Drug Pricing Lab
Memorial Sloan Kettering

January 29, 2019

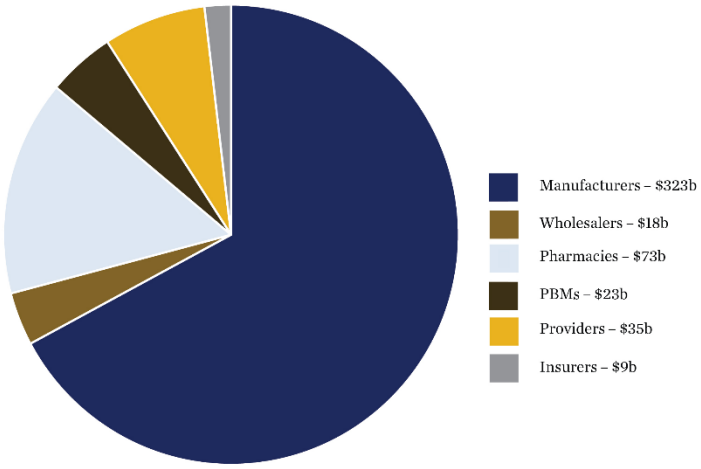
TESTIMONY OF PETER B. BACH, MD
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Before the United States Senate Committee on Finance
Drug Pricing in America: A Prescription for Change, Part I

Chairman Grassley, Ranking Member Wyden, and members of the Senate Finance Committee,

Thank you for the opportunity to testify before you regarding the important and pressing topic of pharmaceutical prices and affordability. My name is Peter Bach, I am a physician at Memorial Sloan Kettering Cancer Center in New York where I lead the Drug Pricing Lab, which is funded by the Laura and John Arnold Foundation, Kaiser Permanente, and my institution. I have received speaking fees from pharmaceutical companies, PBM's, insurers, and trade associations. Each of these is listed at the bottom of this testimony.

Overview of the pharmaceutical supply chain

Although the lion's share of pharmaceutical product revenues goes to their manufacturers, the distribution and payment system for pharmaceuticals does capture a meaningful share of total spending, which was approximately $500B in 2018. Our group looked at the net retained revenues across the supply chain associated with all pharmaceutical sales based on a collection of different inputs and found that the pharmaceutical corporations capture around two-thirds of all dollars spent on drugs, seen below. It is worth noting that although PBM's are frequently blamed for capturing a large share of total spending in the form of rebates, in fact they capture around 5% of total spending. We cannot tell from this analysis whether the net savings PBM's achieve through negotiation are greater than or less than this amount. [1]



[1] Yu N, Atteberry P, Bach PB. Spending on Prescription Drugs In The US: Where Does All The Money Go? *Health Aff Blog*. 2018 Jul 31. doi: 10.1377/hblog20180726.670593. Accessed from https://www.healthaffairs.org/do/10.1377/hblog20180726.670593/full/.

Inflationary distortions in the supply chain:

I would like to review some of the inflationary distortions in the current system of pharmaceutical distribution and payment, in particular for specialty drugs, that now comprise 39.6% of spending even as they are fewer than 2% of total prescriptions.[2,3,4] An organizing theme of the pharmaceutical supply chain is that all participants benefit as both drug prices and total spending rise. Pharmaceutical corporations logically seek to profit by charging high prices, but ideally the other parties in the supply chain would serve as a countervailing force to push prices down. They often do not. Rather, most of the participants in this system benefit over the long term from rising spending and prices. While in any particular period one participant or another may seek to lower costs, in general terms, all make a profit that is linked to the underlying cost of the drugs that they handle.

Pharmaceutical products are often marked up in percentage terms as they pass through the supply chain. This means that more expensive drugs on average bring larger profits. This pattern applies to wholesalers and pharmacies. It also applies to physicians and hospitals when they use expensive infused drugs covered by Medicare Part B. This is because the reimbursement formula for Part B drugs includes a mark-up over the average acquisition price of the drug. The formula is often referred to as "ASP+6". Due to the percentage based mark-up, profits are larger for those drugs that are more expensive. We recently reviewed studies that examine whether or not the profit potential for various Part B drugs influences prescribing; across the studies we examined, the conclusion was consistent that they do. On the margin physicians will prescribe the more profitable of drugs when there are options to choose from.[5] Aaron Mitchell and colleagues published a review of this topic as well. That authors graded the quality of the literature along with summarizing its findings, and arrived at the same conclusion. Physicians systematically select more profitable drugs to prescribe when they are able to choose among clinically substitutable options.[6]

