**PUBLIC FORUM DEBATE**

**November-December 2018**

John F. Schunk, Editor

**“Resolved: The United States federal government should impose price controls on the pharmaceutical industry.”**

**CON**

C01.

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**CON**

**SK/C01.**

**1.**

SK/C01.01) Maria Castelluci, MODERN HEALTHCARE, November 13, 2017, p. 0002, Gale Cengage Learning, Expanded Academic ASAP. Healthcare prices rose just 1.1% year-over-year through September, representing the lowest price growth rate in roughly two years, according to an Altarum report released last week. That growth rate was just slightly higher than the all-time low of 0.9% in December 2015. The figure has fluctuated between 1.2% and 2.3% over the past year. The small spike was likely due to a decline in prescription drug prices.

**2.**

SK/C01.02) Jim Greenwood, PHARMACEUTICAL TECHNOLOGY, June 2017, p. 10, Gale Cengage Learning, Expanded Academic ASAP. There is a perception that prescription drug spending is the primary driver of rising healthcare costs in America. The facts don't bear this out. Several new reports highlight that drug prices are slowing compared to other healthcare costs. The Centers for Medicare & Medicaid Services (CMS) recently found that prescription drug spending not only experienced the largest slowdown of all healthcare categories in 2016, it actually slowed down the overall rate of growth in healthcare spending. In separately report data, CMS projects 1.6% pricing growth for 2017, which would be the lowest inflation rate for drugs since 2007.

SK/C01.03) Jim Greenwood, PHARMACEUTICAL TECHNOLOGY, June 2017, p. 10, Gale Cengage Learning, Expanded Academic ASAP. But are rising drug costs driving growth in insurance premiums? The short answer is no. Avalere used data reported by the insurance companies themselves to determine what really drove premium increases in 2017. Avalere found that more than 75% of health-related claims costs in the Affordable Care Act's individual and small-group markets were attributed to hospitals and doctors in 2015. Drug spending accounted for just 17.7% of allowed claims.

**3.**

SK/C01.04) Haig Armaghanian [President & CEO, Haig Barrett Management], MANUFACTURING CHEMIST, November 2017, p. 46, Gale Cengage Learning, Expanded Academic ASAP. These unreasonable price hikes, and prices for new biologic drugs that can run into the tens of thousands of dollars per year, contribute to the perception by many consumers, advocacy groups and politicians that drug pricing is arbitrary and only driven by the pursuit of profits. For ethical drug manufacturers, the truth is quite different. Establishing drug pricing strategies is a complex process that is influenced by numerous, often dynamic factors. It has become even more complicated by the growing need to justify and defend the valuation process to a broad range of special-interest stakeholders with little or no understanding of the issues involved.

**4.**

SK/C01.05) THE ECONOMIST, May 12, 2018, p. 57(US), Gale Cengage Learning, Expanded Academic ASAP. A new report from IQVIA says that although list prices for branded drugs increased by 6.9% in 2017, after discounts and rebates, net growth was only 1.9%.

**5.**

SK/C01.06) U.S. OFFICIAL NEWS, September 29, 2018, pNA, NexisUni. New research finds that prescription drug prices climb twice as fast during a shortage than they normally would. Immaculada Hernandez, PharmD, PhD, and colleagues at the University of Pittsburgh School of Pharmacy examined the relationship between price hikes and low inventory, noting how price changes were mediated by the number of manufacturers supplying a medication. The study, published in Annals of Internal Medicine, included 90 drug products that were subject to a shortage between December 2015 and December 2016.

SK/C01.07) U.S. OFFICIAL NEWS, September 29, 2018, pNA, NexisUni. Based on pricing data from AnalySource, the cost of drugs with three or fewer suppliers went up 27.4% in the 11 months after a supply crunch began vs. 12.1% in the 11 months before. The price of medications with more than three manufacturers, meanwhile, rose by 4.8% after a supply shortfall compared with 2.5% before. "Prescription drug shortages may result in substitution of less effective drugs, delays in necessary treatments, and omission of or reductions in doses," the investigators concluded. "These shortages cause an estimated $230 million in additional costs each year because of the rising prices of drugs under shortage and the higher costs of substitute drugs."

**6.**

SK/C01.08) William Schultz [law firm Zuckerman Spaeder], THE WASHINGTON POST, August 6, 2017, p. C4, NexisUni. The one bright spot in drug pricing has been generic drugs. A 1984 law, enacted in exchange for patent extensions to the branded drug companies, created the modern generic drug industry. Today, generics account for 89 percent of prescriptions filled in the United States but only 26 percent of the total spending on prescription drugs. Generic drugs lower drug prices through competition. Once the patents on brand-name drugs expire and anticompetitive business tactics by branded companies have been overcome, less expensive generic versions of these products are allowed to enter the market, and drug prices typically drop dramatically. Patients and taxpayers realize the savings from generic drugs every day.

**7.**

SK/C01.09) Harris Meyer, MODERN HEALTHCARE, April 9, 2018, p. 0020, Gale Cengage Learning, Expanded Academic ASAP. Simply comparing total healthcare spending in the U.S. versus other countries may be misleading because the quality and intensity of services here may be higher, said Katherine Baicker, dean of the University of Chicago Harris School of Public Policy, who wrote an editorial accompanying the JAMA article. What really matters, she argues, is the value of each additional dollar spent.

SK/C01.10) Harris Meyer, MODERN HEALTHCARE, April 9, 2018, p. 0020, Gale Cengage Learning, Expanded Academic ASAP. On quality and outcomes, however, the JAMA study found a mixed picture for the U.S. compared with other countries. The U.S. ranked low on population health outcomes such as life expectancy and maternal and infant mortality, while rating well on mortality rates on heart attack and stroke outcomes.

