically with the goal of protecting family planning providers. Additionally, during a floor debate in the Senate on December 19, 2007, one of the main bill sponsors noted during the floor debate that the bill was explicitly intended "to ensure that family planning services and birth control pricing are restored." Lastly, as the 2009 omnibus was being considered on the Senate floor, Senate Finance Chairman Baucus and Senator Stabenow engaged in a colloquy where they identified family planning clinics that do not participate in the 340B pharmacy program as the intended beneficiary of this legislative fix: "This access should begin immediately upon enactment, and manufacturers should feel confident that they can extend discounts to family planning clinics such as Planned Parenthood."

Thank you again for the opportunity to comment on access to family planning. Again, we ask that you explicitly state in final rulemaking that section 1927(c)(1)(D)(i)(IV) includes all non-340B family planning clinics and other women's health centers, so that they are eligible for discounted drug pricing. As always, we look forward to working with you on improving the health of our nation and ensuring that all women have access to recommended preventive health services.

Sincerely,




JOSEPH CROWLEY  
Member of Congress



CHARLES W. DENT  
Member of Congress




LOUISE MCINTOSH SLAUGHTER  
Member of Congress



HOWARD L. BERMAN  
Member of Congress



JOHN CONYERS, JR.  
Member of Congress



SANDER M. LEVIN  
Member of Congress



STEVE ISRAEL  
Member of Congress



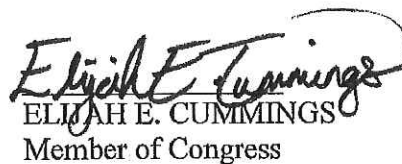
GEORGE MILLER  
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CHRIS VAN HOLLEN  
Member of Congress

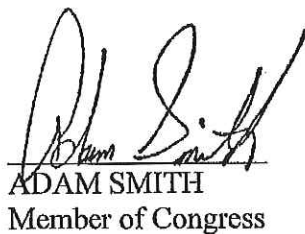
  
BARNEY FRANK  
Member of Congress

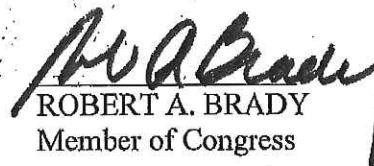
  
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ELIJAH E. CUMMINGS  
Member of Congress

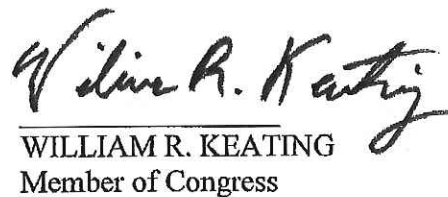
  
LINDA T. SANCHEZ  
Member of Congress

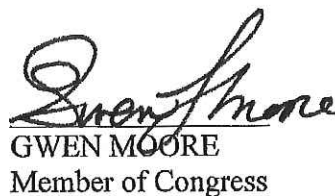
  
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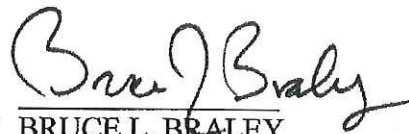
EARL BLUMENAUER  
Member of Congress



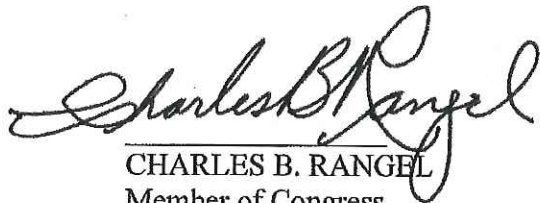
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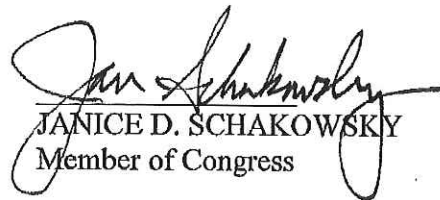
TIM RYAN  
Member of Congress



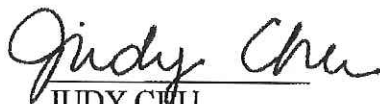
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JUDY CHU  
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MICHAEL E. CAPUANO  
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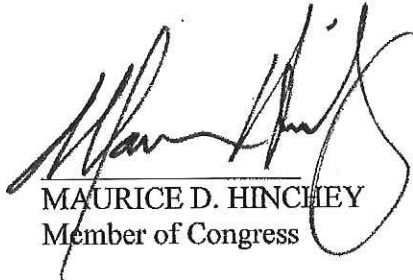
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LUCILLE ROYBAL-ALLARD  
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MAURICE D. HINCHEY  
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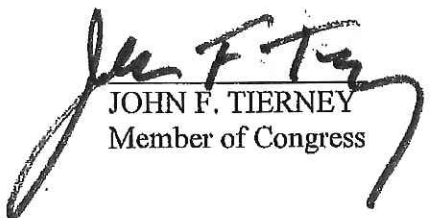
  
