

December 31, 2018

Honorable Alex Azar  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Re: CMS-5528-ANPRM; Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Secretary Azar:

The undersigned organizations—representing patients, people with disabilities, family members, caregivers, veterans, seniors, providers and others—are writing to provide input on the Advance Notice of Proposed Rulemaking released by the Center for Medicare & Medicaid Services (CMS) to utilize an “International Pricing Index” (IPI) to set reimbursement for medicines in Medicare Part B. We appreciate the Administration’s efforts to support more affordable patient care and reduce high drug prices. However, we are deeply concerned that in this instance, CMS has chosen an approach that would lead to discriminatory barriers in access to care and ignores the real-world implications for our communities. We urge the Administration to instead work with us to develop sound, patient-centered solutions that recognize that each of us has value and shared human dignity.

We strongly oppose this proposal for two reasons. First, by referencing the policies underpinning coverage and reimbursement of foreign governments, it effectively endorses the use of discriminatory cost-effectiveness standards used by foreign governments here in the U.S. Second, the proposal would be implemented through a large scale, mandatory “demonstration” that effectively forces almost half of doctors (and their Medicare patients) in the U.S. into a radical change in policy with unknown, and potentially very serious, effects on their patients without necessary safeguards to ensure their basic protections.

Addressing health care costs, including drug prices, is an important and meaningful effort that should center on achieving outcomes that matter to those being served by health systems (patients, people with disabilities, veterans, seniors and other marginalized communities) such as improved quality of care and lower out-of-pocket costs. We are hopeful the Administration will reconsider their plan to import international cost-effectiveness standards into the U.S. and instead advance patient-centered, non-discriminatory approaches and establish meaningful protections for our communities in future demonstrations.

**CMS Must Reject Use of Discriminatory Quality-Adjusted-Life-Year (QALY)-based Cost-Effectiveness Standards and Honor the Safeguards Against Their Misuse in Medicare**

Under the IPI model proposed by CMS, Medicare would establish a new, lower reimbursement rate for complex medicines infused by physicians in their offices. To set the new payment rate, Medicare would reference prices set in 14 other countries, such as the United Kingdom (U.K.), Canada, Greece, and the Czech Republic.<sup>1,2</sup> As you know, many of the referenced countries make reimbursement and coverage decisions based on Quality-Adjusted-Life-Year (QALY) cost-effectiveness assessments, which estimates the costs and gains of health interventions.<sup>3</sup> These QALY assessments assign a financial value to health improvements and outcomes. When applied to health care decision-making, the results can mean some patients, people with disabilities, veterans and seniors are deemed “too expensive” to receive care.

We are very concerned that, in adopting this construct, CMS would undermine core protections against discrimination for patients, people with disabilities, veterans, seniors and others. In particular, the Affordable Care Act very clearly states that the Secretary of Health and Human Services has no authority to deny coverage of items or services “solely on the basis of comparative effectiveness research” nor to use such research “in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.”<sup>4</sup>

The Affordable Care Act specifically prohibits the development or use of a “dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended.” Additionally, “The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII” (Medicare). The proposal appears to strike at the heart of this critical safeguard against discrimination for patients, people with disabilities, and other vulnerable populations.<sup>5</sup>

This provision of statute reflects long-standing opposition by policy-makers, and the American public, of this blunt, subjective standard in public policy to determine the value of caring for patients and people with disabilities. The U.S. has repeatedly rejected QALYs and similar cost-effectiveness assessments as the basis for making drug coverage and reimbursement decisions, instead opting for a more patient-centered legislative and regulatory frameworks that protects vulnerable populations from this kind of discrimination.

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<sup>1</sup> United States, Department of Health and Human Services, “HHS Advances Payment Model to Lower Drug Costs for Patients,” Press Release, October 25, 2018. Accessed December 3, 2018. [Web](#).

<sup>2</sup> United States, Department of Health and Human Services, Centers for Medicare and Medicaid Services, “Medicare Program; International Pricing Index Model for Medicare Part B Drugs,” Advance Notice of Proposed Rulemaking with Comment,” October 30, 2018. Accessed December 3, 2018. [Web](#).