**SK/C02.**

**1.**

SK/C02.01) Rafael Fonseca [Division of Hematology & Oncology, Mayo Clinic], MAYO CLINIC PROCEEDINGS, August 2018, p. 976, Gale Cengage Learning, Expanded Academic ASAP. Like many other innovative industries, the returns from a few successful products cover the R&D costs of many failures. One study found that two-thirds of drugs brought to market have a net present value of returns (lifetime sales) below the cost of development. Evidence also suggests that the pharmaceutical industry does not earn excessive profits relative to other industries once one properly accounts for the costs and risks of uncertain R&D.

**2.**

SK/C02.02) THE ECONOMIST, March 17, 2018, p. 66(US), Gale Cengage Learning, Expanded Academic ASAP. The most controversial source of excess spending, though, is rent-seeking by health-care firms. This is when companies extract outsize profits relative to the capital they deploy and risks they take. Schumpeter has estimated the scale of gouging across the health-care system. Although it does not explain the vast bulk of America's overspending, the sums are big by any other standard, with health-care firms making excess profits of $65bn a year. Surprisingly, the worst offenders are not pharmaceutical firms but an army of corporate health-care middlemen.

SK/C02.03) THE ECONOMIST, March 17, 2018, p. 66(US), Gale Cengage Learning, Expanded Academic ASAP. Everyone hates pharmaceutical firms, but their share of health-care rent-seeking is relatively trivial, especially once you include the many midsized and small firms that are investing heavily. Across the economy, average prices received by drug manufacturers have risen by about 5% per year, net of the rebates. But their costs have risen, too. As a result, even for the 15 biggest global drugs firms, returns on capital have halved since the glory days of the late 1990s, and are now barely above the cost of capital.

**3.**

SK/C02.04) Megan O’Neil, THE CHRONICLE OF PHILANTHROPY, September 2018, p. 14, Gale Cengage Learning, Expanded Academic ASAP. Major pharmaceutical companies including Eisai, GlaxoSmithKline, Johnson & Johnson, Merck, and Pfizer have given billions of dollars' worth of pharmaceutical products, as well as cash, to help eliminate global diseases, making those companies some of the biggest donors year after year, according to data collected by the Chronicle of Philanthropy.

SK/C02.05) Megan O’Neil, THE CHRONICLE OF PHILANTHROPY, September 2018, p. 14, Gale Cengage Learning, Expanded Academic ASAP. In 2017, for example, pharmaceutical companies were three of the top 10 companies in terms of giving cash, according to the newly published Chronicle survey of corporate giving. In terms of product contributions alone, pharmaceutical companies were seven of the top 10, with Pfizer and Merck at No. 1 and No. 2, respectively. Even though the pharmaceutical industry is much maligned in the United States for what critics decry as outrageously high drug prices--and for some drug makers' part in the substance-use crisis--pharmaceutical companies' seismic role in markedly improving the lives of hundreds of millions of people in developing countries is indisputable, say global health experts.

SK/C02.06) Megan O’Neil, THE CHRONICLE OF PHILANTHROPY, September 2018, p. 14, Gale Cengage Learning, Expanded Academic ASAP. "I am not naive about the complexities of the corporate world, but I do have to say, under their corporate social responsibility, the thing that is quite impressive is these haven't been time-limited investments," Wainwright [senior operations adviser for the United States Agency for International Development's program for neglected tropical diseases] says. "These companies have been making this available for decades now. They have systematically grown every year, particularly over the last 10 years."

**4.**

SK/C02.07) Megan O’Neil, THE CHRONICLE OF PHILANTHROPY, September 2018, p. 14, Gale Cengage Learning, Expanded Academic ASAP. The milestones keep coming in the global fight against trachoma. In May, the World Health Organization officially declared Nepal free of the progressive eye disease, which often begins with repeated childhood infections that turn the eyelids inward, leading the eyelashes to painfully scrap the surface of the eyes. It was the sixth country to eliminate trachoma, and the first in Southeast Asia. One month later, Ghana, too, was confirmed to be trachoma free, the first sub-Saharan Africa country to eliminate the disease. During the last seven years, the number of people living in areas where they are at risk for trachoma--the leading infectious cause of blindness globally--has been slashed by more than half to about 158 million, according to the International Coalition for Trachoma Control.

SK/C02.08) Megan O’Neil, THE CHRONICLE OF PHILANTHROPY, September 2018, p. 14, Gale Cengage Learning, Expanded Academic ASAP. The strides made in reducing trachoma, as well as several other neglected tropical diseases such as lymphatic filariasis and schistosomiasis, is the result of a massive, decades-long multilateral undertaking by governments, the World Health Organization, and nonprofits including the Edna McConnell Clark, Gates, Hilton, and Lions Clubs International foundations, among others. Still, global-health experts say that none of the work would exist on the scale that it does today without corporate philanthropy.

**SK/C03.**

**1.**

SK/C03.01) Jessica Wapner, NEWSWEEK, May 4, 2018, pNA, Gale Cengage Learning, Expanded Academic ASAP. In fact, according to a report published in March by the minority staff of the Homeland Security and Governmental Affairs Committee, prices for the top 20 drugs prescribed to older Americans rose by an average of 12 percent annually during this five-year span. For seven of these drugs, the total increase was more than 100 percent. Such spikes don't necessarily translate into customers paying more at the pharmacy, but experts in health care economics say they do raise frustrating questions about the future of Medicare and prescription drugs in general.

