POLICY BRIEF

TO: Nancy Pelosi, Democratic Speaker of the House
FROM: Andrew Hennessy-Strahs
DATE: March 8, 2018
RE: Health Policy Legislative Recommendations in Anticipation of the 2020 Election

EXECUTIVE SUMMARY

In furtherance of the following three health outcome domains – 1. *health insurance/access to care*; 2. *cost-containment*; and 3. *enhancing quality/value of healthcare* – on behalf of Democratic Speaker of the House, Nancy Pelosi, this policy brief advises the pursuit of the following three policy agendas: 1. fostering the continued spread of Medicaid expansion; 2. legislating drug price negotiation between Medicare/Medicaid and pharmaceutical manufacturers and their affiliates; and, 3. direct-to-consumer (DTC) advertising mitigation reforms, including requiring Medicare/Medicaid to conduct comparative effectiveness analysis between treatment options, followed by stratification of the cost of those treatments to consumers, based upon the relative benefits thereof (i.e., relatively low-benefit treatments would cost more and relatively high-benefit treatments would cost less). The rationale for these recommendations derives from political considerations, namely the extent to which these policy recommendations will acquire *public support* and the prospects of *political feasibility and sustainability*.

In constructing this policy brief, it is important to note that the Republican agenda was rejected. That agenda had included, for example, policy choices such as undermining the Patient Protection and Affordable Care Act (PPACA) by (1) directly fostering its repeal, or (2) indirectly weakening the protections of the PPACA, by restricting access to Medicaid by encouraging states to impose administrative obstacles upon relatively poor and struggling citizens who aspire to procure state Medicaid coverage. To its credit, parts of the Republican

agenda were quite compelling, such as recommending market-based reforms to pharmacy benefit managers (PBM's) in an effort to add transparency to a confusing and shrouded pharmaceutical marketplace. However, there were aspects of the Republican agenda that were quite disturbing, such as a limitless expansion of DTC advertising that would have permitted pharmaceutical companies to advertise drugs, without restriction, directly to consumers (under such a policy, manufacturers, for example, could market diabetes medications to consumers for weight loss, an unapproved use, which in turn, could lead to an unintended – albeit predictable – increase in adverse events associated with the use of these drugs, such as necrotizing fasciitis of the perineum, also known as Fournier's gangrene).[i]

In addition to rejecting the Republican agenda, Democratic alternatives were also rejected. A policy endorsing importation of drugs from Canada was rejected, as was a Medicare-for-All policy, which would have supplanted the PPACA in its entirety. Drug importation from Canada was rejected because it would be unsustainable in the long run and because it amounts to a defeatist admission that the United States lacks the ability to legislate (and thus must avail itself of a superior Canadian drug pricing regime). Medicare-for-All was rejected not because it is a poor policy choice *per se*, but rather because it is most likely politically impossible at this point in time, as Medicare-for-all would demand a nearly insurmountable expense of political capital (and require significant ancillary policy reforms and major structural insurance marketplace changes).

I. WHY THE REPUBLICAN AGENDA WAS REJECTED OUTRIGHT

The Republican agenda was comparably less effective than the Democratic options elucidated in this brief, when evaluated in terms of (1) *improving health insurance/access to care*, (2) *cost containment*, and (3) *enhancing the quality/value of care*. The Republican policy

to repeal the PPACA would destabilize the insurance marketplace and reduce access to care. More than twenty million Americans have acquired health insurance since the enactment of the PPACA, mostly through expansion and subsidized health insurance.[ii] Republicans do not have meaningful alternatives to the PPACA, and, hence, stand to deprive millions of Americans of the access to healthcare extended to them through the PPACA. Both Trump's skeletal health insurance reform outline (establish high risk pools, allow interstate sale of health insurance, and expand the use of health savings accounts) and retired House Speaker, Paul Ryan's, plan (Trump's outline, plus tax credits in lieu of insurance subsidies, premium caps on preexisting conditions provided that consumers do not allow their insurance to lapse, and medical malpractice reform) project to deprive millions of Americans of health insurance.[iii] Furthermore, Republicans, who failed to pass the American Health Care Act of 2017,[iv] do not have a viable path to enact reform, having lost control of the House of Representatives in the 2018 midterm election, with House Minority Leader Kevin McCarthy explicitly attributing the GOP stance on health care to the loss of 40 House seats and unified control of Congress.[v] In other words, Republicans lack both the votes and the political will to reform health care by targeting legislative efforts at the PPACA.

