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A Pro-Growth Agenda for the 117th Congress

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American consumers benefit from a bounty of choice, competition, and innovation in health care. Nevertheless, America's health care system is plagued by rapidly rising costs, inconsistent quality, and a lack of patient control. Moreover, persistent access and affordability limitations have led policy makers to adopt a series of funding and regulatory measures during the past six decades that have substantially increased government involvement in the health care sector. Ironically, that has exacerbated cost inflation, restricted choice and competition, dampened innovation, and shifted increasingly greater control over health care choices into the hands of governments and health insurers. Yet many advocates and policy makers continue to demand even greater government control.

The cure for America's health care system does not lie in additional increases in government involvement, but in policies that put more control over health care spending in the hands of patients, regulatory approaches that permit and reward innovation and competition, and deregulation of the market for health services, health care technology, and health insurance. Policy makers should embrace dynamic, market-oriented reforms that leverage technology, competition, and innovation to increase health care quality while reducing costs.

PERMANENTLY REPEAL FEDERAL RULES THAT HINDER OR FORBID TELEMEDICINE AND TELEHEALTH

Telemedicine and telehealth—the use of electronic and telecommunication tools by health care professionals to evaluate, diagnose, and treat patients remotely, or by patients themselves to monitor their own health and well-being—have grown in popularity in recent decades. Many health services cannot be provided remotely, but when only consultation is needed, telemedicine can improve access to health specialists located in distant parts of the country, increase convenience for patients who no longer need to travel to a health care provider's physical office, and lower health expenditures by reducing overhead costs and increasing the number of patients a provider can serve.

Congress should:

- Permanently repeal federal rules that hinder or forbid telemedicine and telehealth, including:
  - Medicare and Medicaid reimbursement policies that require in-person consultations.
  - Medicare regulations that specify the types and location of facilities where health services may be provided.
  - Medicare and Medicaid rules that prevent health care providers licensed in one state from offering care to patients in another.
  - Patient privacy and data security rules promulgated under the Health Insurance Portability and Accountability Act (HIPAA).

Telemedicine has become especially useful during the COVID-19 pandemic, as social distancing and concerns about transmission fueled a surge in demand for remote health care consultations. Initially, a number of state and federal policies had hindered the use of telehealth and made it more costly for providers and patients. Many of those policies have been temporarily suspended during the pandemic to ease burdens on health care facilities and to make it easier for patients to stay at home. But easing such restrictions is useful not only during a pandemic. With that in mind, Congress, federal regulators, and state governments should permanently repeal any of the suspended rules that are not clearly necessary to protect patients.

Among the most significant barriers to telemedicine are rules that implicitly forbid its use by requiring the in-person provision of certain health services. For example,

state licensing and scope-of-practice laws often require conducting initial patient consultations in person, as do various Medicare and Medicaid reimbursement policies. Medicare regulations often specify the types and location of facilities where health services may be provided, which tend to preclude remote consultations. And state medical licensing rules, along with Medicare and Medicaid rules, can prevent health care providers licensed in one state from offering care to patients in another, making some telehealth services less useful or practical.

Perhaps the most significant restrictions on telehealth services are patient privacy and data security rules promulgated under HIPAA. Those rules require the following:

- That the technologies health professionals use when providing remote services meet strict standards for health data protection;
- That secure permanent storage of any medical data shared during the telehealth consultations is provided; and
- For health care professionals to have a binding Business Associate Agreement with any third-party platform that shares or stores health information, under which the technology platform assumes legal responsibility for specified privacy protection measures.

Those requirements make it unlawful or impractical to use many common communication tools, such as email, texting, instant messaging platforms, or video chat applications like Skype, Zoom, and FaceTime that are not viewed as sufficiently secure or with whom providers cannot obtain a Business Associate Agreement. Providers generally must select a less convenient and more expensive specialty product, and patients must download and use the telehealth application chosen by their providers.

In March 2020, the Department of Health and Human Services used its enforcement discretion to temporarily allow the use of otherwise noncompliant technologies and to waive various reimbursement and location-of-services rules that would preclude use of telehealth consultations. According to a survey of primary care and specialty providers by the health care consulting firm IQVIA, fewer than 10 percent of patient interactions were conducted via telehealth before COVID-19, but over 50 percent were conducted via telehealth during the month of April. Still, many providers expect use of telehealth services to return to near pre-pandemic levels once the COVID-19

public health emergency ends and HIPAA privacy rules and other restrictive regulations are reinstated.

Congress should act quickly to repeal or reform the various HIPAA, Medicare, and Medicaid rules that inhibit the broader adoption of telehealth services, and it should encourage state governments to act as well.

