

# PATIENTS FOR AFFORDABLE DRUGS NOW™

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*Submitted To The*

**Committee on Ways and Means Subcommittee on Health**  
**U.S. House of Representatives**

*for a hearing on*

*Medical Innovation and Patient Access to Therapies*

**May 10, 2023**

## ***Section I. Background and Introduction***

My name is David Mitchell. I am the founder of Patients For Affordable Drugs Now. We are a bipartisan organization focused on policies to lower prescription drug prices. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

Our job is to collect and amplify the stories of patients struggling to pay high drug prices, and to help them share their experiences with policymakers and elected officials. You can read more than 33,000 stories on our website today. And we have built a community of more than 400,000 patients and allies who support policies to lower drug prices.

More importantly for the Committee, I have an incurable blood cancer, and prescription drugs are keeping me alive — literally.

My doctors currently have me on a four-drug combination of infused and oral cancer drugs which carry a combined list price of more than \$900,000 per year. Just one of my oral drugs, called Pomalyst, is priced at more than \$23,000 for 21 capsules, which I must buy every 28 days. And because people on Medicare like me pay our costs in Part D based on list price, I will spend

more than \$17,000 out of pocket this year — just for Pomalyst. For people with my cancer — multiple myeloma — drugs account for 60 percent of the cost of treatment.<sup>1</sup> Sixty percent.

I am a very lucky man — these drugs are currently keeping my cancer at bay, and I tolerate them well. But eventually I will fail on this combination, too. When that happens, I will need a new treatment. Fortunately, there are options out there and more in development.

The point is: I need these innovative drugs. I care deeply about innovation and new drug development. My life depends on it. Without innovation, I will die sooner than I hope to. That is just an unfortunate fact.

But my more than 12-year journey as a cancer patient has taught me one irrefutable fact: Drugs don't work if people can't afford them.

## ***Section II. The Price of Drugs and Need for Change***

Despite historic reforms enacted last year, too many drugs are still too expensive in the United States, and there is no justification for the high prices. When drug makers hike prices, they don't do so because the drug suddenly becomes more innovative or clinically effective. Drug companies raise prices because they can. We let them. Starting this year we will curb these price increases in Medicare through the Inflation Reduction Act, but there is currently no direct mechanism to rein in these increases in the commercial market.

The result is that Americans pay nearly four times what people in other wealthy nations pay for the exact same brand-name drugs.<sup>2</sup>

Consequently, nearly 40 percent of people in this country report having difficulty affording their medications.<sup>3</sup> When their prescription drug prices are too high, patients don't adhere to their drugs and this harms their health<sup>4</sup>.

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<sup>1</sup> Tran, D., Kamalakar, R., Manthena, S., & Karve, S. (2019, November 13). Economic Burden of Multiple Myeloma: Results from a Large Employer-Sponsored Real-World Administrative Claims Database, 2012 to 2018. *Blood*, 134, 3414. <https://doi.org/10.1182/blood-2019-131264>

<sup>2</sup> Schondelmeyer, S., Purvis, L. (2021). Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2020. *AARP Public Policy Institute* <https://www.aarp.org/content/dam/aarp/ppi/2021/06/trends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans.10.26419-2Fppi.00143.001.pdf>

<sup>3</sup> Nguyen, A. (2021, March 22). Survey: Americans Struggle to Afford Medications as COVID-19 Hits Savings and Insurance Coverage. *GoodRx*. <https://www.goodrx.com/blog/survey-covid-19-effects-on-medication-affordability/>

<sup>4</sup> Congressional Budget Office. (2023). How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. <https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf>

Due to high drug prices, Americans face challenges affording other expenses, such as food and housing. One survey found that over 20 percent of people took on debt or declared bankruptcy because of their medications.<sup>5</sup>

High drug prices disproportionately harm communities of color. One in two Latinos in the United States takes a prescription medication, and 20 percent are uninsured.<sup>6</sup> Black Americans are more likely to live with chronic pain, diabetes, and high blood pressure than white Americans and are nearly two times more likely to be uninsured.<sup>7</sup>

Too many Americans with and without insurance are struggling everyday to pay high prices.

But instead of lowering prices, the drug industry maintains that this unacceptable status quo in which they can charge whatever prices they please is necessary in order to guarantee they can invest in future research and development (R&D). In other words, drug companies take the position that patients must suffer poor health and financial harm in the short term in order for drug companies to preserve the possibility of potential innovation in the future.