The Republican plan to undermine Medicaid by encouraging work restrictions would also reduce access to health care. Kentucky estimates that its own work restriction §1115 Medicaid waiver would result in 95,000 people losing Medicaid coverage, leaving it vulnerable to legal challenges of contradicting the legislative intent of §1115 waivers.[vi] Moreover, the winds of public opinion have shifted; most Americans now support the expansion (and not the contraction) of Medicaid.[vii]

Another Republican option that was soundly rejected was an attempt at cost control by tinkering with the complex arrangements between insurance companies, pharmaceutical benefit managers (PBMs) and patients. The reason this plan was rejected was because this plan has not been clearly articulated or sufficiently studied, relegating observers to pure speculation about what the actual ramifications of these malformed policies might be.[viii] The difficulty Republicans already have articulating the mechanisms and consequences of such market tinkering is likely not a winning political platform-level issue, as Americans historically pay limited attention to policymaking – even more so, when the media does not cover an issue extensively (as is likely here given the current struggle Republicans are having in framing "PBM market tinkering" to the American public).[ix]

Unconstrained DTC advertising was rejected because it is not believed that such a policy would enhance consumers' ability to make informed decisions. Consequently, the quality of care would not be increased. Historically, direct to consumer advertising has provided low quality information that failed to support therapeutic claims with data, did not quantify the risks of those therapies, and coaxed consumers into unapproved drug uses.[x] Instead of steering consumers toward informed health decisions, DTC advertising serves primarily to increase demand for advertised drugs (expensive brand name drugs), which in turn increases the cost of prescription drugs.[xi] Given the particular consumer susceptibility to pharmaceutical influence campaigns, it is likely that the unchecked expansion of DTC advertising would exacerbate the problem of manipulating consumers into making uninformed choices, as opposed to fostering rational, informed drug choice decision-making.[xii] As behavioral economists, Richard Thaler and Cass Sunstein, write, in their book *Nudge*, "[t]he key point here is that for all their virtues, markets often give companies a strong incentive to

cater to (and profit from) human frailties, rather than to try to eradicate them or to minimize their effects."[xiii] For the reasons articulated in Section I, the Republican agenda was rejected in favor of a subset of Democratic options.

II. FOSTERING THE CONTINUED SPREAD OF MEDICAID

The drafters of the PPACA had originally contemplated an expansion of Medicaid to all states, which would have provided access to healthcare for all low-income adults, up to 138% of the federal poverty level, with provisions for federal funds matching, stabilized at 90%, beginning in 2020.[xiv] However, the John Roberts court held, in *NFIB v. Sebelius*, that requiring all states to expand Medicaid or forfeit the entirety of their federal Medicaid funding was unconstitutional, pursuant to the coercion doctrine.[xv] The case for expansion is compelling, with even the conservative-leaning Commonwealth Fund staunchly advocating expansion as a rational policy states can use to save money (by reducing spending on uncompensated care as uninsured people gain coverage, which is heavily subsidized by the federal government through multiple layers of PPACA matching funds and health program subsidies), increase coverage, and generate jobs and economic growth due to a healthier workforce.[xvi] Currently, thirty-six states, plus the District of Columbia, have expanded Medicaid coverage to adults at 138% of the federal poverty guideline.[xvii] Twenty-four of those states, plus the District of Columbia, had expanded Medicaid coverage at the first opportunity on January 1, 2014. Michigan and New Hampshire expanded Medicaid at later dates in 2014; Pennsylvania, Indiana, and Alaska expanded Medicaid in 2015; Montana and Louisiana expanded Medicaid in 2016; Virginia and Maine expanded Medicaid in 2019; and Idaho, Nebraska, and Utah have all recently expanded Medicaid but have not yet provided a date for their expansions to take effect.[xviii] The delayed Medicaid expansion in conservative states can

be explained by persistent opposition from conservatives, primarily on account of partisanship and heuristics (i.e., using cognitive shortcuts to evaluate information, such as trusting people in positions of authority—e.g., elected representatives).

However, the partisan opposition has dissipated over time when voters have spoken on the issue directly. Notably, in the 2018 general election, citizens in predictably conservative states, empowered to participate in direct democracy via the ballot referenda processes of Utah, Idaho, Nebraska, and Montana*, recognized that the value of expanding Medicaid with federal funds outweighed the costs of not doing so and overrode the objections of their elected officials.[xix] Moreover, the support for expansion was robust in the 2018 midterm election. Utah voters passed Proposition 3 with 54% of the vote; Nebraskans supported Initiative 427 with 53% of the vote; and 62% of Idaho voters voted to expand Medicaid through Proposition 2.[xx] To underscore how conservative these states are: Utah is the second most conservative state in the country with the second highest percentage of Republican/lean Republican voters at 54% of the electorate; Idaho is tied for sixth at 49% of the electorate; and Nebraska is the ninth most conservative state by this metric at 47%.[xxi]

It is eminently possible that Medicaid expansion will occur in nearly half of the holdout states that have not expanded Medicaid on or by the 2020 general election. Of the fourteen remaining states that have not expanded Medicaid, six states allow for ballot referenda in some capacity.[xxii] Two, in particular, stand out - South Dakota and Wyoming. These two states are surrounded by a combined eight states, which have now all expanded Medicaid.[xxiii] Furthermore, four of those contiguous states voted to expand Medicaid in 2018, indicating growing momentum for expansion and the waning of partisan recalcitrance.[xxiv] (The other four ballot referenda states are Florida, Mississippi, Missouri, Oklahoma.)

