Senators Wyden and Grassley,

This letter is in response to your request for feedback after the Sovaldi investigation. I have bulleted specific recommendations below.

Oppose the TPP.

What are the effects of a breakthrough, single source innovator drug on the marketplace?

Reject a premise of drug manufacturers or payers as "winners."

Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?

Oppose the 21st Century Cures Act.

Ban prescription drug advertising.

Co-sponsor and pass S.31, the Medicare Prescription Drug Price Negotiation Act of 2015.

What role does the concept of ‘‘value’’ play in this debate, and how should an innovative therapy’s value be represented in its price?

“Value” cannot be ascribed to essential drugs that are rationed when they are unaffordable. Until Congress establishes essential medicines as a public good, drug companies will get away with murder.

Reintroduce and pass S.1782 American Health Security Act of 2013.

What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?
The real problem is thinking that health care should be a delivered in a competitive marketplace. Awareness of price gouging is step one toward a health care delivery system that puts people over profits.

Amend HIPAA to address conflicts of interests that arise with big data aggregators.

Solicit recommendations from the Universities Allied for Essential Medicines and the American Medical Student Association.

Eliminate trade secret protections for pharmaceutical price negotiations.

What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

Co-sponsor and pass S.1364 – Medicaid Generic Drug Price Fairness Act of 2015.

Co-sponsor and pass S.2023 - Prescription Drug Affordability Act of 2015

Thank you for the opportunity to give this feedback.

Kris Alman MD

Portland, Oregon

In a world of rising tensions within and among nations, of accelerating climate and environmental change, we would be wise to design the production systems on which we rely to be able to evolve as rapidly as the human and natural worlds around us evolve.

Barry C. Lynn / Harper's July 23, 2006[1]

We would be wise if we generated and shared knowledge with all members of society to improve the human condition. A knowledge society is far different than the knowledge economy.[2] In the knowledge economy, patents[3] restrict access to intellectual property. As such, financial innovations rapidly evolve, enriching few. The knowledge economy has become rigged.[4]

The World Health Organization[5] says there is “an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way.” Sovaldi is “the poster child of a U.S. health care system that is being bankrupted by greed, lobbying and indefensible policies on drug pricing” according to Jeffrey Sachs.[6] Irrational drug pricing in the U.S goes hand in hand with irrational use of drugs globally.

It hasn’t always been this way.

Pfizer was at the forefront of the battle over intellectual property rights and a campaign to wall off common access to essential medicines.[7] In 1982, Edmund Pratt, the President of Pfizer International

wrote a NY Times OpEd, “Stealing from the Mind.” Pratt was directly involved with the Advisory Committee on Trade Negotiations that would link trade negotiations and foreign policy. [8] US Trade Representatives could bully foreign governments into enacting legislation that favored American industry interests. Any government that didn’t protect patent rights was essentially committing piracy.

What’s Pfizer up to these days? This summer, 166 years after being founded in New York City, Pfizer will renounce its American identity. Americans for Tax Fairness sums it up in “Pfizer: Price Gouger, Tax Dodger.”[9]

Dean Baker, Co-Director of the Center for Economic and Policy Research[10] says[11]: “While tariffs and quotas rarely raise the price of goods by more than 30 or 40 percent, patents on prescription drugs typically raise the price of protected products by 300 to 400 percent, or more, above the marginal cost. In some cases, patent protected drugs sell for hundreds or thousands of times as much as the competitive market price.”

The negotiators of the Tran-Pacific Partnership grant pharmaceutical and medical device makers more power to influence participating governments. The TPP will make it more difficult to respond to global challenges that threaten humanity. By listing the Centers for Medicare and Medicaid Services, the annex of the TPP[12] makes it clear Americans would be vulnerable to TPP rules that could undermine future public health initiatives.[13] An international coalition of public health advocates[14] opposes the Trans-Pacific Partnership.

Congress should oppose the TPP.

What are the effects of a breakthrough, single source innovator drug on the marketplace?

A recent Dutch study found that chronically ill people have a relatively low level of trust in future health care.[15] The researchers speculated that these people were more concerned about current social developments: how they would be affected by changes in financing system of health care and the higher costs arising from this change and how non-financial matters play a role, such as waiting lists and the quality of care delivered by institutions.

That’s how I feel about “innovator drugs” and the precision medicine initiative.[16] An “innovator drug” is in the eye of the investor. Investors desire single source innovators that can command monopoly pricing—all the better when a drug is approved quickly, giving the drug more time to monopolize the market.

IMS Health says pharmaceutical companies should generate compelling “real world evidence” strategies to “maintain value post launch.” [17] IMS Health views the pricing and market outlook of big PhRMA as

a global strategy. Pricing relies on big data—and that gives IMS Health the edge since they are the largest vendor of prescription drug data in the U.S.[18] In their analysis, the “winners” are either pharma manufacturers or payers. “Physicians are knights (in shining armor?) Powerful players that protect the pawns (patients) and support the king (shareholders). Patients are pawns: Relatively weak and numerous; easily manipulated or sacrificed for larger purpose of protecting the king (shareholders).”