**This is a false choice, aiming to prey upon the hopes and fears of patients and their families. We can achieve balance to have innovative, safe, and effective drugs at prices all people can afford. The Inflation Reduction Act is an example of policy that takes us in the right direction.**

### *Section III: The Inflation Reduction Act Protects and Incentivizes Innovation*

Implementation of the Inflation Reduction Act (IRA) is a critical step towards achieving a future where the need for innovation is balanced with affordability. For the first time, people on Medicare will be protected from catastrophic financial hardship due to drug costs with a \$2,000 cap on out-of-pocket costs. For the first time, drug companies will not be able to raise prices at will in Medicare year after year. And finally, after years of effort to achieve reform, the government will be able to negotiate lower prices for a subset of the most costly drugs on behalf of beneficiaries.

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<sup>5</sup> Nguyen, A. (2021, March 22). Survey: Americans Struggle to Afford Medications as COVID-19 Hits Savings and Insurance Coverage. *GoodRx*. <https://www.goodrx.com/blog/survey-covid-19-effects-on-medication-affordability/>

<sup>6</sup> UnidosUS Action Fund. (2021, January). *A Vicious Cycle of Health Inequity: How High Prescription Prices Hurt Latino Health and Prosperity*. <https://www.lowerdrugpricesnow.org/wp-content/uploads/UNIDOS-RX-REPORT-Vicious-Cycle.pdf>

<sup>7</sup> Patients For Affordable Drugs Now. (2020, December 14). *High Prescription Drug Prices Perpetuate Systemic Racism. We Can Change It*. <https://patientsforaffordabledrugsnow.org/2020/12/14/drug-pricing-systemic-racism/>

Big drug corporations and their allies tell us that the IRA will devastate the industry and obliterate innovation — but this is another false narrative repeated by opponents of reform who are actually *proponents* of higher prices and the harmful status quo for patients.

In fact, the IRA improves and builds upon existing incentives for innovation in two key ways:

- Currently, drug companies can pursue profits by recycling — and jacking up the prices on — old blockbuster products that have no competitors despite enjoying monopoly periods far beyond what is intended under law. The Medicare price hike rebates and negotiation provisions in the IRA address this directly by penalizing price increases higher than inflation and by targeting negotiation to old drugs that should have competition, but don't. This much-needed shift in incentives will force drug companies to invest instead in new and truly innovative products that can command high prices.
- In contrast to the industry's current process of setting arbitrary prices, the Centers for Medicare & Medicaid Services (CMS) will begin to negotiate prices on a subset of very old and costly drugs based on the *clinical benefit* of a drug and other key factors to be sure we reward important and high quality new drugs with prices befitting their contribution to health and an appropriate profit. It is axiomatic that to stimulate and reward innovative new drug development, we should pay more for high value drugs and less for low value drugs. The IRA negotiating process is structured to encourage truly innovative, high value drugs.

The IRA also preserves existing incentives in law for innovation:

- Drug companies can continue to set prices at launch and enjoy years of market exclusivity to ensure they are well-compensated for investment and risk before possibly being eligible for Medicare negotiation.
- Medicare must cover all drugs in six protected classes, which even the Pharmaceutical Research and Manufacturers of America (PhRMA) acknowledges ensures access to these drugs.<sup>8-9</sup>
- Medicare must cover at least two drugs in each class of drugs.<sup>10</sup>

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<sup>8</sup> Centers for Medicare & Medicaid Services. (2019, May 16). *Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F)*. <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f>

<sup>9</sup> Powaleny, A. (2015, December 10). Medicare Part D's six protected classes. *PhRMA*. <https://catalyst.phrma.org/medicare-part-d-six-protected-classes>

<sup>10</sup> *What Medicare Part D drug plans cover*. (n.d.). CMS.gov. Retrieved May 3, 2021 from <https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover>

- Medicaid must cover every drug offered by a manufacturer in the United States if the manufacturer agrees to give Medicaid a best-price guarantee.<sup>11</sup>

#### ***Section IV. The Truth About Innovation and Drug Prices***

Of course, the reason the biopharmaceutical industry seeks to undermine the IRA is because *it opposes any reforms that curb its unilateral power to dictate prices for brand drugs*. It insists it must be able to set prices as high as it wants for virtually as long as it wants or it won't be able to attract investment. So it rolls out its well-worn claim that any limits on its ability to set high prices will destroy innovation and access to new drugs.

No one cares more about innovation than patients. But if you pull back the curtain on this fear-mongering, the industry's arguments don't hold up.