Though Wisconsin does not allow ballot referenda, the Badger state is also worth mentioning. Wisconsin currently covers all adults up to 100% of the poverty line, pursuant to a 2014 partial expansion of Medicaid, and is commendable compared to the other thirteen states that allow adults in poverty to go without health insurance.[xxv] However, partial expansion has not generated the benefits promised; a conversion to full expansion would increase coverage by 80,000 adults and generate net taxpayer savings of $190 million. Additionally, in 2018, Wisconsin voters elected Democratic Governor, Tony Evers, who has already signed two executive orders to expand Medicaid (a policy which is supported by over 60% of the electorate), and has embraced vitriolic confrontation with the GOP legislature.[xxvi] The combined pressure of the partial expansion of Medicaid in 2014, with the progressive battle plans of Tony Evers may tip Wisconsin into expansion because the GOP legislature will need to prioritize its own strategic platform and would fear the opprobrium of losing its own "Battle of the Little Bighorn" to defend $190 million in foregone taxpayer savings to deny 80,000 Wisconsinites health insurance.[xxvii]

A case study in federalism is useful here. Adults now have the right to marry consenting adults, regardless of gender, because the Gay Marriage movement, in 2004, inspired by the incremental civil rights movement strategy, coalesced upon incremental legislative and judicial victories at the state level, to be achieved by gradually building public support among the "moveable middle," a constituency that was uncomfortable with gay marriage, although ultimately receptive to arguments based on equality and antidiscrimination.[xxviii] The movement's 2004 "Winning Marriage" strategy was a "strategic communications success story, taking an issue that elicited both confusion and strong disapproval and – over two

decades – changing millions of minds."[xxix] Expanding access to healthcare for poor people assuredly faces fewer public relations challenges than gay marriage.

III. WHY MEDICARE FOR ALL WAS REJECTED

Medicare-for-All, supported by 70% of the American public and likely supported by a current majority of the House of Representatives, in contrast to the incremental Medicaid expansion advocated above, is a broad, sweeping – and losing – proposition.[xxx] Medicare-for-All is essentially a reincarnation of the public option, an enchanting Siren that has tempted many a shipful of eager Democrats, only to cast those ships asunder against the cliff. Leading healthcare thinkers convened at Berkeley in 2001-02 to create the CHOICE proposal.[xxxi] CHOICE stood to establish a health insurance marketplace exchange (c.f., the exchanges of the PPACA) and, crucially, a public option that would reimburse providers at Medicare's reimbursement rates.[xxxii] The Lewin Group projected that 64% of Californians would participate in the exchanges and that 32% of those participants (11 million people) would enroll in the public option.[xxxiii] Californians never warmed to the CHOICE plan, however, and it never became law.[xxxiv] The Robert Wood Johnson Foundation resurrected the CHOICE plan a year later, as a national policy recommendation that would task individual states with creating and administering a public option as part of incipient exchange marketplaces.[xxxv] Failing to garner much interest, the public option quietly returned to its crypt until 2007, when John Edwards unveiled his own CHOICE-inspired public option plan during the early stages of the Democratic primaries.[xxxvi] Jacob Hacker of Yale debuted a similar plan two weeks prior, which involved a federal public option for individuals and employers that resembled an expansion of Medicare.[xxxvii] Hillary Clinton and Barack Obama debuted plans with public options later that same year.[xxxviii] On November 7, 2009, House Democrats passed the Affordable Health Care

for America Act, H.R. 3962, which included a public option.[xxxix] That same month, Senator Joe Lieberman tolled the public option's death knell when he threatened to filibuster, following an internecine autumn of Democratic brawling over the public option and its related policy scions.[xl]

Following Massachusetts Senator Ted Kennedy's death and the election of Republican Scott Brown, Democrats lost their sixty-vote super majority and modified efforts to pass health reform legislation in the traditional manner. Instead, the Democrats sent two bills (House Bill 3590 and House Bill 4872) to President Obama for signature, with H.B. 3590 passed under traditional Senate parliamentary procedures and H.B. 4872 passed under budget reconciliation, an alternative single-use legislative process, which permits bills affecting spending or taxing only to avoid a Senate filibuster, subject to the Byrd rule (prohibiting extraneous matters in reconciliation bills not affecting spending or taxing), and subject to preordained instructions in the Annual Congressional Budget Resolution.[xli] In theory, a unified Democratic party could have passed health reform that included a public option.