Experts: Gregory Conko, Joel Zinberg

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REJECT PRICE CONTROLS FOR PRESCRIPTION DRUGS

Prescription drug prices are a significant concern for many Americans, which makes them a popular target for lawmakers. So during the past three decades, Congress and nearly every presidential administration have proposed a range of policies intended to lower pharmaceutical prices. It is worth noting, however, that most Americans do not spend very much on prescription drugs. To the extent that a problem exists with high drug prices, it is a narrower one than often claimed. Therefore, such concerns should be addressed, not by imposing price controls or other heavy-handed measures that would inhibit the development of innovative new treatment options, but by removing obstacles to market access and allowing competitive pressures to help lower prices.

Congress should:

- Reject price controls for prescription drugs, including both express price caps and indirect price controls, such as:
  - Reimportation of drugs from countries that impose their own price controls.
  - Domestic reimbursement rates based on other countries' price controls.
  - Direct negotiation of prescription drug prices by Medicare and Medicaid.
  - Compulsory licensing of innovative drug patents.

In the United States, nine out of every 10 prescriptions are filled with generic drugs, which are much cheaper than their brand-name equivalents. And most Americans have prescription drug coverage as part of a private health insurance plan or as a benefit of their enrollment in government-run health programs, such as Medicare and Medicaid. So, the out-of-pocket expenditures for the average American who uses at least one prescribed drug ($143 per person in 2017) is far less than in many other industrialized nations and roughly on par with that in Canada ($144 per person). Very high prescription drug costs tend to be a problem only for patients who must take a large number of prescribed medicines, patients who suffer from complex chronic diseases, or patients who must take newly approved therapies that have no lower-priced alternatives.

It is not unusual for news headlines to deplore the launch of a new prescription drug with a seemingly exorbitant price tag. For example, in 2014 the hepatitis C drug Sovaldi was introduced at a price of $84,000 for a standard, 12-week treatment regimen. The

drug was the first therapeutic option that could actually cure hepatitis C for most patients, making it superior to the long-term chronic treatments it replaced—which themselves were more expensive than a course of Sovaldi. But politicians and patient advocates roundly condemned the drug's price, initiated investigations into the company's pricing decision, and called for price controls. Within three years, though, several other competing drugs had been introduced, some at prices less than one-third of Sovaldi's, thus forcing the price of all hepatitis C treatments downward sharply.

As the Sovaldi example shows, it is important that policy makers not lose sight of the tremendous value that innovative new medicines deliver. According to one empirical study, new medicines accounted for three-quarters of life expectancy gains in higher-income countries between 2000 and 2009. And expensive drugs that treat cancer, heart disease, and other life-threatening conditions are the main reasons for those gains. That is why health insurers are willing to pay seemingly high prices for prescription drugs.

Using price controls, caps, or other regulatory efforts to artificially bring down drug prices may produce modestly lower prices for some patients in the short term. But doing so would harm patients more than help them by short-circuiting the dynamic research-and-development process that has delivered a steady stream of innovative new treatments. In short, price controls would lead to fewer breakthrough treatment options in the future and would do significant harm to patient health.

The process of developing a new drug and bringing it to market is lengthy and expensive. It takes an average of about 12 years to get a new molecular entity from laboratory testing to final approval. Even then, only about 10 percent of the drugs that enter clinical trials are ultimately approved by the Food and Drug Administration. Including the costs of the drugs that are never approved, it takes an estimated $2.5 billion to get a new drug from the laboratory to the pharmacy. Even then, many of the drugs that are approved never become profitable. A 2018 Congressional Budget Office study concluded that drug companies need to make a profit margin of 62.2 percent on their successful drugs just to average a 4.8 percent rate of return on their entire portfolios.

It is not the case that drug prices are high because manufacturers must recoup the vast expense of research, development, testing, and the drug approval process. After all, many drugs are never profitable, but their manufacturers cannot raise prices because

purchasers (usually private insurance companies or the Pharmacy Benefit Managers that administrate prescription drug programs for insurers and large companies that self-insure) will pay only as much as the expected life-saving or health-enhancing value for prescription drugs. Drug makers will try to charge the highest price that will maximize revenue for their products, but institutional purchasers have negotiating clout and an incentive to pay the lowest prices possible. The prices eventually agreed to by the parties are determined by complex calculations that reflect the availability and cost of alternative treatments, including competing drugs; whether a medicine may reduce doctor visits, hospital admissions, and the use of other health care services; how many patients may want or need the medicine in question; and myriad other factors.

Ultimately, given very high development and approval costs, manufacturers cannot afford to lower prices because the revenues are necessary to incentivize investment in the next generation of pharmaceutical products—each of which has a low probability of success. So, imposing pharmaceutical price controls will inevitably lead to less medical research and development and, as a result, fewer new drugs reaching patients in the future.