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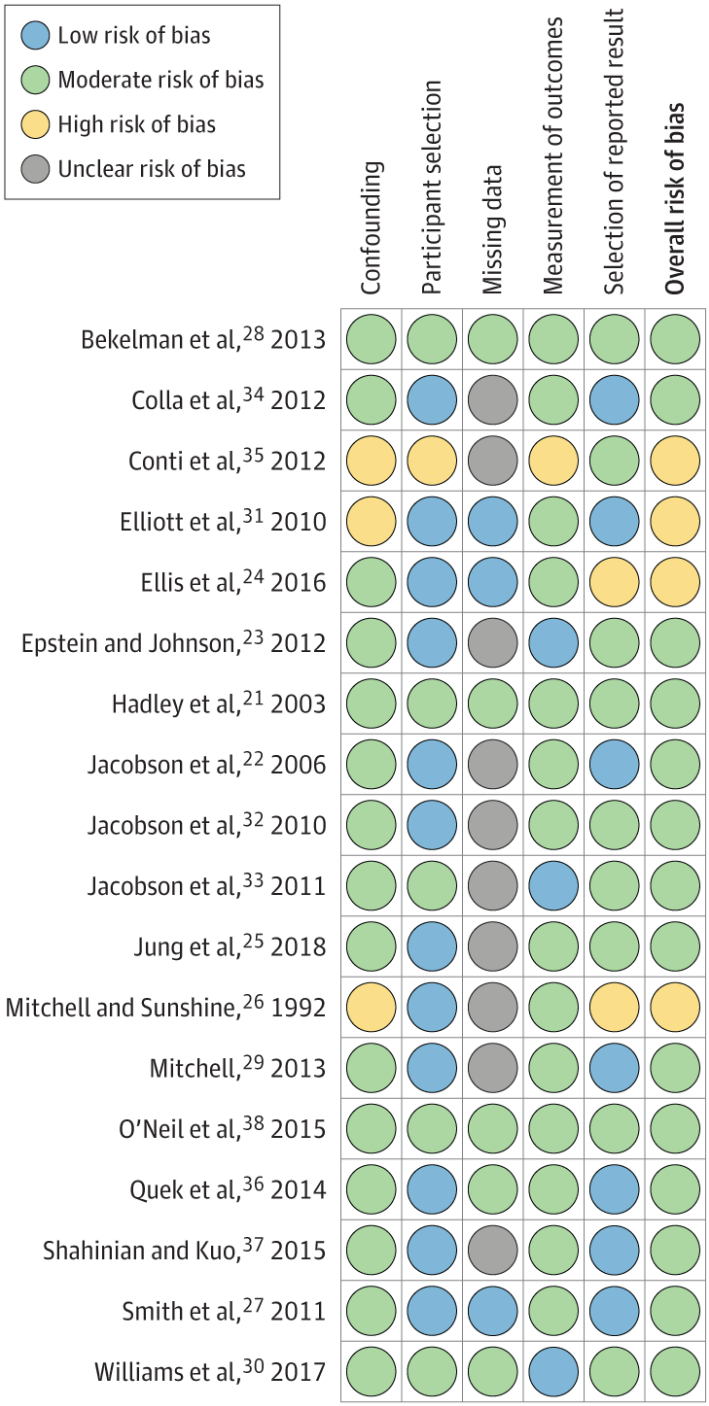
[2] IQVIA. *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021,* IQVIA. Published 2017. Accessed at https://www.iqvia.com/institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2016.

[3] Hirsch BR, Balu S, and Schulman KA. "The Impact Of Specialty Pharmaceuticals As Drivers Of Health Care Costs", *Health Aff.* 2014; 33(10), p. 1714-1720.

[4] IMS Institute for Healthcare Informatics (IMS Institute). *Medicine use and shifting costs of healthcare: A review of the use of medicines in the United States in 2013*, IMS Institute for Healthcare Informatics. Published 2014. Accessed from http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf.

[5] Bach PB, Ohn J. Does the 6% in Medicare Part B drug reimbursement affect prescribing? *Drug Pricing Lab.* https://drugpricinglab.org/wp-content/uploads/2018/05/Part-B-Reimbursement-and-Prescribing.pdf. Published May 9, 2018. Accessed January 27, 2019.