On Christmas Eve of 2009, the Senate, in a 60-39 vote, approved H.B. 3590, originally named the Service Members Home Ownership Tax Act of 2009.[xlii] The bill had been amended to include much of the text that became the PPACA, including an amendment formally changing the name of H.B. 3590 to the Patient Protection and Affordable Care Act.[xliii] On March 21, 2010 the House of Representatives passed H.B. 3590, sending it to President Obama for signature, and on March 25, 2010 the House and Senate both voted to send H.B. 4872 to President Obama for signature.[xliv] Neophytes who are smitten with the public option and wish to embark on a similar legislative odyssey should heed John Cannan's explication of the modern legislative process:

> "Th[e three-minute *School House Rock* cartoon—"I'm Just a bill"] conception of legislative history has been the standard for decades and continues to be how the practice is taught in law schools today. While a convenient generalization in many cases, it no longer reflects the modern process of lawmaking, and sole reliance upon it may now be more misleading than it is helpful.
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> Passing legislation has always been a procedural chess game where proponents try to move bills through both chambers while opponents attempt to kill or delay them. . . . [A]s Congress has been buffeted by political, social, and technological forces— 'hyper-partisanship,' the intense scrutiny of the 24-hour news cycle, deficits, the demands of campaign finance, and social media—the paradigm has shifted more dramatically away from the traditional model."[xlv]

Medicare-for-All is not politically feasible in 2018 and is likely to encounter a veritable minefield of procedural obstacles, even if Democrats acquired a 2020 Senate majority and even if Democrats found a way to use budget reconciliation for aspects of a proposal.

IV. DRUG PRICE NEGOTIATION REFORM

Repealing 2003 Medicare drug price negotiation restrictions is likely to enjoy broad public support from the electorate and to have immediate ramifications on pricing, despite the protestations of the prescription drug industry. In 2003, Congress enacted prescription drug coverage via Medicare Part D and simultaneously prohibited Medicare from negotiating drug prices with prescription drug manufacturers, which has ultimately catalyzed the inflation of prices Medicare pays for prescription drugs.[xlvi] Currently, according to a 2018 Kaiser Family Foundation Poll, 92% of Republicans, 92% of Independents, and 96% of Democrats supported allowing the federal government to negotiate drug prices for Medicare beneficiaries.[xlvii] Additionally, there is growing legislative momentum for reform, as state governments have already begun enacting prescription drug price control laws.[xlviii]

Drug price increases are not driven by innovation, but instead by year-over-year price increases of drugs already on the market.[xlix] Medicare, alone, counts for 29% of national retail pharmacy spending on prescription drugs.[l] Because Medicare is not able to negotiate the prices

of prescription drugs, Medicare pays more for prescription drugs than other government programs, which are allowed to do so. A study from Public Citizen found that Medicare pays 80% more for prescription drugs than the Veteran's Health Administration and 73% more for prescription drugs than Medicaid; and if Medicare could negotiate to pay the same prices, it would save from $15.2 billion to $16 billion each year.[li] Another study from the Journal of General Internal Medicine found that if Medicare could negotiate drug prices, Medicare would save $21.9 billion per year (notably, with a 95% confidence of interval of $21.1 billion to $22.8 billion).[lii] Internationally, the narrative is the same. Medicare pays 198% of the median cost of what 31 OECD countries pay for the same drugs (when factoring in price adjustments).[liii]

There is a glut of misinformation on the reasons Medicare pays a premium for prescription drugs, including from the pharmaceutical industry, which is not a reliable source to consult for arguments against repealing the prohibition against negotiation. For example, Kimberly Leonard's *Not Up for Negotiation* report is glaringly incorrect on one justification for high drug prices:

> "One reason drug prices can be high is that pharmaceutical companies have several years of patent exclusivity to medicines before other companies are allowed to develop generics, which use the same drug recipe but are marketed at a cheaper price. This is meant to incentivize drug companies to invest in developing new medicines, but it also limits negotiators' power."[liv]

Kimberly Leonard fails to consider that the pharmaceutical patent regime is not a unique feature of the United States market, nor is it a unique feature of the market Medicare engages in to buy prescription drugs. The United States is bound under international law, as one of 162 nation-state parties, to the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which mandates that all countries extend patents for a period of twenty years from the date of filing.[lv] Leonard's article also quotes

PhRMA spokeswoman, Ally Funk, who bizarrely justifies prohibiting a free market by arguing that the market is simply free enough:

> "The drug industry says Medicare's partnership with private insurance allows the system to operate as it should with the use of free-market principles that encourage competition – resulting in spending that is $346 billion beneath budget projections. 'What's commonly missed in the debate is that there is already substantial negotiation,' says Ally Funk, a spokeswoman for PhRMA."