Rather than feeling knight-like, I felt I had become a handmaiden to big PhRMA when I abruptly left my medical career in 1999. Board certified in endocrinology, I left when my career should have been peaking. Treating insulin deficiency and obesity related insulin resistance—the bread and butter of the endocrinologist—had lost its luster.

The following is an ex-handmaiden’s tale about big PhRMA.

I’ll start with the words of Shire CEO Angus Russell,[19] who in May 2011 (just months prior to his retirement[20]) said, "Prices were just shoved up every year to make more money and meet earnings, to be blunt." He was referring to mass marketed drugs used to treat common conditions. “Insulin represents a golden goose for the pharmaceutical industry, especially as the number of people with Type 2 diabetes on insulin therapy increases,” says Craig Idlebrook,[21] Editor and Publisher of Insulin Nation.

To maximize revenue growth, global pharmaceutical companies must strategically decide whether their business model relies on mass market or specialty.[22] PriceWaterhouseCoopers advises pharmaceutical companies on sales-force effectiveness. PWC sees the tide turning toward specialty drugs, “structured in the most tax-efficient manner, while still meeting business, legal and regulatory requirements.”

With the passage of time, single source innovator drugs generally fade when me-too drugs,[23] flood the market. The FDA is the last hurdle in the race to get a drug through the R&D pipeline.

Blamed for delaying innovation, the FDA has sped up the regulatory process for serious conditions[24] and boasts that 2/3 of the novel drugs approved in 2015 were first approved in the U.S.[25] Last year there were 45 novel drugs approved as new molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs).[26] Harvoni was among 41 new molecular entities approved in 2014.[27]

Insulin is the grandfather of all biologics,[28] approved by the FDA as the first genetically-engineered drug product in 1982. American company Eli Lilli manufactured human insulin, trademarked as Humulin. U.S. drug manufacturers discontinued pork insulin[29] (the remaining animal-sourced insulin) in 2006

even though a comparison of the effects and the adverse reaction profile of human and animal insulin[30] did not show clinically relevant differences.

Subsequently, there have been many synthetic analogs that are either bioengineered through recombinant DNA in two molecular factories: E. Coli (Eli Lilly[31] and Sanofi[32]) and yeast (Novo Nordisk[33]). Allergies to bioengineered “human” insulin and analogs occur. Product-related impurities of biologics[34] may actually increase the likelihood and/or the severity of an immune response to a protein product. Eli Lilly outsourced manufacturing of insulin to Puerto Rico in 2001. In 2010, the FDA sent a warning letter[35] stating that Lilly failed to investigate "critical deviations or a failure of a batch to meet its specifications or quality standards."

There is no “generic” insulin on the market. As Dr. Kasia Lipska[36] points out, this essential medicine has become unaffordable. Most pharmacies price one vial of Humulin R for over $120. Lantus, insulin glargine, is more than double that price.

Launched in 2000, Lantus earned blockbuster status through touting a “peakless”[37] 24-hour release of insulin. Lantus is a genetically engineered long-acting analogue of insulin manufactured by the Sanofi-Aventis pharmaceuticals group, a merger of a French company and German company Hoechst AG.[38] Lantus was developed in Frankfurt and is Germany's largest and most important export pharmaceutical product.[39]

A systematic review and network meta-analysis of the management of type I diabetes was published in 2014. Lantus is "probably superior to intermediate acting insulin analogs, although the difference is small for hemoglobin A1c. Patients and their physicians should tailor their choice of insulin according to preference, cost, and accessibility.[40]" Probably superior?

Eli Lilly sought FDA approval for their biosimilar to Lantus, which lost its patent last year. In July 2014, Sanofi, sued Lilly[41] and the FDA delayed market entry of Lilly’s biosimilar by 30 months. E.U. and U.S. drug manufacturers have different exclusivity strategies.[42] Europe approved the drug last September netting a discount of only 15-20%.

For $245 million[43], Sanofi subsequently purchased a "priority review voucher" to expedite FDA approval of LixiLan, a fixed-dose injection that combines Lantus with lixisenatide, an investigational type II diabetes drug. Shortening the review time from 10 months to 6 months will give Sanofi a four month lead on Novo Nordisk, which submitted a similar combination drug[44] for FDA approval in September 2015.

For 16 years, Lantus has been a “single source innovator” drug in the United States without a lot of evidence to account for its blockbuster status.

Reject a premise of drug manufacturers or payers as "winners."

Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?

I am more concerned about whether doctors and patients have adequate information about cost and efficacy of new treatment regimens.