[6] Mitchell AP, Rotter JS, Patel E, Richardson D, Wheeler SB, Basch E, Goldstein DA. Association Between Reimbursement Incentives and Physician Practice in Oncology: A Systematic Review. *JAMA Onc*. 2019 Jan 3 [Epub ahead of print]. Accessed from https://jamanetwork.com/journals/jamaoncology/fullarticle/10.1001/jamaoncol.2018.6196.



Source: Mitchell et al.,[6] 2019

The phenomenon does not appear to be unique to physician offices. Preference for more expensive drugs has been observed in prescribing in hospital outpatient departments. The most dramatic example of this pattern was in a report from the GAO, that found a strong shift to more

expensive drugs in hospitals after they entered the 340B drug discount program.[7] There are not many analyses that compare the relative impact of these incentives on prescribing between physician offices and hospital outpatient departments. The effects could be of similar magnitude, but alternatively one might anticipate physician practices to be more susceptible to them given that physicians in offices are often owners or otherwise directly participate in profit sharing, while hospital based physicians do not. My team conducted an analysis that showed that among treatments in oncology that are not recommended and that involve expensive Part B drugs, the likelihood that these treatments were administered was higher in physician offices than hospital outpatient departments across all the clinical scenarios we examined, a finding that was robust to clinical severity risk adjustment.[8]

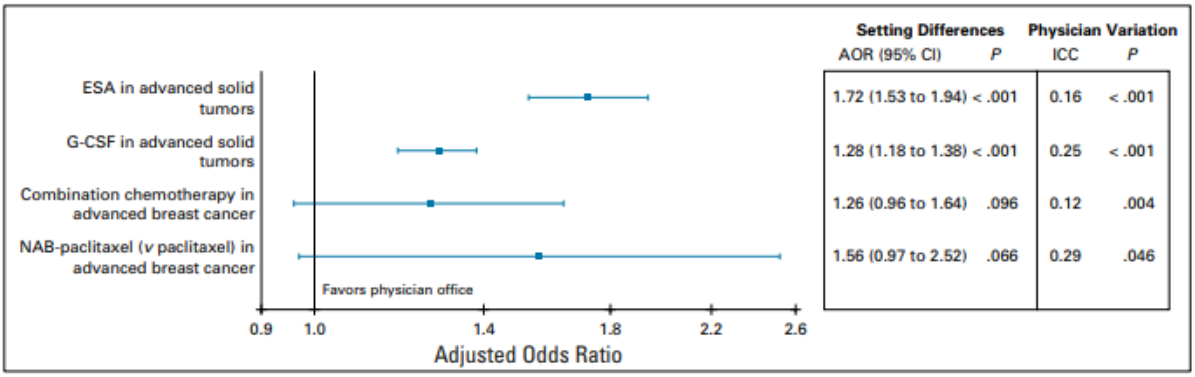


FIG 1. Impact of oncology practice setting on the use of drugs. AOR, adjusted odds ratio; ESA, erythropoiesis-stimulating agent; G-CSF, granulocyte colony stimulating factor; ICC, intraclass correlation; NAB, nanoparticle albumin-bound.

Possible policy options:

Subscription based payment for HCV treatment ("Netflix model"). The subscription model for Hepatitis C virus treatment that Mark Trusheim from MIT, Senator Bill Cassidy and I nick-named "Netflix" solves a problem specific to the Hepatitis C market. The profit maximizing price for treatments is unaffordable for many state Medicaid programs and prison systems.[9] The unique situation with Hepatitis C infection is defined by a number of features. First, there are highly effective treatments that have prices far higher than most states can afford; second, HCV infection is essentially a one time problem that would be amenable to a single elimination effort that would decrease prevalence very sizably and thus reduce infection rates; the market for the products has seen discounting but also collapsing volumes of sales, and as a result the long run prospects for

[7] U.S. Government Accountability Office. Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program. Washington, D.C.: Committee on Energy and Commerce. GAO-18-521R. Accessed from https://www.gao.gov/assets/700/692587.pdf.

[8] Lipitz-Snyderman A, Sima CS, Atoria CL, Elkin EB, Anderson C, Blinder V, Tsai CJ, Panageas KS, Bach PB. Physician-driven variation in nonrecommended services among older adults diagnosed with cancer. JAMA internal medicine. 2016 Oct 1;176(10):1541-8.