<sup>3</sup> World Health Organization, The Health and Environment Linkages Initiative, “Cost-effectiveness analysis for health interventions,” Accessed December 5, 2018. [Web](#).

<sup>4</sup> 42 USC Sec 1320e, 2017. Accessed December 4, 2018. [Web](#).

<sup>5</sup> 42 USC Sec 1320e, 2017. Accessed December 4, 2018. [Web](#).

Even prior to the ACA, Section 504 of the Rehabilitation Act ensured that individuals with disabilities would not “be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination,” under any program offered by any Executive Agency, including Medicare.<sup>6</sup> Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.<sup>7</sup> In 1992, the Administration, under President George H.W. Bush, established that it was a violation of the ADA for states to employ cost-effectiveness standards in Medicaid out of concern that it would discriminate against people with disabilities.<sup>8</sup>

### **Moral and Ethical Implications for America to Replicate Foreign Cost-Effectiveness Standards**

Opposition to QALY-based cost-effectiveness thresholds in health care policy reflect its basic ethical and methodological flaws. The QALY methodology assumes that a year spent in certain states (such as perfect health, represented by 1.0) is more desirable than a year spent in other states (such as paraplegia, ranked by some QALY systems at approximately 0.5, implying that the lives of people with paraplegia are worth approximately half the lives of individuals without).<sup>9</sup>

When applied to assessing a treatment’s value, medicines specifically for younger, and otherwise healthy people have the ability to achieve “better value,” than medicine that treat older or disabled populations. This inherent characteristic of the QALY calculation results in discrimination towards chronically ill patients, seniors, and people with disabilities. Consequently, the QALY methodology also tends to undervalue treatments that delay disease progression, helping patients maintain their current QALY level, compared to treatments that can improve a patient’s QALY level.

This method of determining the value of a treatment completely disregards the fact that an individual living with a chronic condition or disability may be just as satisfied with their life as an individual with perfect health and should not be afforded less access to treatment.<sup>10</sup> From an ethical perspective, valuing “perfect health” over “less than perfect” health is fraught with issues. Indeed, our nation’s constitutional foundation of equality and our public policies such as Emergency Medical Treatment and Labor Act (EMTALA), a federal law that requires anyone coming to an emergency department to be stabilized and treated regardless of their ability to

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<sup>6</sup> 29 USC Sec 794, 2017. Accessed December 5, 2018. [Web](#).

<sup>7</sup> 42 USC Sec 12131, 2017. Accessed December 5, 2018. [Web](#).

<sup>8</sup> See <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

<sup>9</sup> Partnership to Improve Patient Care, “Measuring Value in Medicine: Uses and Misuses of the QALY,” White Paper. Accessed December 5, 2018. [Web](#).; Haagsma JA, Polinder S, Cassini A, Colzani E, Havelaar AH. Review of disability weight studies: comparison of methodological choices and values. *Popul Health Metr*. 2014;12:20. Published 2014 Aug 23. doi:10.1186/s12963-014-0020-2

<sup>10</sup> Pettitt, D., Raza, S., Naughton, B., Roscoe, A., Ramakrishnan, A., Davies, B., . . . Brindley, D. (2016). The Limitations of QALY: A Literature Review. *The Journal of Stem Cell Research & Therapy*, 6(4).

pay,<sup>11</sup> indicates our national ethic to provide the gold standard in care to patients and people with disabilities.<sup>12, 13</sup>

For example, at a roundtable of patient organizations in 2016, “It was strongly suggested that policymakers engage with patients and people with disabilities so they are achieving value from the patient perspective and based on reliable information that accurately reflects the conditions under consideration, recognizing that efforts to achieve cost effectiveness should not be at the expense of our moral and ethical obligation to patients and people with disabilities.” This statement remains our position today.<sup>14</sup>

### **International Implications of QALY-Based and Cost Effectiveness Thresholds**

Concerns with flawed cost-effectiveness standards are not merely theoretical. We need look no further than the countries referenced in the Administration’s proposal to see the painful realities of these standards when put into practice.<sup>15</sup> For example, while U.S. patients have access to 95 percent of new cancer medicines released in the past eight years, patients in the U.K. have access to 74 percent, Japanese patients just 49 percent, and Greek patients only 8 percent.<sup>16</sup>

Our perspectives on the danger of importing QALY-based thresholds are informed by the experiences of patients and people with disabilities in countries where cost-effectiveness measures determine coverage and reimbursement rates. This kind of one-size-fits-all policymaking, like the policy proposed by the Administration, dismisses the life-changing impact of treatments on real people.