**2.**

SK/C03.02) THE ECONOMIST, May 12, 2018, p. 57(US), Gale Cengage Learning, Expanded Academic ASAP. Employers, who sponsor most of the country's health-insurance plans, are also making inroads. The Health Transformation Alliance (HTA), which was created in 2016 to curb rising health-care costs, particularly drug prices, has grown to cover 40 large employers, including American Express, Coca-Cola and Verizon, and collectively spends about $27bn on health care. It is using this heft to extract better contracts from PBMs and to demand more say over the drugs that are covered. The HTA says that in 2018 it reduced members' drug costs by a median of 15%.

SK/C03.03) THE ECONOMIST, May 12, 2018, p. 57(US), Gale Cengage Learning, Expanded Academic ASAP. On May 1st Express Scripts, a PBM, announced it had won a large discount on the $14,600 price of a PCSK9 drug made by Sanofi/Regeneron, a pharma alliance. The new price is somewhere between $4,500 and $8,000 a year, in line with recommendations made by the Institute for Clinical and Economic Review (ICER), an influential drug-evaluating group based in Boston. The price reduction comes in the form of a large rebate that will be split between Express Scripts and insurers, and should eventually end up reducing the price of health insurance. Patients will also pay less in out-of-pocket costs.

**3.**

SK/C03.04) Jessica Wapner, NEWSWEEK, May 4, 2018, pNA, Gale Cengage Learning, Expanded Academic ASAP. Pharmaceutical companies say that the increases are justified and that patients won't be denied access on account of the cost. "Our decision to change prices can be based on a range of considerations, reflecting competitive and market dynamics," says Pfizer spokesman Thomas Biegi.

**SK/C04.**

**1.**

SK/C04.01) USA TODAY, October 2017, p. 14, Gale Cengage Learning, Expanded Academic ASAP. Premature death rates have declined in the U.S. among Hispanics, blacks, and Asian/Pacific Islanders (APIs)--in line with trends in Canada and the United Kingdom--but increased among whites and American Indian/Alaska Natives (AI/ANs), reveals a comprehensive study of the entire U.S. population from 1999-2014. This divergence was reported by the National Cancer Institute, Rockville, Md., and the College of Nursing at the University of New Mexico, Albuquerque.

SK/C04.02) Toon van der Gronde [Utrecht Institute for Pharmaceutical Sciences, the Netherlands] et al., PLoS ONE, August 16, 2017, pe0182613, Gale Cengage Learning, Expanded Academic ASAP. Cancer mortality has been reduced by 20% in the last two decades through the introduction of new drugs, but that is also due to screening, prevention, vaccination and surgical improvements.

**2.**

SK/C04.03) USA TODAY, October 2017, p. 14, Gale Cengage Learning, Expanded Academic ASAP. In contrast, overall premature death rates for whites and AI/ANs [American Indian/Alaska Nativdes] were driven up by dramatic increases in deaths from accidents (primarily drug overdoses), as well as suicide and liver disease.

SK/C04.04) USA TODAY, September 2018, p. 16, Gale Cengage Learning, Expanded Academic ASAP. Research suggests that behaviors, such as smoking, poor diet, overeating, and lack of exercise are the most-important determinants of premature death. Over the last 25 years, the percentage of Americans with healthy lifestyles (exercise, good diet, "normal" body fat, nonsmoking) has dropped from 6.8% to three percent. More than two-thirds of adults and nearly one-third of children and youth in the U.S. either are overweight or obese.

SK/C04.05) USA TODAY, September 2018, p. 16, Gale Cengage Learning, Expanded Academic ASAP. Let’s face it: many Americans have been duped into ignoring responsibility for their own health. With the drug companies' relentless ads, prescription drugs have become the equivalent of "As Seen on TV" products. These advertisements send the unstated message that the latest diabetes or lung disease medication will take care of you, so you do not have to take care of yourself and possibly avoid these diseases in the first place. It is no surprise that 70% of Americans take at least one prescription medication.

**SK/C05.**

**1.**

SK/C05.01) Linda A. Johnson & Nicky Forster, THE ASSOCIATED PRESS, September 24, 2018, pNA, NexisUni. Pfizer, the biggest U.S. drugmaker, angered Trump by raising prices on July 1 for 40 medicines and vaccines, totaling more than 100 products, with some increases hitting 9 percent. Pfizer had already hiked list prices in January for all but two of those medicines, most by 9 percent to 9.5 percent, according to Elsevier's data. "Pfizer & others should be ashamed that they have raised drug prices for no reason. ... We will respond!" Trump tweeted . After a call with Trump, Pfizer executives reversed those price hikes until January at the latest. Seven other major drugmakers, perhaps hoping to avoid their own Twitter spanking by Trump, have since said they wouldn't increase prices for the rest of the year.

SK/C05.02) Paulina Firozi, THE WASHINGTON POST, October 2, 2018, p. A18, NexisUni. An HHS official pointed to its own reports, including one from August that noted that "15 drug companies have reduced list prices, rolled back planned price increases, or committed to price freezes for the rest of 2018." "Bottom line: Change of the magnitude proposed by the Trump administration is not going to happen overnight, but there is no disputing that the administration has taken significant action which has begun to move the needle - the market is beginning to react in a way that benefits patients," the official told The Health 202.

**2.**

SK/C05.03) Linda A. Johnson & Nicky Forster, THE ASSOCIATED PRESS, September 24, 2018, pNA, NexisUni. Elsevier drug pricing expert Kay Morgan said the data indicate companies are being more cautious about price increases, but Trump's criticisms are just one factor. "It's everyone saying, 'This has got to stop,'" Morgan said. She cited frequent media coverage, patients and their advocacy groups pressuring members of Congress to fight high drug prices, and Congress holding hearings on huge price increases. Those include hikes for EpiPen emergency allergy shots and the actions of disgraced former pharma executive Martin Shkreli, who hiked the price of an old infection treatment from $13.50 to $750 per pill overnight.