Funk fails to clarify what she means when she appeals to "free-market principles" to justify a ban on the orthodox free market principle of negotiation between buyers and sellers. Funk is unpersuasive when she claims "there is already substantial negotiation" as the 2003 non-interference clause precludes negotiation.[lvi] For the above reasons, policymakers should embrace reinstating Medicare's prescription drug negotiation power as an effective means of cost containment.

V. WHY PRESCRIPTION DRUG IMPORTATION FROM CANADA WAS REJECTED

Despite support from 72% of Americans, the plan to allow importation of prescription drugs from Canada is a deeply flawed suggestion that does not address the root cause of why prescription drugs in the United States are so expensive and fails to account for the ramifications of a nationwide policy endorsing importation.[lvii] In isolation, some geographically proximate consumers may travel to Canada to buy drugs and take advantage of an arbitrage opportunity. Still others may import drugs through the mail as postal inspectors turn a blind eye.

If the United States were to enact legislation permitting this opportunity, Canada would most likely experience drug shortages.[lviii] Pharmaceutical companies would not have an incentive to increase their supply of drugs to Canada so that U.S. consumers could divert those drugs into the United States in order to avoid paying higher U.S. prices. It is not so easy to

pull the wool over the eyes of PhRMA, so to speak. There is nothing to prevent Canada from enacting a retaliatory law to ban U.S. importation of Canadian drugs, in order to safeguard prescription drugs for the Canadian public. Lastly, the FDA lacks the resources to oversee an importation program of this magnitude.[lix] In other words, should Canadian importation be permitted, there is no guarantee that the regulations and resources to enact importation would be in place. A policy that works for an individual consumer here and there is not necessarily a good policy for a nation of 330 million.

A. Comparative Effectiveness Analysis & Cost Stratification of Treatments to Consumers

Comparative Effectiveness analysis is a paternalistic, though prudent, policy to correct consumer preferences that have become distorted from direct to consumer prescription drug advertising. The classic case study of how these distortions work is how AstraZeneca transferred 40% of Prilosec patients to Nexium in 2001 with a $500 million DTC advertising campaign when its patents expired on Prilosec and generic entrants came onto the market.[lx] Nexium and Prilosec, for all intents and purposes, are the same drug, being entantiomers (essentially molecular mirror images); Nexium is an optical isomer of Prilosec.[lxi] AstraZeneca's 2001 $500 million DTC advertising campaign helped lead to a decade that saw $48 billion in profits.[lxii] Rational consumers would have taken the Prilosec generic had they had an opportunity to evaluate the benefits of generic Prilosec versus its optical isomer, Nexium. However, few consumers are this sophisticated, and it should go without saying that most Americans are not sufficiently adept in the chemistry of entantiomers and optical isomers to conduct this kind of comparative effectiveness analysis.

Comparative effectiveness analysis is not new to the American healthcare system. In 2009, Congress passed the American Recovery and Reinvestment Act, which allocated $1.1 billion for comparative effectiveness analysis.[lxiii] In 2010, the PPACA established the Patient-Centered Outcomes Research Institute (PCORI), funded with $1.26 billion from 2010-2019.[lxiv] Beyond disseminating information to the public about the relative effectiveness of medical treatments, comparative effectiveness analysis has also been used to conduct trials, synthesize evidence from different sources, and establish patient registries to extract data on outcomes.[lxv] Democrats would be wise to emphasize both the difficulties consumers have in assessing comparative effectiveness on their own, as well as the potential synergies that such analysis creates.

Cost stratification is also not a new concept. Instead, it is the corollary that follows comparative effectiveness analysis. Drug formularies stagger prices for drugs, depending upon some combination of efficacy and cost. Insurance plans, particularly PPO's, charge consumers higher prices to see out of network medical providers, with whom the insurer was unable to negotiate a lower price or who may yield poorer treatment outcomes than in-network providers. Comparative effectiveness analysis and resultant stratification, while paternalistic, are appropriate means of improving quality and value of care for Americans, who are typically not sophisticated enough to routinely make optimal decisions.