#### What is the impact of cost-effectiveness assessments for patients with chronic conditions?

The impact of an IPI-type model has clear implications for a wide array of patients. For example, cancer patients in other developed countries have access to new cancer medicines on average two years later than patients in the U.S.<sup>17</sup> Even when other health authorities eventually approve new medicines, additional access restrictions, such as limiting treatment durations,

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<sup>11</sup> Centers for Medicare & Medicaid Services. (2012, March 26). *Emergency Medical Treatment & Labor Act (EMTALA)*. Retrieved 2018, from <https://www.cms.gov/regulations-and-guidance/legislation/emtala/>

<sup>12</sup> Rosenbaum, S. (2007). The Americans with Disabilities Act in a Health Care Context. In *The Future of Disability in America*. National Academy of Sciences. Retrieved from <https://www.ncbi.nlm.nih.gov/books/NBK11429/>

<sup>13</sup> Ervin, D. A., Hennen, B., Merrick, J., & Morad, M. (2014, July). Healthcare for Persons with Intellectual and Developmental Disability in the Community. *Frontiers in Public Health*, 2, 1-8. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4098023/pdf/fpubh-02-00083.pdf>

<sup>14</sup> [http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc\\_roundtable\\_summary\\_-\\_value\\_to\\_the\\_patient.pdf](http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_roundtable_summary_-_value_to_the_patient.pdf)

<sup>15</sup> The Editorial Board, “Why Are Drugs Cheaper in Europe?” Opinion, *The Wall Street Journal*, October 28, 2018. Accessed December 5, 2018. [Web](#).

<sup>16</sup> Ibid.

<sup>17</sup> IQVIA. Global Oncology Trends 2018, May 2018.

continue to create barriers for patients.<sup>18</sup> Nearly 80% of cancer medicines approved for coverage in the U.K. between 2007 and 2014 had some kind of access restriction.<sup>19</sup> And patients pay the price for delayed and restricted access to life-saving medicines – five-year survival rates for breast, colon, lung, and prostate cancers are higher in the U.S. than in Canada, France, Germany, Italy, Japan, and the U.K.<sup>20</sup>

*Karen McLaren and Ashley McDonald*

*The stark contrast between the experiences of Karen McLaren and Ashley McDonald, two Canadian women who met in elementary school and then worked together in their early twenties, illustrates the profound impact of restricted access to cancer medication. The friends were both diagnosed with breast cancer as young women and underwent mastectomies and aggressive chemotherapy, only to have their cancer return and metastasize. McDonald, a dual U.S.-Canadian citizen, receives health insurance through her American employer, and was prescribed a drug that ultimately put her cancer into remission.<sup>21</sup> McLaren has extended Canadian medical coverage, and the same drug was not a covered drug until April 2018.<sup>22</sup> At that time, the British Columbia Cancer Agency announced a severely restricted coverage policy, covering it only for “post-menopausal women with ER-positive, HER2-negative advanced breast cancer who have had no prior treatment for their metastatic disease.” At 42, this eliminates coverage for McLaren, who has been paying out-of-pocket for the treatment, as do thousands of other women across Canada.<sup>23</sup>*

In the U.K., a new treatment was approved for relapsing and remitting multiple sclerosis (MS) but not for primary progressive MS, despite its potential to delay wheelchair use for as long as seven years.<sup>24</sup> Cost-effectiveness assessments, particularly those based on QALYs, tend to undervalue medicines that halt or slow disease progression and where there may be less of a measurable incremental improvement in health.<sup>25</sup>

*The Ford and Elias Families*

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<sup>18</sup> “Mum with lung cancer taken off life-saving drug,” November 7, 2018. Accessed December 5, 2018. [Web](#).