Experts from both sides of the aisle agree it's possible to rein in the pharmaceutical industry's abusive pricing power without threatening valuable innovation.<sup>12-13</sup> Here are six reasons why:

- 1) Biopharma corporations enjoy profit margins that are almost three times the average of the S&P 500.<sup>14</sup> Brand-name pharmaceutical companies could lose \$1 trillion in sales over 10 years and remain the most profitable industry in the United States.<sup>15</sup> There is more than enough headroom to lower drug prices and leave drug companies with plenty of profit to attract investment and fund research and development. And if drug pricing legislation curbs profits, the industry can maintain or even increase R&D investment by shifting the billions spent on stock buybacks, marketing, advertising, and lobbying.<sup>16</sup>
- 2) It doesn't cost nearly as much as the industry says it does to develop a new drug. Pharma claims it costs \$2.87 billion to bring a new drug to market. But that's based on industry-

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<sup>11</sup> Kaiser Family Foundation. (2019, May 1). *Medicaid's Prescription Drug Benefit: Key Facts*. <https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/>

<sup>12</sup> Frank, R. G. (2019, November 13). Drug companies exaggerate — controlling drug prices won't threaten innovation. *The Hill*. <https://thehill.com/opinion/healthcare/470266-drug-companies-exaggerate-controlling-drug-prices-wont-threaten-innovation>

<sup>13</sup> Waikar, S. (2020, September 2). Pharma Companies Argue That Lower Drug Prices Would Mean Fewer Breakthrough Drugs. Is That True?. *Kellogg School of Management at Northwestern University*. <https://insight.kellogg.northwestern.edu/article/pharma-companies-argue-lower-drug-prices-fewer-breakthrough-drugs>

<sup>14</sup> Yardeni Research. (2021, January 19). *S&P 500 Sectors & Industries Profit Margins (quarterly)*. <https://www.yardeni.com/pub/sp500margin.pdf>

<sup>15</sup> West Health. (2019, November 14). *New Analysis Finds Large Drugmakers Could Lose \$1 Trillion in Sales and Still Be the Most Profitable Industry*. <https://www.westhealth.org/press-release/new-analysis-finds-large-drug-makers-could-lose-1-trillion-in-sales-and-still-be-the-most-profitable-industry/>

<sup>16</sup> Angelis, A. et al. (2023). High drug prices are not justified by industry's spending on research and development. *BMJ*. <http://press.psprings.co.uk/bmj/february/drugprice.pdf>

funded research and undisclosed source data.<sup>17-18</sup> Independent studies have found the cost to develop a drug is likely less than \$1 billion.<sup>19-20</sup>

- 3) A tremendous amount of research and development is coming from taxpayers. The National Institutes of Health (NIH) is the single largest biomedical research agency in the world. NIH-funded research is associated with all 356 new drugs that were approved by the FDA from 2010 to 2019.<sup>21</sup> Former NIH Director Francis Collins has said: “Finding new treatments thus requires NIH to play a lead role — by investing in the early stage of therapeutic development to ‘de-risk’ such projects.”<sup>22</sup> Drug companies argue high drug prices are required to reimburse the industry for the financial and scientific risk it takes on during research and development. In reality, the U.S. government takes on most of those early risks, further undermining the industry’s argument for high prices.

Our experience with COVID-19 vaccines illustrates this point with crystal clarity. Drug companies were not investing in vaccines in the 1990s and early 2000s because vaccines were seen as too risky and offering low profits<sup>23</sup>. Drug makers only mobilized in response to Operation Warp Speed when the government offered billions of dollars in contracts to develop COVID-19 vaccines and therapeutics. Our government de-risked the investment and privatized the profit so now COVID vaccines are among the highest grossing drug products of all time.

One noted industry expert, Jack Scannell, summed it up this way: “Before we pat the drug industry on the back too much, one has to recognize it got involved in this partly because the whole thing has been de-risked by government.”<sup>24</sup>

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<sup>17</sup> DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20-33. <https://doi.org/10.1016/j.jhealeco.2016.01.012>

<sup>18</sup> Tufts Center for the Study of Drug Development. (n.d.). *Financial Disclosure*. <https://csdd.tufts.edu/financial-disclosure>

<sup>19</sup> Wouters, O. J., McKee, M., & Lutyen, J. (2020). Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*, 323(9), 844-853. <https://doi.org/10.1001/jama.2020.1166>

<sup>20</sup> Prasad, V., & Mailankody, S. (2017). Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval. *JAMA Internal Medicine*, 177(11), 1569-1575. <https://doi.org/10.1001/jamainternmed.2017.3601>

<sup>21</sup> Ledley, F., Cleary, E., & Jackson, M. (2020, September 2). US Tax Dollars Funded Every New Pharmaceutical in the Last Decade. *Institute for New Economic Thinking*. <https://www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade>