[9] Trusheim MR, Cassidy WM, Bach PB. Alternative State-Level Financing for Hepatitis C Treatment--The "Netflix Model". *JAMA*. Published online October 29, 2018. doi:10.1001/jama.2018.15782. Accessed from https://jamanetwork.com/journals/jama/article-abstract/2712366.

revenues generated by sales of these treatments in relatively poor states are not good and the expectation is that even over the next decade the number of infected individuals who will be treated will be low. That phenomenon can be seen here.

eTable. Example of Possible Projections of HCV Prevalence, 10-Year Treatment Rates, 10-Year Annual and Net Present Value of Gilead Pharmaceuticals Anti-HCV Regimen Sales

		10-year Projections											
		Anticipated treatment overall under current model, No. (%)[b]	Gilead Pharmaceuticals' HCV Revenues by State (in the Millions), $[c]										
State	HCV Prevalence[a]		*Net Present Value, ($mm, 2019-2028)*[d]	2018[e]	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Arkansas	37,500	7,875 (21)	60	16	12	11	10	9	9	8	7	6	6	5
Louisiana	73,000	17,247 (23.6)	130	34	27	24	21	20	19	17	15	14	12	11
Oklahoma	94,200	16,811 (17.8)	126	33	27	23	21	19	19	17	15	13	12	11
New Mexico	45,000	8,949 (19.9)	67	18	14	12	11	10	10	9	8	7	6	6
Tennessee	122,500	32,665 (26.7)	244	64	52	45	41	38	37	33	29	26	23	21

Abbreviation: HCV, hepatitis C virus.

[a]Data from Rosenberg et al.[10] or State Department of Health figures if available.

[b]Based on consensus estimates of HCV sales for both Gilead and AbbVie (including price declines and market share shifts).

[c]Proportional revenues based on state's percentage of HCV prescriptions for HCV for 2017 and HCV prevalence as % of US prevalence.

[d]Net Present Value of 10- year HCV revenue projections for Gilead (2019-2028, using an 8% discount rate); net present value was calculated as follows: NPV= $\frac{Annual\ cash\ flow}{(1+interest)^n}$

[e]Estimated annual HCV revenues for Gilead attributable to each state.

eReference

1. Rosenberg ES, Hall EW, Sullivan PS, Sanchez TH, Workowski KA, Ward JW, Holtzman D. Estimation of state-level prevalence of hepatitis C virus infection, US states and District of Columbia, 2010. *Clin Infect Dis*. 2017;64(11):1573-81. doi: 10.1093/cid/cix202.

Under our proposal, a purchasing coalition within a state would run an auction to obtain a market-based price for flat subscription payments for a set number of years during which time the coalition would work with the winning manufacturer to eliminate HCV infection in the state. This idea has begun to take shape in several states, and in the past months two states -- Louisiana and then Washington -- posted solicitations for manufacturers to participate in a subscription based payment model to treat HCV infected residents. [10,11,12]

Reform Part D: My team recently worked with reporters at the Wall Street Journal and showed that Part D plans appear to be bidding in a strategic manner to increase their profitability while shifting costs onto the Federal reinsurance portion of the benefit. One solution to this problem is

[10] Louisiana Department of Health. Request for Information on Subscription Payment Models. August 24, 2018. Accessed from http://www.ldh.la.gov/assets/docs/SPM_RFI.pdf

[11] Washington State Health Care Authority. HCA issues request for proposals from drug manufacturers for hepatitis C treatment and services. January 23, 2019. Accessed from https://www.hca.wa.gov/about-hca/hca-issues-request-proposals-drug-manufacturers-hepatitis-c-treatment-and-services

[12] State of Washington, Office of the Governor. Directive of the Governor: Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach. September 28, 2018. Accessed from https://www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf.

that at this point, a dozen years after the commencement of the program, plans could take over the risk (or at least the lion's share) that is currently borne by Medicare through individual level reinsurance. From the perspective that these protections were put in place at the time Part D launched to ease the transition and lessen the risk of plans entering this new market, our analysis suggests that the plans have matured to the point that they are not only comfortable with the program, but actually able to take advantage of the protections to increase their profitability. We should explore rebates at point of sale so patients can have full benefit of plan negotiated price concessions. This will ensure that when a plan selects a drug with a high list price and a large rebate, the beneficiary pays the net price after the rebate when they are paying coinsurance or in their deductible. A preliminary assessment from the CMS actuary suggested that adding point of sale rebates to Part D would increase total Medicare spending under current rules.[13,14] There are many possible configurations of this policy that were not directly explored. Some may provide relief to specific subgroups of patients without increasing Medicare spending meaningfully.