SK/C05.04) Linda A. Johnson & Nicky Forster, THE ASSOCIATED PRESS, September 24, 2018, pNA, NexisUni. Edward Jones drug analyst Ashtyn Evans said, "companies are self-policing more." She noted many firms are now taking one price hike near 10 percent once a year, instead of two or three smaller hikes each year.

SK/C05.05) Jessica Wapner, NEWSWEEK, May 4, 2018, pNA, Gale Cengage Learning, Expanded Academic ASAP. Sanofi-Aventis, which makes Lantus and Lantus Solostar, both among those top seven drugs in the committee's report, insists its pricing strategies decrease patient copays and discounts for Medicare beneficiaries. And in a 2016 blog post, Brent Saunders, the CEO of Allergan, which makes Restasis--priced at $167.62 in 2012 and $321.26 in 2017, according to the committee's report--vowed to avoid predatory pricing practices. "We will take price increases no more than once per year," he wrote, "and, when we do, they will be limited to single-digit percentage increases."

SK/C05.06) THE ECONOMIST, December 10, 2016, p. 34(US), Gale Cengage Learning, Expanded Academic ASAP. And in recent years health insurers, their intermediaries, and hospitals have become increasingly combative about the price of drugs and the value they deliver. Nor will the clamour to appraise medicines more critically go away, which is good news for consumers.

**SK/C06.**

**1.**

SK/C06.01) Alicia Gallegos, FAMILY PRACTICE NEWS, July 1, 2017, p. 37, Gale Cengage Learning, Expanded Academic ASAP. Maryland's law is part of a growing movement among states to address unreasonable pricing spikes in prescription drugs, noted Dr. Greene and Dr. Padula, both of Johns Hopkins University in Baltimore. In April, Louisiana health officials requested feedback about the possibility of invoking an obscure U.S. patent and copyright law to ensure better affordability of hepatitis drugs. In May, the Nevada Senate passed a bill that would force drug makers to publish the list prices they set and the profits they make on insulin, as well as the amount of insulin discounts they give third parties. Additional pharmaceutical price-transparency laws have been proposed in 16 states and Puerto Rico.

SK/C06.02) THE ECONOMIST, May 12, 2018, p. 57(US), Gale Cengage Learning, Expanded Academic ASAP. States, too, are fighting back. On April 26th, in a case being followed with interest nationwide, New York's Medicaid board demanded a hefty 70% discount from Vertex, a pharma firm, on its costly cystic-fibrosis drug, Orkambi. A new report from ICER suggests Orkambi should cost something like $83,000 a year (rather than $250,000). So even without action from Mr Trump, there is a meaningful pushback on drug prices.

**2.**

SK/C06.03) Heather Boerner, PHYSICIAN LEADERSHIP JOURNAL, November-December 2017, p. 54, Gale Cengage Learning, Expanded Academic ASAP. Perhaps as a result of stalled progress on the federal level, states have begun trying to address the issue. The laws vary, but most create caps on out-of-pocket prescription costs--from about $108 a month in Vermont to $150 a month in Delaware, Louisiana and Maryland, to $250 a month in California. California's law also sets out-of-pocket costs at $500 for so-called "bronze plans"--which have lower monthly premiums but higher costs for services than other plans--sold on the health insurance marketplaces established by the ACA, that limit prescription deductibles.

SK/C06.04) Heather Boerner, PHYSICIAN LEADERSHIP JOURNAL, November-December 2017, p. 54, Gale Cengage Learning, Expanded Academic ASAP. In addition, some of these laws, like Delaware's price-control law, prohibit insurers from placing all medications for a certain high-cost condition in their highest tier, commonly called the specialty tier, on their drug formulary. New York's law also prohibits specialty tiers at all in the plans sold in its state marketplace.

SK/C06.05) Heather Boerner, PHYSICIAN LEADERSHIP JOURNAL, November-December 2017, p. 54, Gale Cengage Learning, Expanded Academic ASAP. "Ultimately, these states have developed policies that relieve high-risk patients from extremely high drug costs by spreading those costs across a broader risk pool including healthy and sick people," the Urban Institute report states. "For many patients in need of specialty drugs, that kind of risk-spreading means they no longer have to forgo those drugs or experience financial hardship to obtain treatment."

**SK/C07.**

**1.**

SK/C07.01) The Times-Tribune (Scranton, Pennsylvania], TRIBUNE CONTENT AGENCY, March 2, 2017, pNA, NexisUni. High medicine prices help drive health care inflation, yet Congress actually has acted against reducing those prices. The system so favors pharmaceutical manufacturers that the law precludes Medicare from using the market power of its huge Part D drug program to negotiate lower prices with manufacturers. And federal law also precludes importing drugs.

SK/C07.02) THE ECONOMIST, May 19, 2018, p. 10(US), Gale Cengage Learning, Expanded Academic ASAP. The government could give Medicare, the health scheme for the elderly, more power to negotiate prices and more freedom to determine the drugs it has to provide by law. At the moment it cannot haggle directly with drug companies.

SK/C07.03) Jessica Wapner, NEWSWEEK, May 4, 2018, pNA, Gale Cengage Learning, Expanded Academic ASAP. It's unclear how the country can avoid this looming crisis. Granting Medicare the power to negotiate drug prices--currently forbidden by federal law--might help, says Cubanski [Kaiser Family Foundation]. Seniors enrolled in Medicare can choose from a large number of private plans that are free to negotiate with drug companies. Keeping the federal government out of those deals creates competition among the individual plans, which drives health care costs down. But as the single biggest insurer in the country, many experts say, Medicare could force companies to lower their prices.