CONCLUSION

By pursuing a pragmatic strategy of Medicaid expansion, Democrats would optimize access to healthcare. The alternative, Medicare-for-All was rejected because it is likely saddled with unanticipated legislative obstacles and its benefits are more speculative. A policy of repealing the prohibition on Medicare negotiation with prescription drug manufacturers was

also chosen over a policy of importing drugs from Canada. The proposal to allow Medicare to negotiate with prescription drug manufacturers was deemed likely to yield cost savings, based upon a comparison to alternative federal agencies that were allowed to negotiate and based upon international comparisons to OECD countries. The arguments of the pharmaceutical industry were rejected as unpersuasive and internally inconsistent. The Canadian importation policy was rejected because it failed to consider the repercussions of scaling up an unsanctioned policy of a handful of free riders into a bona fide national policy, supported with sufficient regulatory, financial, and personnel resources.[lxvi] Lastly, a policy of comparative effectiveness analysis and resultant cost staggering was resoundingly endorsed as a libertarian paternalistic hedge against consumer naiveté.

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[i] U.S. Food & Drug Admin., *FDA Warns About Rare Occurrences of a Serious Infection of the Genital Area with SGLT2 Inhibitors for Diabetes* (Aug. 29, 2018).

[ii] Jonathan Oberlander, *The End of Obamacare*, 376 N. ENG. J. MED. 1, 2 (Jan. 5, 2017).

[iii] *Id.* "None of the handful of policies Trump has proposed would do anything meaningful to restore the access to health insurance that repealing the Affordable Care Act would take away from millions of Americans."

[iv] H.R. 1628, 115th Cong. (2017).

[v] *See, e.g.*, Mike DeBonis, *McCarthy Blames Republican Loss of House Majority on GOP Health Care Bill*, WASH. POST, Feb. 12, 2019, https://www.washingtonpost.com/powerpost/mccarthy-blames-republican-loss-of-house-majority-on-gop-health-care-bill/2019/02/12/651e967a-2eed-11e9-813a-0ab2f17e305b_story.html?noredirect=on&utm_term=.cb2795f08100.

[vi] Eliot Fishman, *Medicaid Waivers Restricting Adult Eligibility: A Legal and Political Update*, HEALTH AFFAIRS, Jan. 24, 2019 (Blog); Andrew Hennessy-Strahs, Work Requirements for Medicaid: What Does that Really Mean?, THE HENNESSY CENTER FOR LAW & HEALTH, Jan. 14, 2018, http://hennessycenter.org/work-requirements-for-medicaid-what-does-that-really-mean/

> "Because of the cost of Medicaid and because of political ideologies, some states and government officials would like to change how Medicaid is administered. They can do this by requesting what are known as '1115 waivers.' The Medicaid website describes these waivers as giving 'the Secretary of Health and Human Services authority to approve experimental, pilot, or demonstration projects that are found by the Secretary to be likely to assist in promoting the objectives of the Medicaid program.'
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> . . .
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> We can expect more states to file for 1115 waivers to add work requirements. We can also expect legal challenges to these waivers."

[vii] Colleen Grogan and Sunggeun Park, *The Politics of Medicaid: Most Americans Are Connected to the Program, Support Its Expansion, and Do Not View It as Stigmatizing*, 95 THE MILBANK QUARTERLY 749 (2017).

[viii] Rachel Sachs, *Trump Administration Releases Long-Awaited Drug Rebate Proposal*, HEALTH AFFAIRS, Feb. 1, 2019 (Blog)

> "Yesterday, the Trump Administration released a proposed rule, which aims to eliminate rebates from pharmaceutical companies to pharmacy benefit managers (PBMs) in Medicare Part D and in Medicaid managed care organizations.
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> . . .

Potential Implications

One particularly striking feature of the proposed rule is the level of uncertainty the administration has about its effects."

[ix] Mark Schlesinger, *Public Opinion* (Ch. 15), 219.

[x] Kristina Klara, *Direct-to-Consumer Broadcast Advertisements for Pharmaceuticals: Off Label Promotion and Adherence to FDA Guidelines*, 33 J INTERNAL MED. 651, 657.

[xi] *Id.*

[xii] *Id.*

[xiii] RICHARD THALER & CASS SUNSTEIN, NUDGE 74 (Penguin Books, Revised & Expanded ed., 2009).

[xiv] See, e.g., Daniel Béland, Philip Rocco, Alex Waddan, *Implementing Health Care Reform in the United States: Intergovernmental Politics and the Dilemmas of Institutional Design*, 116 HEALTH POLICY 51, 55 (2014)

> "In its original form, the ACA planned a major expansion of the Medicaid program so that anyone with an income below 138 percent of the federal poverty line would qualify for that program. The law did this by placing the federal government at the center of the proposed expansion in a manner that effectively would have left the states little option but to co-operate in this significant reshaping of Medicaid, which historically was a program that had left the states with some discretion about whom to cover within a framework of federally mandated minimum standards."