<sup>19</sup> Zhang Y et al. [Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries](#). *J Manag Care Spec Pharm*. 2017;23(2):247-54. [Web](#).

<sup>20</sup> World Health Organization (WHO). WHO mortality database. PhRMA analysis of WHO mortality database, using age-specific death rates. Accessed May 2018. [Web](#).

<sup>21</sup> Ghossoub, Michelle, “A tale of 2 friends with breast cancer; 1 has coverage for costly drug, the other forced to pay,” Canadian Broadcasting Company, January 20, 2018. Accessed December 5, 2018. [Web](#).

<sup>22</sup> Taminga, Monique, “No celebrating cancer drug coverage, says B.C. woman,” *The Langley Times*, April 17, 2018. Accessed December 5, 2018. [Web](#).

<sup>23</sup> <https://www.cbc.ca/news/canada/british-columbia/a-tale-of-2-friends-with-breast-cancer-1-has-coverage-for-costly-drug-the-other-forced-to-pay-1.4495123>

<sup>24</sup> Knapton, Sarah, “MS patients denied drug which could keep them out of wheelchair”, *The Telegraph*, September 10, 2018. Accessed December 5, 2018. [Web](#).

<sup>25</sup> Partnership to Improve Patient Care, “Measuring Value in Medicine: Uses and Misuses of the QALY,” White Paper. Accessed December 5, 2018. [Web](#).

*Holly Ford is one of those 15,000 Brits unable to receive treatment for her primary progressive MS. Diagnosed in early 2018, the 25-year-old call center worker must already use a wheelchair for long distances and says the thought of further erosions to her independence is “terrifying.”<sup>26</sup> She knows that without treatment, MS will eventually result in further mobility impairments, and that a new drug can delay the progression of the disease. She said the treatment, “won’t make me better... but it could stop me from getting worse.”<sup>27</sup>*

A new drug brought hope to individuals with spinal muscular atrophy (SMA), a rare, debilitating condition that previously had no treatment for its underlying cause.<sup>28</sup> Unfortunately, because it failed to meet the QALY-based cost-effectiveness review used by the United Kingdom and several other national health systems, it remains unavailable to many patients seriously in need.

### *The Newell Family*

*Finley Newell, from Haddenham in Buckinghamshire, has spinal muscular atrophy, which means he can’t walk and a common cold could be enough to kill him. A drug which could reverse his illness already exists the NHS initially argued it is not value for money. His mother called the decision “an abomination” and “discrimination.” A former nurse said, “It’s incredibly cruel to use the cost-effectiveness line and it makes me shake with rage.”<sup>29</sup>*

## **CMS’ IPI Concept Would Impose a Radical Shift in Policy Via Misuse of Agency Authority, Exposing Patients and People with Disabilities to Discrimination on a National Scale.**

CMS proposes to implement the IPI via a vast new “demonstration” program in the Center for Medicare and Medicaid Innovation (CMMI). Over the past several years, advocates for patients and people with disabilities have repeatedly called on policymakers to establish clear safeguards at CMMI to protect patients— including criteria for patient-centeredness as called for in the statute – before advancing major new initiatives at CMMI. We were heartened to see some of these concepts referenced in the “New Direction for CMMI” document released by the Administration in 2017, which touted a “new focus on patient-centered care.” We are deeply disappointed that the agency has not taken any further steps to establish these safeguards, and has instead advanced a major, new, mandatory demonstration that relies on cost-effectiveness thresholds that are inherently not patient-centered.

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<sup>26</sup> Knapton, Sarah, “MS patients denied drug which could keep them out of wheelchair”, *The Telegraph*, September 10, 2018. Accessed December 5, 2018. [Web](#).

<sup>27</sup> Knapton, Sarah, “MS patients denied drug which could keep them out of wheelchair”, [The Telegraph](#), September 10, 2018.

<sup>28</sup> National Organization for Rare Disorders, “Spinal Muscular Atrophy,” Accessed December 5, 2018. [Web](#).

<sup>29</sup> Blanchard, Sam, “Parents beg officials to approve the life-saving £450,000 drug which can treat the rare condition crippling their five-year-old son”, *The Daily Mail*, October 19, 2018.