Insert competition where possible for high priced therapies: In the category of high priced therapies, Medicare currently has an open National Coverage Decision on CAR-T therapies, the expensive one-time treatments for various cancers. One option for Medicare would be to consider ways to use its coverage authority (particularly Coverage under Evidence Development) in conjunction with CMMI authority to test alternative payment approaches, with the objective of inserting price competition between CAR-T treatments. I outlined this approach recently in the New England Journal of Medicine.[15] The agency should be seeking to create competition based on price when it has opportunities between products with similar effectiveness. The article included a decision matrix that CMS could use to consider its options based on its conclusions along several dimensions of its analysis.

[13] https://www.cms.gov/newsroom/fact-sheets/cms-proposes-policy-changes-and-updates-medicare-advantage-and-prescription-drug-benefit-program

[14] Dusetzina SB, Conti RM, Yu NL, Bach PB. Association of Prescription Drug Price Rebates in Medicare Part D With Patient Out-of-Pocket and Federal Spending. *JAMA Int Med.* May 2017;177(8):1185-1188. doi:10.1001.jamainternmed.2017.1885.

[15] Bach PB. National Coverage Analysis of CAR-T Therapies – Policy, Evidence, and Payment. *N Eng J Med*. 2018 Aug 15; 379(15):1396-8. doi: 10.1056/NEJMp1807382. Accessed from https://www.nejm.org/doi/full/10.1056/NEJMp1807382.

Strategy for CMS's Evaluation of Potential Coverage and Payment for the Various CAR-T Therapies.*

Key Question and Level of Confidence	Are the ancillary service costs similar?	
	Adequate level of confidence in answer	Uncertain level of confidence in answer
Are the net benefits similar?		
Adequate level of confidence in answer	Competitive bidding Competitive acquisition Consolidated payment code	Case-rate payment Bundled payment Gain sharing†
Uncertain level of confidence in answer	RCT: compare net benefits (and other outcomes)	RCT: compare net benefits (and other outcomes), gather detailed resource-utilization data

* This strategy applies to the overlapping indications for axicabtagene ciloleucel are relapsed or refractory large B-cell lymphoma in an adult who has received two or more lines of systemic therapy. RCT denotes randomized, controlled trial.
† These approaches would bridge payment between inpatient and outpatient settings, incorporating the prospective inpatient (i.e., diagnosis-related group) payment.

Recapture funds spent on discarded drugs: My team identified a pervasive problem in Medicare Part B, which was that it spends enormous sums on discarded leftover drug in vials. This problem primarily plagues those drugs that are dosed based on individual patients' body size, but these types of drugs are common in conditions such as cancer.[16] The reason for this is that in many situations the vials containing drugs are 'single dose', meaning that once the vial is accessed, if there is more drug than is needed to treat the patient in it, the leftover is discarded. Medicare, under buy and bill, pays for all of the drug in the vial when any portion is administered. The article reporting these findings includes an interactive graphic displaying each of the drugs that we examined, seen here: https://www.bmj.com/content/352/bmj.i788 In 2017 Medicare instituted mandatory use of the JW modifier for portions of drug billed to Medicare that was in fact leftover and discarded as waste. Our understanding is that the OIG has investigated how much drug is coded as discarded and found it to be hundreds of millions in 2017. With this mandatory code now designating what part of each billed vial was discarded, CMS could, with appropriate authority, 'claw back' from the manufacturer those funds expended on discarded drugs recorded as billed with the JW modifier.

[16] Bach PB, Conti RM, Muller RJ, Schnorr GC, Saltz LB. Overspending driven by oversized single dose vials of cancer drugs. *BMJ*. 2016 Feb 29;352:i788. doi: 10.1136/bmj.i788. Accessed from https://www.bmj.com/content/352/bmj.i788.