[xv] NFIB v. Sebelius, 567 U.S. __, 58-59 (2012).

> "The Affordable Care Act is constitutional in part and unconstitutional in part. The individual mandate cannot be upheld as an exercise of Congress's power under the Commerce Clause. That Clause authorizes Congress to regulate interstate commerce, not to order individuals to engage in it. In this case, however, it is reasonable to construe what Congress has done as increasing taxes on those who have a certain amount of income, but choose to go without health insurance. Such legislation is within Congress's power to tax.
>
> As for the Medicaid expansion, that portion of the Affordable Care Act violates the Constitution by threatening existing Medicaid funding. Congress has no authority to order the States to regulate according to its instructions. Congress may offer the States grants and require the States to comply with accompanying conditions, but the States must have a genuine choice whether to accept the offer. The States are given no such choice in this case: They must either accept a basic change in the nature of Medicaid, or risk losing all Medicaid funding. The remedy for that constitutional violation is to preclude the Federal Government from imposing such a sanction. That remedy does not require striking down other portions of the Affordable Care Act."

[xvi] Susan Hayes, et al., *The Fiscal Case for Medicaid Expansion*, THE COMMONWEALTH FUND (Feb. 15, 2019), https://www.commonwealthfund.org/blog/2019/fiscal-case-medicaid-expansion.

[xvii] Kaiser Family Foundation, *Status of State Action on the Medicaid Expansion Decision*, Feb. 13, 2019, https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D. Note, the matching rate debuted at 100% and transitioned through phases to 90%.

[xviii] *Id.*

[xix] Amy Goldstein, *Three Deep Red States Vote to Expand Medicaid*, WASH. POST, Nov. 7, 2018, https://www.washingtonpost.com/national/health-science/three-deep-red-states-vote-to-expand-medicaid/2018/11/07/6586ae58-e1dc-11e8-ab2c-b31dcd53ca6b_story.html?utm_term=.3992df6a7ced.
*Although Montana temporarily expanded Medicaid in 2016, voters in 2018 made Medicaid expansion permanent

[xx] *Id.*

[xxi] Pew Research Center, *Party Affiliation by State (2014)*, PEW FORUM (2019), http://www.pewforum.org/religious-landscape-study/compare/party-affiliation/by/state/.

[xxii] National Conference of State Legislatures, *Initiative and Referendum States*, 2019, http://www.ncsl.org/research/elections-and-campaigns/chart-of-the-initiative-states.aspx.

[xxiii] Kaiser Family Foundation, *Status of State Action on the Medicaid Expansion Decision*, Feb. 13, 2019, https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[xxiv] Idaho, Nebraska, Utah, Montana (which voted to make the 2016 expansion permanent).

[xxv] Jon Peacock, *Wisconsin's Partial Medicaid Expansion Covers Far Fewer People at Much Greater Cost*, GEORGETOWN UNIVERSITY, CENTER FOR CHILDREN & FAMILIES (Jan. 5, 2018),

https://ccf.georgetown.edu/2018/01/05/wisconsins-partial-medicaid-expansion-covers-far-fewer-people-at-much-greater-cost/.

[xxvi] *Evers Issues Limited Health Care-Related Executive Orders*, US NEWS & WORLD REPORT (Jan 8, 2019), https://www.usnews.com/news/best-states/wisconsin/articles/2019-01-08/evers-issues-limited-health-care-related-executive-orders; *Tony Evers Seems to Be Following Scott Walker's Playbook*, THE ECONOMIST (Mar. 7, 2019), https://www.economist.com/united-states/2019/03/09/tony-evers-seems-to-be-following-scott-walkers-playbook.

[xxvii] *See*, *Tony Evers Seems to Be Following Scott Walker's Playbook*, THE ECONOMIST (Mar. 7, 2019), https://www.economist.com/united-states/2019/03/09/tony-evers-seems-to-be-following-scott-walkers-playbook (discussing the possible concession of Republicans on Medicaid expansion to prioritize other policy ambitions).

[xxviii] John F. Kowal, *The Improbable Victory of Marriage Equality*, THE BRENNAN CENTER FOR JUSTICE (Sep. 29, 2015), https://www.brennancenter.org/analysis/improbable-victory-marriage-equality.

[xxix] *Id.*

[xxx] Sanjay Kishore, et al., *What Do the Midterms Mean for Medicare for All?*, HEALTH AFFAIRS (blog), Dec. 3, 2018.

[xxxi] Helen Halpin & Peter Harbage, *The Origins and Demise of the Public Option*, 29 HEALTH AFFAIRS 1117, 1118 (June 2010).

[xxxii] *Id*.

[xxxiii] *Id.*

[xxxiv] *Id.*

[xxxv] *Id*.