BARBARA LEE  
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TAMMY BALDWIN  
Member of Congress

  
JACKIE SPEIER  
Member of Congress

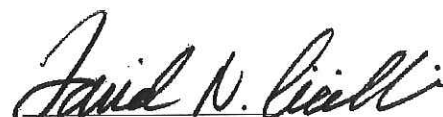
  
RUSH D. HOLT  
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STEVE COHEN  
Member of Congress

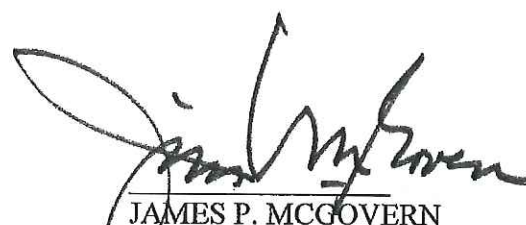
  
JOHN F. TIERNEY  
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ALCEE L. HASTINGS  
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DAVID N. CICILLINE  
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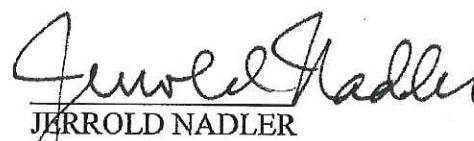
  
NIKI TSONGAS  
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JERROLD NADLER  
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GENE GREEN  
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JAMES A. HIMES  
Member of Congress

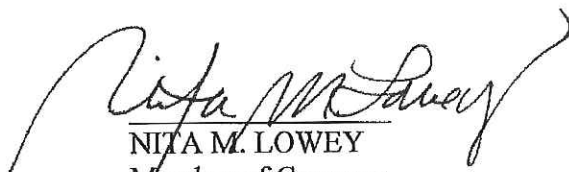
  
KATHY CASTOR  
Member of Congress

  
DAVID LOEBSACK  
Member of Congress


  
JARED POLIS  
Member of Congress

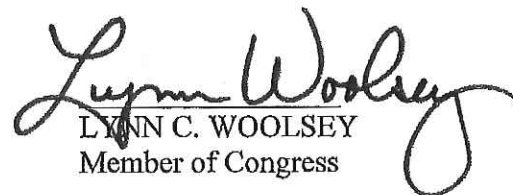
  
JOHN W. OLVER  
Member of Congress



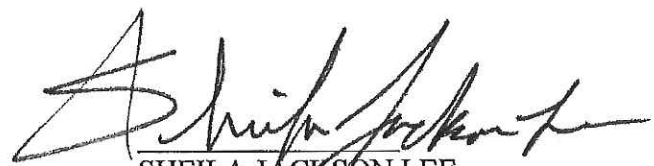
  
NITA M. LOWEY  
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JOHN GARAMENDI  
Member of Congress

  
RON KIND  
Member of Congress

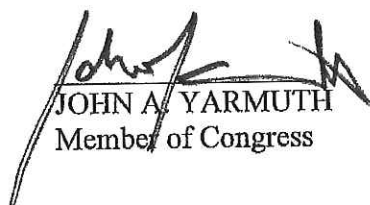
  
DANNY K. DAVIS  
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MIKE QUIGLEY  
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LOIS CAPPS  
Member of Congress

  
BRAD SHERMAN  
Member of Congress

  
MIKE THOMPSON  
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JOHN A. YARMUTH  
Member of Congress



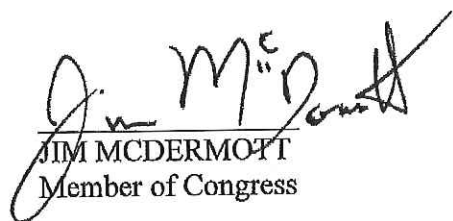
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BETTY MCCOLLUM  
Member of Congress



ED PERLMUTTER  
Member of Congress



JIM MCDERMOTT  
Member of Congress



SILVESTRE REYES  
Member of Congress



SAM FARR  
Member of Congress



ZOE LOFGREN  
Member of Congress



DENNIS J. KUCINICH  
Member of Congress