SK/C07.04) Alex Kacik, MODERN HEALTHCARE, April 23, 2018, p. 0012, Gale Cengage Learning, Expanded Academic ASAP. Allow the government to negotiate drug prices with manufacturers. This is one of the most controversial ideas. Some supporters argue that allowing the government to consolidate its bargaining power would swiftly bring down drug prices.

SK/C07.05) Patrick Healy & Margot Sanger-Katz, THE NEW YORK TIMES, September 23, 2015, p. A13, NexisUni. Another [proposal] would require drug makers to offer discounts to the federal government when it purchases drugs for patients in the Medicare and Medicaid programs. The Congressional Budget Office estimates that the policy would save the government $103 billion over 10 years.

**2.**

SK/C07.06) Jessica Wapner, NEWSWEEK, May 4, 2018, pNA, Gale Cengage Learning, Expanded Academic ASAP. A better approach, says Kesselheim [associate professor of medicine at Harvard's Brigham and Women's Hospital], would be to grant Medicare, or any insurer, the power to exclude drugs from the list of medications it covers. He cites the Department of Veterans Affairs as an example of how effective the threat of omission can be: The VA health system obtains the best drug prices among all government insurers.

**3.**

SK/C07.07) Reading Eagle (Pennsylvania], TRIBUNE CONTENT AGENCY, May 21, 2018, pNA, NexisUni. Most analysts said Trump's proposals are good but are likely to make a difference over the long term, not the short term. He proposed, for example, to shift drugs from Medicare's Part B to Part D, which would allow private health insurance companies to bargain for lower prices from drugmakers. That should make a difference, since under Part B, Medicare pays a drug's average sales price, plus 6 percent.

**SK/C08.**

**1.**

SK/C08.01) MODERN HEALTHCARE, June 19, 2017, p. 0013, Gale Cengage Learning, Expanded Academic ASAP. The [AMA] House of Delegates approved several items aimed at bringing more transparency to drug pricing. Among other things, the group approved policies supporting laws that would: -- Allow the CMS to negotiate drug prices; Require drug companies to list the suggested retail price of medications in any direct-to-consumer advertising; Require drugmakers make public any price increases of 10% or more in a given year; Accelerate review of generic drug applications,

**2.**

SK/C08.02) U.S. OFFICIAL NEWS, October 5, 2018, pNA, NexisUni. In May, Congressman Gonzalez joined Congressman Doug Collins (R-GA-09) to introduce H.R. 5958, the Phair Pricing Act of 2018, bipartisan legislation to lower the cost of prescription medications for patients in the Medicare Part D program. The Phair Pricing Act would direct all price concessions, incentive payments and price adjustments between a pharmacy and a prescription drug plan (PDP) sponsor or Pharmacy Benefit Manager (PBM) to be included at the point of sale in order to decrease patients' medication costs. The bill seeks to bring transparency to a notoriously complex industry by compelling PBMs to disclose to Centers for Medicare and Medicaid (CMS) fees, price concessions and programs that they employ. This requirement would prevent companies from circumventing CMS regulations by restructuring or renaming their fees.

SK/C08.03) Jessica Wapner, NEWSWEEK, May 4, 2018, pNA, Gale Cengage Learning, Expanded Academic ASAP. Guaranteeing that doctors are educated about new drugs by neutral parties with no financial stake--not, in other words, a pharma representative--might also help. As would forced transparency. California recently passed legislation requiring drug companies to disclose any price increase of 10 percent or higher. "This may not lower out-of-pocket costs," Cubanski [Kaiser Family Foundation] says, "but the public release of this information may have a shaming effect on pharmaceutical companies."

SK/C08.04) Alex Kacik, MODERN HEALTHCARE, April 23, 2018, p. 0012, Gale Cengage Learning, Expanded Academic ASAP. Require transparency throughout the supply chain. Policy experts argue that insurers and drug companies should disclose the average net price paid for drugs, and that pharmacy benefit managers should reveal how much of the rebates they pocket versus how much is passed onto payers and consumers. Lawmakers want drugmakers to notify authorities when they are planning drug price hikes, and explain their reasoning.

**3.**

SK/C08.05) Alex Kacik, MODERN HEALTHCARE, April 23, 2018, p. 0012, Gale Cengage Learning, Expanded Academic ASAP. Limit direct-to-consumer and direct-to-physician advertising. The U.S. and New Zealand are the only countries that permit direct-to-consumer advertising, which is linked to unnecessary prescriptions and higher healthcare spending. Meanwhile, drugmakers spent more than $24 billion on marketing directly to physicians in 2012.

**4.**

SK/C08.06) Ceci Connolly, HEALTHCARE FINANCIAL MANAGEMENT, August 2017, p. 26, Gale Cengage Learning, Expanded Academic ASAP. Although there is little support for price controls, there are straightforward ways to foster competition. One way is to increase access to generics and improve the entry of biosimilar products into the market. Streamlining the FDA's drug-approval process would ensure affordable alternatives are readily available.

SK/C08.07) Alex Kacik & Tara Bannow, MODERN HEALTHCARE, January 22, 2018, p. 0006, Gale Cengage Learning, Expanded Academic ASAP. The FDA has reformed policy to create more competition by expediting applications for generic drugs that have fewer than three competitors. The agency also published a list of sole-source drugs to spur applications and is working to clear the orphan drug backlog.