Move to flat fee reimbursement for Part B drugs

As noted above, the proportional mark-up model for Part B drugs tends on the margin to favor the prescribing of more expensive drugs. This is problematic on two fronts. 1) It leads to higher program spending (and beneficiary out of pocket spending for those without secondary coverage. 2) It creates an environment where pharmaceutical corporations can actually increase market share in part by charging higher prices, the reverse pattern of a typical competitive market. Changing to a flat fee add on above ASP is a more rational policy. This flat fee should be calibrated to the complexity of handling, storing and preparing the product for administration, rather than having a mark-up that is based entirely on the cost of the underlying drug. A hybrid fee, with the majority being made up of the 'handling' component, and a small percentage mark-up, would be a reasonable middle ground. There is a plausible argument that two parts of the cost of drugs are related to their underlying cost. It costs more to finance the purchase of more expensive drugs, and when coinsurance is uncollected the amount lost is larger when the drug costs more.

Definitional issues related to 'value-based pricing'

'Value based pricing' has been proposed by a number of analysts for new branded drugs with no competition. Today we often end up with drugs priced at levels well beyond what their benefits justify. We then see payers attempt to counteract these high prices. Payers insert barriers to access including shifting costs to out of pocket, delaying access through utilization management, and generally thinning the quality of the insurance benefit for patients who most need insurance. This push-pull makes all parties worse off. The core notion of value-based pricing is that in exchange for drug prices being based on their measurable benefits, payers would provide favorable formulary placement and low out of pocket costs coverage for eligible patients. It is important to note that this approach is distinct from several other approaches that have been suggested which at times include the word 'value' in their moniker. We recently reviewed these alternative approaches, the key table is included below.[17]

Outcomes-based contracts, which provide the payer with refunds when a drug does not work, is an example. This approach does not guarantee that prices are value-based, because it leaves untouched how much a drug costs when it does work. Most proposals and agreements in place with outcomes based arrangements have this basic flaw. One such example was outlined in the Annals of Internal Medicine,[18] in which my colleagues and I wrote an editorial explaining that these outcomes arrangements may be an attempt to distract from the underlying question of how much a drug should cost when it does work.

Long term financing for one-time treatments should be viewed cautiously as well. This approach has been proposed by pharmaceutical corporations as a way to push through multi-million dollar prices fo their products, and embraced by some commercial payers as a means to help smooth

[17] Kaltenboeck A, Bach PB. Value-Based Pricing for Drugs: Themes and Variations. *JAMA.* 2018;319(21):2165–2166. doi:10.1001/jama.2018.4871. Accessed from https://jamanetwork.com/journals/jama/fullarticle/2680422.

[18] Mailankody S, Bach PB. Money-Back Guarantees for Expensive Drugs: Wolf's Clothing but a Sheep Underneath. Ann Intern Med. 2018;168:888–889. doi: 10.7326/M18-0539

expenditures and pass through costs into future premiums. It is important to note that we can't solve the affordability problem by pushing costs into future years. Financing does not reduce total spending, it just changes current obligations. It is also relevant to appreciate that, whether for student loans or home mortgages, long-term payment arrangements are inflationary.

Table. Comparison of Value-Based Pricing and Adjacent Concepts

Concept	Definition	Rests on Existing Evidence of Benefit	Aligns Price With Benefit at Market Entry	Examples
Value-based pricing	Price of a drug set on the magnitude of its benefit	Yes	Yes	Pricing of dupilumab according to ICER value-based price
Indication-specific pricing	Drug price specific to each of its uses	Yes	Yes	Tisagenlecleucel sold at 2 different prices for 2 different cancer indications
Outcomes-based contracts	Manufacturer refunds or rebates payer when an agreed-upon outcome is unmet	No	No	Amgen agreement with Harvard Pilgrim to refund cost of evolocumab for treated patients who have a myocardial infarction while taking the drug
Mortgage pricing	Commits a payer to pay for expensive treatments over time	No	No	No known examples
Value-based insurance design	A health benefit design that reduces out-of-pocket expense for high-value medical care and treatments	Yes	No	Prime Therapeutics program to reduce copayment and increase amount dispensed for insulins; Pitney Bowes' initiative to reduce or eliminate cost sharing for statins and clopidogrel

Abbreviation: ICER, Institute for Clinical and Economic Review.