While the current proposal impacts approximately half of providers and includes only physician-administered medicines covered under Part B, we have no reason to believe this demonstration will be isolated. CMMI demonstrations are typically tested on a limited scale, with the goal to expand if the demonstration is successful. Under the current CMMI rules, if the model meets statutory requirements, it could presumably be expanded nationwide and beyond drugs administered under Part B.<sup>30</sup> Additionally, this proposal appears to have fueled efforts on Capitol Hill to import foreign drug pricing and coverage policies beyond Medicare Part B,<sup>31</sup> lending false credence to use of QALYs and cost effectiveness in other areas of care. We know that people with disabilities<sup>32</sup> and older patients<sup>33</sup> report discrimination in the healthcare system, and that would now be exacerbated if we choose to make QALY-based cost effectiveness standards acceptable in our public programs. Instead, we want to mitigate the use of discriminatory standards for accessing care within state and federal programs.

### **We Recommend Putting Patients and People with Disabilities at the Center of CMMI and Committing to Uphold Protections Against Discrimination.**

Despite progress, such as the creation of the Patient-Centered Outcomes Research Institute (PCORI) and Patient-Focused Drug Development at the U.S. Food and Drug Administration, we continue to struggle to ensure patients, people with disabilities, veterans and seniors are at the center of policymaking in Medicare and Medicaid. While we are disappointed that we continue to be excluded from early-stage policy discussions at CMS that directly impact our communities, we remain open and willing to engage on future initiatives that prioritize patient outcomes when developing alternative payment models. Therefore, we hope that the Administration and Congress will pause to consider the discriminatory implications experienced domestically and internationally before moving forward to overturn our existing precedent recognizing QALY's inherent discrimination.<sup>34</sup>

Unfortunately, the proposed demonstration does not align with our understanding of the Administration's priorities and came as a surprise to patients and people with disabilities after the Administration's Blueprint to Lower Drug Prices referenced challenges with access to care internationally,<sup>35</sup> the Council on Economic Advisers criticized health care access in other countries,<sup>36</sup> and your expressed concerns about international reference pricing at Congressional

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<sup>30</sup> 42 USC Sec 1315a, 2011. Accessed December 3, 2018. [Web](#).

<sup>31</sup> "Merkley Proposes Bill to Slash Drug Prices," Press Release, The Office of Senator Jeff Merkley, November 29, 2018. Accessed December 3, 2018. [Web](#). See also "Sanders, Khanna to Introduce Legislation to Drastically Lower Prescription Drug Prices," Press Release, The Office of Senator Bernie Sanders, November 20, 2018. Accessed December 3, 2018. [Web](#).

<sup>32</sup> Krahn GL, Walker DK, Correa-De-Araujo R. Persons with disabilities as an unrecognized health disparity population. *Am J Public Health*. 2015;105 Suppl 2(Suppl 2):S198-206.

<sup>33</sup> Lilleston, Randy, "Do Older Patients Face Care Discrimination", AARP, Dec. 19, 2017. [Web](#).

<sup>34</sup> Sullivan, Louis W. M.D. Secy. of Health and Human Services, Washington, (Aug. 13, 1992). *Oregon Health Plan is Unfair to the Disabled*, New York Times. [Web](#).

<sup>35</sup> American Patients First, HHS, May 2018 [Web](#).

<sup>36</sup> The Opportunity Costs of Socialism, White House, 2018. [Web](#).

hearings. Additionally, Administration officials have stated that they acknowledge and embrace the effort to place patients at the center of our health care system. As CMS Administrator Seema Verma recently stated: “we will not achieve value-based care until we put the patient at the center of our healthcare system. Until patients can make their own decisions based on quality and value, health care costs will continue to grow at an unsustainable rate.”<sup>37</sup> You have similarly encouraged people to “imagine a system where patients are in the driver’s seat.”<sup>38</sup>

The current proposal highlights the need for a larger conversation around the process for developing, implementing, and evaluating alternative payment models via CMMI. Advocates have consistently urged three concrete steps: (1) Establish the “patient-centeredness criteria” mandated under Section 1115A of the Affordable Care Act, which requires evaluation of alternative payment models against patient-centeredness criteria; (2) convene a patient and consumer advisory panels for each of the CMMI models under development as well as those currently being implemented; and (3) define “informed decision-making” as a core criterion of patient-centeredness and a goal of each alternative payment model.<sup>39</sup>

In addition to the development of patient-centered safeguards for CMMI demonstrations, any new proposals should not seek to waive key protections against cost-effectiveness standards currently in statute. We encourage the inclusion of specific language in future proposals that explicitly indicate the Administration’s intent to abide by these protections.