SK/C08.08) Alex Kacik, MODERN HEALTHCARE, April 23, 2018, p. 0012, Gale Cengage Learning, Expanded Academic ASAP. While drug price growth has ebbed in recent months, the problem has led providers to battle unexpected price hikes for decades-old drugs and has cost consumers dearly at the pharmacy counter and in the form of rising insurance premiums. So what could rein in rising drug prices? Modern Healthcare sought to find out. Passing the CREATES Act to limit anticompetitive behavior and bolster generic and biosimilar competition

SK/C08.09) Alex Kacik, MODERN HEALTHCARE, April 23, 2018, p. 0012, Gale Cengage Learning, Expanded Academic ASAP. The Creating and Restoring Equal Access to Equivalent Samples Act would prevent actions such as barring access to branded samples that generic companies need to prove bioequivalence and ultimately earn the Food and Drug Administration's approval. The powerful Pharmaceutical Research and Manufacturers of America, which represents brand-name drug producers, argues that it holds product samples close to its chest to protect patient safety. The FDA has been speedily reviewing new drug applications if there are few approved generics, publishing an off-patent list of branded drugs without an approved generic, and improving communication between manufacturers and the agency. That has led to a record number of approvals--more than 1,000 generic drugs last year--and a tightening of drug costs.

SK/C08.10) Haig Armaghanian [President & CEO, Haig Barrett Management], MANUFACTURING CHEMIST, November 2017, p. 46, Gale Cengage Learning, Expanded Academic ASAP. In addition to implementing novel manufacturing strategies designed to increase efficiency and productivity, thereby bringing down the cost and time needed to develop and commercialise new drugs, the pharmaceutical industry is also looking to other avenues that provide efficiency gains. Generic drugs and biosimilars are one such avenue. Indeed, generic drugs account for a significant portion of small-molecule drug sales today, and as increasing numbers of biosimilars receive approvals, they too will have an impact on pricing in the biopharmaceutical segment of the market.

SK/C08.11) Haig Armaghanian [President & CEO, Haig Barrett Management], MANUFACTURING CHEMIST, November 2017, p. 46, Gale Cengage Learning, Expanded Academic ASAP. Generics are in fact a great example of efficient drug pricing in close-competition environments. When patent exclusivity is lost and generics are introduced to the market, innovator companies refocus their business models on efficient pricing. To that end, they manage production and supply chain costs more diligently. Outsourcing to contract development and manufacturing organisations (CDMOs) with lower cost structures is common at this stage, allowing for increased supply chain flexibility combined with reduced costs.

**5.**

SK/C08.12) Sam Peltzman [Professor of Economics Emeritus, U. of Chicago], REGULATION, Spring 2018, p. 2, Gale Cengage Learning, Expanded Academic ASAP. In their recent Regulation article, David Hyman and Bill Kovacic discuss the pros and cons of having the U.S. Food and Drug Administration consider the effects of regulation on prices as well as on safety and efficacy. ("Risky Business: Should the FDA Pay Attention to Drug Prices?" Winter 2017-2018.) The cons they mention include lack of statutory authority and expertise. One topic their article doesn't discuss is FDA regulation of the transition of drugs from prescription to over-the-counter (OTC) status. The FDA's statutory authority here is clear and its claim of expertise is complete. The effect on prices is also clear: every study of the matter shows substantial price reductions when drugs move to OTC. Of course, total cost--including the cost of physician visits and the value of the time and trouble of securing prescriptions--declines even further when the drug moves to OTC.

SK/C08.13) Sam Peltzman [Professor of Economics Emeritus, U. of Chicago], REGULATION, Spring 2018, p. 2, Gale Cengage Learning, Expanded Academic ASAP. The FDA claims competence to decide when an adequate consumer label can be written. I suggest the FDA should periodically review existing drugs for eligibility for OTC sales. I further suggest that when any prescription drug passes certain milestones--x million prescriptions sold every years with a risk profile similar to, say, ibuprofen or aspirin--there should be a rebuttable presumption that the drug becomes OTC-eligible. It would then be up to the drug's producer or producers to take advantage of the opportunity. Moving more drugs to OTC status is no free lunch, but it is as close to one as consumers are likely to get in the health care sector. And the FDA doesn't need any new statutory authority or new kinds of expertise to make it happen.

**6.**

SK/C08.14) Alex Kacik, MODERN HEALTHCARE, April 23, 2018, p. 0012, Gale Cengage Learning, Expanded Academic ASAP. Eliminate "evergreening" and other monopolistic tactics, and limit the scope of citizen petitions and the Orphan Drug Act. "Evergreening" is when branded manufacturers develop a slightly different version of their drug to earn a new drug approval, which extends the patent without leaving a window to obtain samples for bioequivalence testing. Another strategy involves citizen petitions, which are intended to bring concerns to the FDA, but are often filed by brand-name drug manufacturers to delay the approval of generics. It takes months for the FDA to respond to the inquiries, which are being sent more frequently.

**7.**

SK/C08.15) The Times-Tribune (Scranton, Pennsylvania], TRIBUNE CONTENT AGENCY, March 2, 2017, pNA, NexisUni. Tuesday, Sanders, Casey and other Democrats introduced bill to allow imports and address the safety issue. The Affordable and Safe Prescription Drug Importation Act would allow drugs to be bought from Canadian distributors that are safety-certified by the FDA. Later, that would extend to countries of the Organization for Economic Cooperation and Development. President Donald Trump said during his campaign that he favored prescription imports. He should embrace this bill to do so safely as a means to counter soaring prescription prices.