<sup>22</sup> Collins, F. S. (2017, May 17). Testimony on the Transformative Power of Biomedical Research. *National Institutes of Health*. <https://www.nih.gov/about-nih/who-we-are/nih-director/testimony-transformative-power-biomedical-research>

<sup>23</sup> Patients For Affordable Drugs. (2021, February). *Big Pharma’s Big Lie: The Truth About Innovation and Drug Prices*. <https://patientsforaffordabledrugs.org/2021/02/03/innovation-report/>, 45-46

<sup>24</sup> Neville, S., & Kuchler, H. (2020, November 27). Covid vaccines offer Big Pharma a chance of rehabilitation. *Financial Times*. <https://www.ft.com/content/75029036-13f3-4ca2-8954-5a7207c0c3db>

- 4) Pharma’s claims that patients will suffer an alarming loss of new drugs as a result of the IRA simply isn’t supported by the facts. According to the CBO, the Inflation Reduction Act will decrease the number of new drugs over the next 30 years by only about 15 out of 1,300 expected – that’s less than 2 percent. Since only 10 to 15 percent of “new” drugs represent true therapeutic advancements, of the 15 new drugs foregone, only one or two might actually be true innovations<sup>25-26</sup>. The loss of a few drugs each year will have minimal to no impact on the health of Americans.
- 5) The industry has plenty of money for innovation. In the wake of the Inflation Reduction Act passage, investors are upbeat. Drug company stocks are doing fine.<sup>27</sup> The industry is flush with cash and has great access to capital.<sup>28</sup>
  - Pfizer is buying biotech company Seagen for \$43 billion.<sup>29</sup>
  - Sanofi is buying a diabetes product company for \$2.9 billion.<sup>30</sup>
  - Novartis is spending \$15 billion in a stock buyback.<sup>31</sup>

Even in the face of the Inflation Reduction Act, drug companies are reporting *increased* investment in R&D. For example, in 2022 10-K filings<sup>32</sup>, J&J reported an 11.8% increase in R&D spending in 2022, Merck reported an 11% increase in R&D spending, and Moderna reported a 65% increase in R&D spending and projected further increases in 2023.

- 6) Big Pharma threatens that patients in the U.S. will lose access to newly developed drugs. It points out that more drugs are available — and are available faster — in the United

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<sup>25</sup> Congressional Budget Office. (2022, July). Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation. <https://www.cbo.gov/publication/58290>

<sup>26</sup> Light D W, Lexchin J R. (2012, May) Pharmaceutical research and development: what do we get for all that money? *BMJ*

<sup>27</sup> Berk, Cheddar C. (2023, March). Health care stocks 2023 Big pharma still favored but good bets in biotech are out there, *CNBC*. <https://www.cnbc.com/2022/12/21/health-care-stocks-2023-big-pharma-still-favored-but-good-bets-in-biotech-are-out-there.html>,

<sup>28</sup> Cranmer, Jeff. (2023, March) Market rebound on hold, but pharma’s open for business, says J.P. Morgan’s Gaito. *Biocentury*. <https://www.biocentury.com/article/647325>

<sup>29</sup> Hopkins, Jared & Rockoff D., Jonathan (2023, March) Pfizer Agrees to Buy Seagen for \$43 Billion. *The Wall Street Journal*. [https://www.wsj.com/articles/pfizer-agrees-to-buy-seagen-for-43-billion-180a9117?st=155cczi2koglmah&reflink=desktopwebshare\\_permalink](https://www.wsj.com/articles/pfizer-agrees-to-buy-seagen-for-43-billion-180a9117?st=155cczi2koglmah&reflink=desktopwebshare_permalink)

<sup>30</sup> Feurestein, Adam. (2023, March). French pharma Sanofi buys maker of diabetes treatment for \$2.9 billion. *STAT*. <https://www.statnews.com/2023/03/13/french-pharma-sanofi-buys-maker-of-diabetes-treatment-for-2-9-billion/>

<sup>31</sup> Burger, Ludwig. (2023, March). Novartis initiates new trading line for share buybacks. *Reuters*. <https://www.reuters.com/business/healthcare-pharmaceuticals/novartis-launches-new-share-buyback-up-10-its-stock-2023-03-13/>

<sup>32</sup> Patients For Affordable Drugs Now. (2022). Talking Points Based on Review of 2022 SEC 10K filings. <https://patientsforaffordabledrugsnow.org/wp-content/uploads/2023/04/TPs-10-K-0315202380.pdf>



States than in other wealthy countries. It frequently references a white paper from the White House Council of Economic Advisers (CEA) to explain why: “Drug manufacturers usually pursue market access in the United States before other markets due to the higher prices in the United States.”<sup>33</sup> The CEA could also have mentioned the other big reason drug companies file for approval first in the United States: It is the *largest* market in the world.<sup>34-35</sup>