### **CMMI Should Engage Patients, People with Disabilities, Veterans, Seniors, Family Members and Caregivers to Advance Patient-Centered Alternatives.**

Patients, people with disabilities, veterans, seniors, family members and caregivers deserve a seat at the table in the creation of alternative payment models that pay for quality and measurable outcomes. Therefore, we urge Congress and the Administration to collaborate with health care stakeholders, particularly those representing our communities, on advancing patient-centered alternatives and meaningful protections against discrimination.

Innovative efforts to leverage data and advance personalized medicine represent promising, patient-centered approaches to increase access and improve affordability. By empowering patients and their providers, we can advance an informed health care system that better assesses the clinical effectiveness of treatment options for each unique individual.<sup>40</sup> And by investing in shared decision-making aligned with the recommendations of the National Quality

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<sup>37</sup> United States, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Seema Verma, “Speech: Remarks by CMS Administrator Seema Verma at the HIMSS18 Conference,” Press Release. March 6, 2018. Accessed December 4, 2018. [Web](#).

<sup>38</sup> United States, Department of Health and Human Services, Alex Azar, “Remarks on Primary Care and Value-based Transformation,” Speech. November 8, 2018. Accessed December 4, 2018. [Web](#).

<sup>39</sup> Partnership to Improve Patient Care, “PIPC Submits Joint Letter to CMMI Emphasizing Patient-Centered Payment Models,” Letter, August 2, 2018. Accessed December 5, 2018. [Web](#).

<sup>40</sup> id

Partners Playbook on Shared Decision-Making,<sup>41</sup> we can advance policies that measure and reward achieving outcomes that matter to patients.<sup>42</sup>

Unfortunately, the Administration's proposal is not in the best interest of patients, people with disabilities, veterans, and seniors. In some cases, access to care can mean the difference between life and death for patients and people with disabilities. And just as importantly, access to innovative medicines translates into higher quality of life and/or extended life and allows patients and people with disabilities to better integrate and participate in their communities and families. While more must be done to reduce health care costs, it must not come at the expense of access to medications with such an important impact on the lives of real people.

We wish to partner with the Administration and Congress to advance alternative payment models that put patients and people with disabilities at the center. In doing so, we must learn from the experience of patients and people with disabilities in other countries and choose to advance policies that protect the most vulnerable Americans. While the American health care system may have many flaws, maintaining our commitment to non-discrimination is not one of them.

We, the undersigned organizations, urge the Administration to reconsider the proposed CMMI demonstration that would import cost-effectiveness standards to the U.S. and undermine key protections for patients, people with disabilities, veterans and seniors. Your response may be directed to Tony Coelho, Chairman of the Partnership to Improve Patient Care, 100 M St SE, Suite 750, Washington, DC 20003.

Sincerely,

Aimed Alliance  
Alliance for Aging Research  
Allies for Independence  
American Association of People with Disabilities  
Association of University Centers on Disabilities  
Autistic Self Advocacy Network  
CancerCare  
Center for Autism and Related Disorders  
Center for Public Representation  
Disability Rights Education and Defense Fund  
Ernest Merritt  
Heart Valve Voice

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<sup>41</sup> Letter to CMS Administrator Seema Verma and Director Kate Goodrich, Nov. 13, 2018. [Web.](#)

<sup>42</sup> PIPC Submits Comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, July 16, 2018. [Web.](#)

International Foundation for Autoimmune & Autoinflammatory Arthritis  
Lupus and Allied Diseases Association, Inc.  
National Alliance on Mental Illness  
National Council on Independent Living  
National Patient Advocate Foundation  
Partnership to Improve Patient Care  
Whistleblowers of America