**8.**

SK/C08.16) Joshua P. Cohen [Tufts Center for the Study of Drug Development] et al., HEALTH SERVICES RESEARCH, August 2018, p. 2758, Gale Cengage Learning, Expanded Academic ASAP. Pharmacy benefit managers assert that they are implementing exclusion lists as a way to contain drug costs and counter the increase in the number of brand-name (single source) drugs in the United States with coupon or co-payment offset provisions offered to patients by drug manufacturers. Coupons reduce patient out-of-pocket expenses (co-payments).

**SK/C09.**

**1.**

SK/C09.01) HEALTHCARE FINANCIAL MANAGEMENT, September 2018, p. 16, Gale Cengage Learning, Expanded Academic ASAP. Despite a unique price control system for Maryland hospitals, insurers in the state's Affordable Care Act (ACA) health insurance market have requested a 29.45 percent average premium rate increase of for 2019, according to tracking by acasignups.org--the largest such premium increase identified in any state followed by the pro-ACA national tracking website.

**2.**

SK/C09.02) John Wilkerson, INSIDE HEALTH POLICY, September 24, 2018, pNA, NexisUni. He [Jonathan Blum, who headed Medicare during the Obama administration] said it is much more challenging for CMS staff to determine drug prices than it is for drug makers and plans to negotiate prices. "They face political pressures, to be sure," Blum said, referring to private plans. "But to make the decision within CMS, then you get bombarded by every member of Congress, their staffs, different companies that have different interests."

SK/C09.03) John Wilkerson, INSIDE HEALTH POLICY, September 24, 2018, pNA, NexisUni. Scully gave a personal anecdote from 18 years ago, before the creation of Part D and the current pay scheme in Part B, and he said it is an example of a common occurrence at CMS. He received a call from a Democratic House representative of a San Diego district complaining about the time it was taking CMS to determine coverage of the cancer drug Zevalin, which was made by a constituent. Scully checked with staff and found out the agency was approving coverage that week at a price of $29,000 a dose. Scully was taken aback by that price and called the CEO of the company to informally negotiate a lower price. After a week, the company dropped the price to $21,000. Despite the seemingly successful outcome of that story, Scully said that approach is not sustainable. "My point is when you have a system like that where you make these kinds of calls, you get a call from the Hill, you get calls from companies, people run ads. You can't make a rational decision," he said. "Politics play into this stuff all the time, and you're much better off having hopefully a thoughtful pharmacy director at Anthem make this call than somebody in a political system sitting at CMS who has no rational economic factors," Scully added.

**3.**

SK/C09.04) Toon van der Gronde [Utrecht Institute for Pharmaceutical Sciences, the Netherlands] et al., PLoS ONE, August 16, 2017, pe0182613, Gale Cengage Learning, Expanded Academic ASAP. Value-based pricing is a promising but also risky option that is already being used by some countries to reduce costs. The (inter-)national public debates about how much a QALY [quality-adjusted life year] should cost and the regulatory and policy debates about whether and how to continue with the QALY appraisal tools still have to reach a conclusion.

SK/C09.05) Haig Armaghanian [President & CEO, Haig Barrett Management], MANUFACTURING CHEMIST, November 2017, p. 46, Gale Cengage Learning, Expanded Academic ASAP. A switch to value-based pricing won't make the pricing of pharmaceuticals any easier. The complexities of establishing value can be daunting and costly. Efforts must start with data from the earliest development phases through clinical trial results and also include post-approval studies. Value-based pricing as a strategy is particularly difficult to implement for first-in-class therapies and products that intend to establish a new standard of care. For these drugs, there are no existing products to act as comparators. In these cases, ethical considerations become important. For instance, pricing a drug at the level the market can bear may prevent lower-income patients from gaining access to life-saving medicines.

**4.**

SK/C09.06) Reading Eagle (Pennsylvania], TRIBUNE CONTENT AGENCY, May 21, 2018, pNA, NexisUni. "The only way that direct negotiation could possibly save money is by doing something this administration doesn't believe in: denying access to certain medicines for all Medicare beneficiaries through rationing, or setting prices for drugs by government fiat," Azar [U.S. Secretary of Health & Human Services] said. "We don't believe either of these proposals would put American patients first. They would move us toward the kind of socialized medicine systems that have such a notorious reputation for poor quality and access."

SK/C09.07) Carolyn Y. Johnson, THE WASHINGTON POST, September 24, 2015, p. A1, NexisUni. Perhaps, in Mr. Meyerson's magical economic wonderland, the laws of supply and demand don't apply. But here in the real world, when the government arbitrarily holds down prices, there are drastic consequences. Eventually demand chronically exceeds supply. And that leads to rationing. I suspect most seniors wouldn't want a health-care system in which government bureaucrats tell them they're not allowed to have the medications they need.

**5.**

SK/C09.08) John Wilkerson, INSIDE HEALTH POLICY, September 24, 2018, pNA, NexisUni. Former CMS officials, a Democrat and a Republican, discussed the intense political pressure CMS staff would be subject to if Medicare were to negotiate drug prices, and they said the current system is preferable.

**SK/C10.**

**1.**

SK/C10.01) Haig Armaghanian [President & CEO, Haig Barrett Management], MANUFACTURING CHEMIST, November 2017, p. 46, Gale Cengage Learning, Expanded Academic ASAP. Drug development and manufacturing is a risky, costly and lengthy process. Advanced technologies and highly trained scientists are required to understand diseases and discover potential new compounds that effectively target them. Specialised equipment and facilities run by skilled operators are required to develop and implement effective manufacturing processes. The vast majority of drugs that progress to the clinical trial stage ultimately fail to become approved, marketed therapies. Taking into account the costs of all of these failures and the direct R&D and manufacturing costs for a specific new therapy, the cost to develop a commercial drug product is estimated to be in the billions of dollars.