For the reasons stated above, Congress should reject both express price caps and indirect price controls, such as legalizing the reimportation of drugs from countries that already impose price controls, domestic reimbursement rates based on other countries' price controls, direct negotiation of prescription drug prices by Medicare and Medicaid, and compulsory licensing of innovative drug patents.

Instead, Congress should take efforts to incentivize greater competition among pharmaceutical manufacturers by reducing the time and expense of bringing new prescription drugs to market, and by streamlining the generic drug approval process.

Experts: Gregory Conko, Joel Zinberg

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PROMOTE REAL HEALTH CARE PRICE TRANSPARENCY BY GIVING PATIENTS MORE INCENTIVE AND RESPONSIBILITY FOR HEALTH CARE CHOICES

Advocates of government involvement in the health care market have long argued that rising costs are an unavoidable part of any health care system because patients are incapable of making fully informed decisions about the care they receive. They claim patients lack the specialized knowledge needed to know which treatment options are necessary, so they seek and obtain unneeded health services.

In addition, health services are what economists call credence goods, meaning that, even knowledgeable patients generally cannot judge the quality of the care they receive until after the service is rendered.

Most importantly, private insurance plans—often chosen by employers or government health programs—pay the vast majority of health care expenses. That means that providers treat payers, not patients, as their true customers. Thus, patients generally are not given access to useful price or quality information and have little or no incentive to comparison shop.

Congress should:

- Promote real price transparency by giving patients more responsibility for health care choices, and therefore an incentive to demand and heed pricing information. Options to accomplish that include the following:
  - Encourage and facilitate the growth of high-deductible health insurance plans, coupled with generous health savings accounts.
  - Eliminate the tax preference for employer-sponsored health insurance plans, which put third parties in charge of selecting many health plan options.

Many policy makers propose to address the lack of price sensitivity among patients by putting more control over health care decision making in the hands of government and providing greater information to patients about health care price and quality. But while many health policy experts recognize that greater government involvement would separate patients and doctors even further, thereby jeopardizing health care

quality, nearly all believe that increasing price transparency would help combat rising costs. A number of recent policy changes—including elements of the Patient Protection and Affordable Care Act and Trump administration price disclosure regulations—have sought to make information about health care prices public, so patients can comparison shop for the best values.

Unfortunately, many of those attempts at increased price transparency have provided incomplete, out-of-context, or irrelevant information to patients that simply cannot empower them to make value-maximizing choices. Some proposed policies also violate constitutional free-speech protections. And they almost all suffer from a significant flaw that renders them incapable of controlling runaway costs.

As long as third-party payers—whether private insurance plans or government-run health programs—insulate patients from the financial cost of their health-purchasing decisions, they will have little incentive to maximize value because they reap the benefit of higher-quality care while the third-party payer bears most of the cost. A patient with a $150 co-pay or a $1,000 deductible has no clear or direct reason to care whether the hospital charges his or her insurance company $25,000 or $50,000 for a knee replacement surgery.

Recent efforts to force pharmaceutical drug manufacturers and hospitals to disclose prices suffer from all three of those defects. In 2019, for example, the Centers for Medicare and Medicaid Services (CMS) published a rule that would have forced television advertisements for prescription medicines covered under Medicare or Medicaid to disclose the products' "wholesale acquisition cost," which is the price at which manufacturers sell drugs to pharmacies, hospitals, and other providers. The rule could not require disclosure of the prices that consumers are actually charged for prescription drugs because those prices are controlled more by pharmacies than drug manufacturers. They also vary from patient to patient, sometimes substantially, and are influenced by co-pays, deductibles, and dozens of other variables. Because the CMS rule required disclosure of information that patients cannot act on directly, it could not reasonably have been expected to meaningfully influence comparative shopping behavior.

The rule was struck down by the U.S. District Court for the District of Columbia, which held that the CMS lacked statutory authority to promulgate it. But that only

served to revive interest in Congress for legislation to grant the CMS that power. Doing so would be pointless, however, as decades of court precedent make clear that neither private citizens nor businesses can be compelled to say or print things unless there is a substantial government interest in doing so. Because no viable mechanism exists through which the wholesale acquisition cost disclosure rule could achieve its stated goal of "empowering consumers to make better-informed decisions" and "slow[ing] the growth of federal spending on prescription drugs," such a poorly designed transparency requirement would almost certainly be struck down as unconstitutional.

Ironically, some economists believe that, in the absence of incentives to economize, price transparency may lead to higher spending if patients view higher prices as a sign of greater quality. If Congress genuinely wants to empower consumers to make meaningful, price-conscious, and value-maximizing health care choices, it must do two things: (a) ensure that consumers have access to price and quality information that is relevant to them individually as patients and (b) give them greater incentive to choose the value-maximizing option and greater responsibility for making health care choices.