Given that U.S. prices for brand-name drugs are almost four times what many other wealthy nations pay, we can lower prices by a meaningful amount and still offer the highest prices by far in the largest market in the world, preserving the incentive to file first for approval in the United States.<sup>36</sup>

### ***Section V: Recent Innovative Payment Strategies***

Let me be clear. P4ADNow supports investment into medicines for rare and severely underfunded diseases such as Alzheimer’s. We applaud drug companies that are researching and developing truly innovative therapies. And those companies will continue to be paid the highest prices in the world for their successes—even with IRA provisions that improve affordability for patients.

As a country, we should reward drug companies that invent truly innovative products—but our health system cannot afford to pay drug companies arbitrarily high prices for ineffective or even unsafe drugs. Patients and families grappling with Alzheimer’s disease, for example, must have safe and effective treatments. But the way to increase innovation is not to provide incentives for non-innovative or unsafe therapies.

As a cancer patient relying on three drugs that came to market through the accelerated approval pathway, I urge lawmakers to preserve options and incentives for drug companies to bring therapies to market as quickly as possible. But we must also be sure to confirm that accelerated approval drugs are, in fact, safe and effective through timely confirmatory trials. And as a patient on Medicare, I am also glad CMS has tools to protect beneficiaries from paying a portion of an often limited or fixed budget towards a medication that has not been shown to be safe and

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<sup>33</sup> The Council of Economic Advisers. (2018, February). *Reforming Biopharmaceutical Pricing at Home and Abroad*. <https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>

<sup>34</sup> IQVIA. (2020, March 5). *Global Medicine Spending and Usage Trends*. <https://www.iqvia.com/en/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends>

<sup>35</sup> Association of Community Cancer Centers v. Alex M. Azar II. Civil Action No. CCB-20-3531 (2020, April). <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Complaint-on-MFN-Rule-Filed-2020-12-04.pdf>

<sup>36</sup> Mulcahy, A. W., Whaley, C., Tebeka, M. G., Schwam, D., Edenfield, N., & Becerra-Ornelas, A. U. (2021). *International Prescription Drug Price Comparisons*. RAND Corporation. [https://www.rand.org/pubs/research\\_reports/RR2956.html](https://www.rand.org/pubs/research_reports/RR2956.html)



effective—or worse, a drug that might cause harm. Like many other facets of the drug pricing system—utilization of these tools requires balance and discretion. And I am troubled by characterizations of any effort by CMS to create thoughtful guardrails on potentially unsafe drugs as an assault on innovation and patient access.

### ***Section VI: Conclusion***

Pharma’s threats to innovation and access don’t hold up. It is clear that we can balance our system to have fair prices and profits and still get the innovation we need.

Equally important, we must remember that people can’t afford existing drugs they need right now. High prices represent a huge barrier to access and better health. More than 1.1 million people on Medicare could die over the next decade because they cannot afford to pay for their prescriptions.<sup>37</sup> America needs policies that maximize public health while ensuring fair private profit.

It is truly ironic that this committee is holding this hearing after the House of Representatives voted last week to cut next year’s NIH budget by \$10 billion dollars—20 percent! Given the key role of the NIH in developing basic science and the pipeline for new drugs, the House bill will likely do far more harm to new drug development than any of the provisions in the IRA. According to *Medpage Today*, “Lawrence Tabak, DDS, PhD, acting director for the NIH, acknowledged that cuts would have a ‘chilling effect on the entire biomedical research enterprise’ and deter young people from pursuing careers as scientists.”<sup>38</sup> The hypocrisy of this hearing in light of last week’s House vote is breathtaking.

To be clear, those who try to undermine the Inflation Reduction Act and other thoughtful efforts to ensure patients can afford the drugs they need are—practically speaking—advocates for higher drug prices. The key drug price provisions of the IRA are overwhelmingly supported by more than 80 percent of Americans—Democrat and Republicans alike.<sup>38</sup> Elected officials tamper with these reforms at their own political risk.

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<sup>37</sup> West Health. (2020, November 19). *New Study Predicts More Than 1.1 Million Deaths Among Medicare Recipients Due to the Inability to Afford Their Medications*. <https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs/>

<sup>38</sup> KFF. (December 2022) KFF Health Tracking Poll December 2022: The Public's Health Care Priorities For The New Congress <https://www.kff.org/report-section/kff-health-tracking-poll-december-2022-the-publics-health-care-priorities-for-the-new-congress-methodology/>