[xxxvi] *Id.*

[xxxvii] *Id.*

[xxxviii] *Id.*, at 1119.

[xxxix] *Id.*

[xl] *Id.*

[xli] Sarah A. Binder, *Reconciliation in the Senate*, THE BROOKINGS INSTITUTION, Jan. 25, 2010, https://www.brookings.edu/opinions/reconciliation-in-the-senate/.

[xlii] John Cannan, A Legislative History of the Affordable Care Act: How Legislative Procedure Shapes Legislative History, 105 LAW LIBRARY J. 158 (2013), http://liblog.law.stanford.edu/wp-content/uploads/2013/05/A-Legis-Hist-of-ACA-How-Legis-Proced-Shapes-Legis-Hist-Spring-2013.pdf.

[xliii] *Id.*, at 134, 158.

[xliv] *Id.*, at 165-67.

[xlv] *Id.*, at 132-33.

[xlvi] *See, e.g.*, Kimberly Leonard, *Not Up For Negotiation*, US NEWS & WORLD REPORT, Feb. 26, 2016.

[xlvii] Juliette Cubanski, *Searching for Savings in Medicare Drug Price Negotiations*, KAISER FAMILY FOUNDATION, Apr. 26, 2018, https://www.kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/.

[xlviii] Andrew Hennessy-Strahs, *How States Are Targeting High Prescription Drug Prices*, THE HENNESSY CENTER FOR LAW & HEALTH, Mar. 3, 2018, http://hennessycenter.org/states-targeting-high-prescription-drug-prices/.

[xlix] Alison Kodjak, *Prescription Drug Costs Driven by Manufacturer Price Hikes, Not Innovation*, NPR, Jan. 7, 2019, https://www.npr.org/sections/health-shots/2019/01/07/682986630/prescription-drug-costs-driven-by-manufacturer-price-hikes-not-innovation.

[l] Juliette Cubanski, *Searching for Savings in Medicare Drug Price Negotiations*, KAISER FAMILY FOUNDATION, Apr. 26, 2018, https://www.kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/.

[li] Marc-André Gagnon, *Mirror, Mirror on the Wall: Medicare Part D pays needlessly high brand-name drug prices compared with other OECD countries and with U.S. government programs*, PUBLIC CITIZEN, July 23, 2015, https://www.citizen.org/sites/default/files/2269a.pdf.

[lii] Walid Gellad, et al., *What if the Federal Government Negotiated Pharmaceutical Prices for Seniors? An Estimate of National Savings*, J. GEN. INT. MED., Jun. 26, 2008, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2517993/pdf/11606_2008_Article_689.pdf.

[liii] Marc-André Gagnon, *Mirror, Mirror on the Wall: Medicare Part D pays needlessly high brand-name drug prices compared with other OECD countries and with U.S. government*.

[liv] Kimberly Leonard, *Not Up For Negotiation*, US NEWS & WORLD REPORT, Feb. 26, 2016.

[lv] WTO, AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS [hereinafter TRIPS].

> "Article 33
> Term of Protection
> The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date[.]"

[lvi] 42 U.S.C. § 1395w-111(g)(i)
[lvii] KFF Health Tracking Poll, KAISER FAMILY FOUNDATION, Apr. 17-23, 2017.
[lviii] *See, e.g., Nigel Rawson*, Importation of Drugs into the United States from Canada, CAMJ, 2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478407/pdf/189e817.pdf.
[lix] *Id.*
[lx] Jon Hess, *Battle for the Market: Branded Drug Companies' Secret Weapons Generic Drug Makers Must Know*, 3 J. GENERIC MED., Oct. 2005, http://plg-group.com/wp-content/uploads/2014/03/Branded-drug-companies-secret-weapons-Jon-Hess-March-05.pdf.
[lxi] Josh Bloom, *Nexium: The Dark Side of Pharma*, AM. COUNCIL ON SCIENCE AND HEALTH, Jan. 18, 2017, https://www.acsh.org/news/2017/01/18/nexium-dark-side-pharma-10546.
[lxii] *Id.*
[lxiii] *See, e.g.* Riaz Ali, Comparative Effectiveness Research in the United States: A Catalyst for Innovation, J. AM. HEALTH DRUG BENEFITS, Mar. 2011, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4106578/pdf/ahdb-04-068.pdf.
[lxiv] *Id.*
[lxv] *Id.*
[lxvi] It should be noted, that PDUFA helps fund the FDA with user fees from the Pharmaceutical industry, and, in turn, gives the Pharmaceutical industry leverage over the FDA. It is foreseeable that the Pharmaceutical industry would use this leverage to persuade the FDA to object to policies that would lower their profits.