Some policies that require price disclosures may be warranted, but only if they truly give patients information about the prices they pay directly. A more effective approach would be for Congress to minimize the role of third-party payers in the American health care system. Only when patients bear the full cost of their health care purchases will they have the requisite incentive to seek pricing information and maximize value. Correspondingly, once patients actually have an incentive to comparison shop, health care providers will in turn have an incentive to compete for patients by providing pricing information.

We see that phenomenon at work in parts of the health care market, such as elective cosmetic surgery and laser vision correction, where patients generally pay most if not all expenses out of pocket. It is common for providers of laser eye surgery, for example, not only to make pricing information available to patients, but also to advertise and compete on the basis of prices in order to attract patient customers.

Ultimately, Congress can promote real health care price transparency by giving patients more incentive and responsibility over their health care choices. One way of

doing so is to encourage and facilitate the growth of high-deductible health insurance plans, coupled with generous health savings accounts. Another is to eliminate the tax preference for employer-sponsored health insurance plans, which puts third parties in charge of selecting many health plan options. Only when patients themselves are in the driver's seat and benefit directly from economizing health care choices can we expect price transparency to generate lower health care costs.

Experts: Gregory Conko, Joel Zinberg

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MODERNIZE THE FDA'S RULES FOR EVALUATING NEW DRUGS BY EXPANDING FLEXIBILITY IN ADAPTIVE CLINICAL TRIAL DESIGNS

First developed more than 50 years ago, the approach to clinical testing by the U.S. Food and Drug Administration (FDA) relies on multiple trials in three phases of testing in humans. It is premised on the belief that (a) most patients will have similar responses to medical interventions and (b) a drug's benefits and side effects will be easy to identify, given a large enough test population of patients with similar health and physical characteristics. However, we now know that apparently similar patients often respond differently to the same medications, and that the homogeneous patient pools and tightly controlled clinical environments associated with randomized trials do not reflect real-world practice and outcomes well. Such methods are ill-suited for detecting and testing subtle differences that occur in small patient subpopulations. That makes them poor tools for fast-paced, adaptive learning.

Congress should:

- Modernize the FDA's rules for evaluating new drugs by expanding flexibility in its use of adaptive clinical trial designs.

A 2007 report by the FDA Science Board concluded that "FDA's evaluation methods have remained largely unchanged over the last half-century," and that the agency's "inadequately trained scientists are generally risk-averse, and tend to give no decision, a slow decision or even worse, the wrong decision on regulatory approval or disapproval." That report and other critiques served as a wake-up call to the agency and Congress. Coupled with pressure from the public health community, patient advocacy organizations, and the pharmaceutical industry, it prompted the FDA to begin to change. That evolution was pushed along further with Congress' enactment of the 21st Century Cures Act in 2016, but progress in changing the way the FDA regulates clinical trials has remained slow.

To minimize hindsight bias in data analysis, clinical trials begin with a "prespecified" hypothesis and a carefully constructed methodology for testing that hypothesis. When an unexpected or idiosyncratic effect is detected among a subpopulation of the test group, the FDA typically demands that the sponsor form a new hypothesis and initiate one or more entirely new trials. In the process, adaptive learning is

short-circuited, the development process is prolonged, and the costs of drug development rise.

Today, however, new computational tools, a better understanding of disease pathways, the development of biomarkers to predict drug effects, and other technological advances are enabling the use of innovative, adaptive clinical trial methods that allow researchers to learn while trials are in progress and, in turn, change dosing regimens or isolate patient subpopulations that respond especially well or poorly to the test drug. Expanded use of adaptive trial designs could help sponsors collect better, more robust data from fewer patients and in a shorter time.

Indeed, it was the FDA's willingness—and that of regulators in the United Kingdom and the European Union—to permit creative and highly flexible approaches to the clinical testing of COVID-19 treatments and preventatives that made it possible for drug manufacturers to develop, test, and secure approval for COVID vaccines in record time. Regulators should embrace such flexibility in the testing of other essential therapeutics as well.

Even before passage of the 21st Century Cures Act, the FDA had begun to welcome adaptive trial proposals and has accelerated their use over the past few years. The agency has also published several guidance documents intended to aid trial sponsors in developing them. Still, the FDA remains hyper-cautious about the possibility of statistical errors and insists that adaptive trials follow the same prespecification requirement as conventional trials.

Thus, among other things, the agency asks trial sponsors to predict what idiosyncratic results may occur during a trial and decide at the outset how they will change the trial's direction when those results occur. Such rigid constraints have prevented researchers from reaping the full benefits of various innovative methodologies. Therefore, it is imperative that the FDA develop more flexible guidelines for using adaptive trial methods and encourage drug developers to use them.

Experts: Gregory Conko, Joel Zinberg

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