Lastly, when companies say we need to change our payment system to afford their new high-priced treatments, they are framing the issue backwards. Prices for monopoly goods are dictated primarily by what payers are willing to pay for them, as the companies do not face traditional market competition that would put downward pressure on their prices. So, when companies call for long term financing to pay them for their treatments, they are inventing a means by which the market can pay them more than they would get without such a system. But in viewing this proposal, it is important to keep in mind that these drugs do not inherently cost $1 million or $2 million dollars. Rather, it is policy choices that will dictate what they cost, policy should not configure to what the corporations want them to cost.

Other arguments advanced to justify mortgage type financing for one time treatments is that our system does not have a way to pay for cures. This seems like an odd assertion in that many types of one time curative treatments have been available for many years and are paid for without difficulty, including courses of antibiotics and radiotherapy of local cancer. The notion that one time treatments are special and thus need to be paid for at many multiples of other drugs is also problematic. In truth many new expensive drugs on the market are only taken for a short period by each person who receives them. New cancer drugs are a prime example. A single dose versus a handful of doses over a few weeks or months before the patient goes on to some other treatment seems more similar than different. In either case there is a brief period of payment for each unique patient where the drug corporation receives its reward for successful innovation. We can safely conclude that our system pays adequately for the latter scenario, as evidenced by the continued development of new treatments that meet this definition. In fact the current incentive system has led to the creation of a spectacular number of new cancer drugs that are rewarded in this type of treatment horizon.

Lastly, I urge the committee to remember that the purpose of paying high prices for drugs when they are approved is to provide an incentive for companies to undertake the risks of trying to create new treatments that can help the sick. In this context, without any change in the payment system, we are already seeing a large number of spectacular one time treatments come to market. While companies logically will seek to loosen the payment system to accommodate even higher prices, please remember that the treatments they are discussing charging such high prices for actually emerged under current payment approaches. This would suggest that investors eyed the prospects under current payment rules as favorable enough to take the risks to develop them. Those investors have successfully earned their rewards for taking these risks, companies that specialize or solely focus on one-time treatments have achieved multi-billion dollar valuations prior to having any marketed products in multiple cases. If anything, since the launch of these early 'one time treatment' companies, the technology and science of making gene therapies for instance has advanced considerably. New companies entering this domain will face lower risks and higher success rates. This would mean that if anything the rewards can be downsized while maintaining the current level of innovation.

International pricing:

A number of discussions have been undertaken around benchmarking US prices to those in other western countries. In general terms, prices for most drugs are higher in the US, sometimes twice as high or even more. My research team has examined some claims with regards to this observation, including the oft-cited argument that US taxpayers fund the world's research and development in the pharmaceutical sector. When we examined the claim, we looked at whether the additional revenues companies earned from higher prices charged to US patients compared to if they charged prices similar to those in Europe. We then compared that spread with benchmark prices in several European countries. We found that typically a pharmaceutical corporation captured 1.7 times their global research and development spending from charging higher prices to US patients, taxpayers and insurers.[19]

[19] Yu N, Helms Z, Bach PB. R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices. *Health Aff.* Published March 7, 2017. doi: 10.1377/hblog20170307.059036. Accessed from

The 15 Pharmaceutical Companies Responsible For The World's 20 Top-Selling Products In 2015

Company	International price/US price	US premium price percent	US sales (2015, $mm)	Revenue from US premium ($mm)	Revenues from US premium as percent of global research and development
AbbVie	48%	52%	$13,561	$7,092	166%
Amgen	43%	57%	$16,523	$9,355	239%
AstraZeneca	36%	64%	$9,474	$6,078	101%
Biogen	25%	75%	$6,546	$4,934	245%
Bristol-Myers Squibb	45%	55%	$8,188	$4,516	76%
Celgene	45%	55%	$5,525	$3,020	148%
Roche (Pharma Div)	45%	55%	$1,7782	$9,759	119%
Gilead	75%	25%	$21,200	$5,200	173%
GlaxoSmithKline (ex consumer)	48%	52%	$10,188	$5,300	114%
JNJ (just pharma division)	39%	61%	$18,300	$11,127	163%
Merck	39%	61%	$17,519	$10,649	159%
Novartis	52%	48%	$18,079	$8,678	97%
Pfizer (ex Consumer)	21%	79%	$19,906	$15,735	219%
Sanofi	28%	72%	$12,625	$9,123	163%
Teva (specialty meds)	22%	78%	$6,442	$5,018	263%
Average	***41%***				***163%***

Thank you for the opportunity to share my views. I look forward to answering any questions you may have.

Disclosures

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Consulting fees: Foundation Medicine, Grail