SK/C10.02) Haig Armaghanian [President & CEO, Haig Barrett Management], MANUFACTURING CHEMIST, November 2017, p. 46, Gale Cengage Learning, Expanded Academic ASAP. Once a drug is launched, often significant additional monies are spent on further clinical studies, safety monitoring efforts and regulatory activities. Pricing strategies are designed to recoup these costs and allow for some level of profitability.

SK/C10.03) Rafael Fonseca [Division of Hematology & Oncology, Mayo Clinic], MAYO CLINIC PROCEEDINGS, August 2018, p. 976, Gale Cengage Learning, Expanded Academic ASAP. Pharmaceutical companies frequently justify prices on the basis that innovation is risky and that high prices are needed to incentivize company investors to undertake investments that are highly uncertain. Some investigators estimate that 9 in every 10 drugs fail at some point in the research and development (R&D) process, with estimated costs of drug development (including failed therapies) of over $2 billion per marketed drug.

SK/C10.04) THE ECONOMIST, March 17, 2018, p. 66(US), Gale Cengage Learning, Expanded Academic ASAP. Meanwhile the effectiveness of R&D seems to have fallen. Richard Evans of SSR, a research firm, tracks the number of high-quality patents (defined as those cited in other patent applications) that drug firms generate per dollar of R&D. This metric has dropped sharply over the past decade. Shareholders may groan, but for the economy overall the system seems to be working. Big pharma is still splurging on R&D but not making out like a bandit.

**2.**

SK/C10.05) Rafael Fonseca [Division of Hematology & Oncology, Mayo Clinic], MAYO CLINIC PROCEEDINGS, August 2018, p. 976, Gale Cengage Learning, Expanded Academic ASAP. The question of whether reduced profits will lead to reductions in innovation also has an answer, although the economic studies that support this finding are unfamiliar to most clinicians. Nearly all of these studies evaluate how changes in drug profitability (driven by either changes in the market size for a product, changes in reimbursement, or changes in the speed of approval) influence rates of innovation, with all finding that reductions in profitability reduce rates of innovation.

SK/C10.06) Jill Wechsler [editor], PHARMACEUTICAL TECHNOLOGY, January 2018, p. 20, Gale Cengage Learning, Expanded Academic ASAP. A main concern for the biomedical research community is that any form of price controls would discourage private investment in biomedical innovation and limit development of new cures for critical diseases. Even though drug companies enjoy healthy profits, policy makers are reluctant to dampen the current boom in scientific discovery that has led to new gene and cellular therapies and robust R&D pipelines. FDA approved more than 40 novel medicines through early December 2017, heading for a record year.

SK/C10.07) Patrick Healy & Margot Sanger-Katz, THE NEW YORK TIMES, September 23, 2015, p. A13, NexisUni. The Pharmaceutical Research and Manufacturers of America, which represents the country's leading drug makers, said in a statement that Mrs. Clinton's plan would ''turn back the clock on medical innovation.'' ''These sweeping and far-reaching proposals would restrict patients' access to medicines, result in fewer new treatments for patients, cost countless jobs across the country and erode our nation's standing as the world leader in biomedical innovation,'' the statement said.

**3.**

SK/C10.08) Alex Kacik, MODERN HEALTHCARE, February 12, 2018, p. 0002, Gale Cengage Learning, Expanded Academic ASAP. It [White House’s Council of Economic Advisers] also rejected imposing government price-setting on drug manufacturers, a tactic backed by Democrats, arguing that "if the United States had adopted the centralized drug pricing policy in other developed nations 20 years ago, then the world may not have highly valuable treatments for diseases that required significant investment."

SK/C10.09) Rafael Fonseca [Division of Hematology & Oncology, Mayo Clinic], MAYO CLINIC PROCEEDINGS, August 2018, p. 976, Gale Cengage Learning, Expanded Academic ASAP. Existing evidence outside of medicine suggests that a failure to broadly and accurately assess value raises the risk of underinvesting in therapies that may create large benefits for society and perhaps overinvesting in therapies whose societal returns are relatively low. Moreover, a failure to understand empirical evidence that demonstrates economic trade-offs exist between cancer drug pricing and innovation risks promoting policy actions that may have unintended, but economically predictable, consequences for patients: lower prices may increase access to cancer therapies, improve cancer outcomes, and possibly lower cancer spending today but may reduce access to innovative therapies and the possibility of better cancer outcomes moving forward.

**4.**

SK/C10.10) Rafael Fonseca [Division of Hematology & Oncology, Mayo Clinic], MAYO CLINIC PROCEEDINGS, August 2018, p. 976, Gale Cengage Learning, Expanded Academic ASAP. Economic evidence suggests that the societal benefits from cancer care have historically far exceeded the cost. For example, from 1988 to 2000, investments in cancer research resulted in survival improvements generating 23 million additional life-years and $1.9 trillion of social value for Americans. During the same period, health care providers and drug manufacturers appropriated approximately 5% to 19% of this societal value, with the rest of the benefit accruing to patients.

SK/C10.11) Jim Greenwood, PHARMACEUTICAL TECHNOLOGY, June 2017, p. 10, Gale Cengage Learning, Expanded Academic ASAP. Medicine isn't what's causing healthcare costs to rise. Medicine keeps people out of hospitals and doctors' offices, which are the top cost drivers. For example, the new hepatitis C cures are projected to reduce future healthcare spending by $115 billion, according to actuaries at Millman Inc., far less than society will pay for these drugs.