IMS Health attributed innovations in the treatment of hepatitis C, cancer, multiple sclerosis and diabetes to the predominant total drug spending in 2014 ($373.9Bn).[45] In 2014, diabetes spending increased 30.5% to $32.2 billion in 2014, “driven by innovation and partially offset by off-invoice discounts and rebates.” Yet two of the diabetes innovator drugs (the SGLT2 inhibitors[46] and DPP-4 inhibitors[47]) also generated drug safety communications from the FDA the following year.

Drug companies are the main source of information about their products. New drugs aren’t evaluated against older, cheaper medicines. For making claims about efficacy, innovators are compared to placebos—which are also powerful “treatments.”[48] When it comes to efficacy, we should be skeptical because pharma-funded research cherry picks positive results.[49]

More drugs are developed and approved for late stage disease[50] because private investors benefit when there is a shorter time between invention and profitability. Proxy measures (like progression free survival, which measures how long a tumor remains dormant before beginning to grow again) are widely used surrogate measures because they allow for shorter, smaller and cheaper clinical trials. Richard Deyo, MD MPH, a professor of evidence-based medicine at Oregon Health and Science University, says surrogate measures mask complications that work against survival or quality of life.[51]

One out of every four Medicare dollars is spent on services for 5% of beneficiaries in their last year of life.[52] The financial burden can be devastating to a family. In his most recent book Being Mortal, Dr. Atul Gawande[53] admits guilt in giving false hopes and prescribing treatments that can actual shorten lives rather than improve them.

The National Physicians Alliance and other consumer advocates[54] opposed the 21st Century Cures Act,[55] which passed the House last year.

Congress should oppose the 21st Century Cures Act.

Last year, Eli Lilly's type 2 diabetes drug Trulicity,[56] with Gilead's hepatitis-C medication Harvoni, comprised 15% of online advertising to compete in the crowded GLP-1 receptor agonist market.

Pharmaceutical industry spending on Direct To Consumer Advertising[57] rose from $55 million in 1991 to $363 million in 1995. In 2001, DTCA skyrocketed to $2.7 billion.[58] The Kaiser Family Foundation found that each additional dollar spent on DTC advertising in 2000 yielded $4.20 in additional pharmaceutical sales in that year. In 2014, the health care industry spent $14 billion on advertising,[59] of which $4.8 billion was spent on ads for prescription drugs alone.

Orange and Santa Clara County officials sued five of the world's largest narcotics manufactures in 2014, saying a "campaign of deception" to boost sales of potent painkillers created "a population of addicts." Three drug ads were advertised during the Super Bowl, costing $5M per 30 seconds.[60] Ironically, one of these ads[61] pitched Movantik (naloxegol), a drug approved in 2014 to treat opioid-induced constipation in adults with chronic noncancer pain.[62]

The Federal Food, Drug, and Cosmetic Act permits the advertising of prescription drugs as long as the advertisements are accurate and not misleading.[63] That's not happening now and it won't in the future. The AMA supports an advertising ban,[64] reflecting the "negative impact of commercially-driven promotions, and the role that marketing costs play in fueling escalating drug prices."

Congress should ban the advertising of prescription drugs.

The bargaining power of prescription drug plans is weak because that market is so fragmented. This dulls the government's ability to bargain hard with manufacturers.

On the flip side, retail giant Walmart defies antitrust tradition in the pricing of human insulins. Indeed, the disappearance of antitrust enforcement[65] preceded outsourcing and the emergence of new technologies and changes in the global marketplace.

This link[66] states, "Novolin/ReliOn is manufactured for Walmart by Novo Nordisk, the world's leader in insulin production" and the store locator button is for the closest Walmart. Yet that changed in 2010 when Eli Lilly began to co-brand their drug with Walmart[67] under the "dual brand" Humulin® ReliOn®[68]. This is typical of Walmart's clout—the ability to dictate price, packaging, shipping and gathering/processing information on the products' movement.[69]

The Humana Walmart Rx Plan (PDP) sells human insulin for six times what the retail giant sells its “branded generic” in its stores.[70]

Number of Members enrolled in this plan in Oregon: 25,584 members.

Number of Members enrolled in this plan nationally: 1,774,068 members

These similar insulins, while off-patent, are “preferred” brands, subject to 20% of the plans Average Retail Drug Price, which has risen nearly 50% in the past two years. What explains this price hike as demonstrated in the tables below?

The current out-of-pocket cost of Humulin R is $24.38 after a $360 deductible is paid for the negotiated price. That’s on top of the monthly premium of $18.40 or $220.80 annually. The government subsidizes this plan for low-income dual eligibles.[71]

In other words, Walmart sets the price of "generic" human insulin with Eli Lilly, undercutting the "average negotiated retail drug price" by more than $100 per vial when sold through Humana Walmart Rx Plan (and other insurance companies). Higher prices accumulate toward the donut hole, which is "closing" as "average negotiated retail drug prices" of generics and brand name drugs skyrocket.

Terry Gross recently interviewed Tom Wainwright, who has been the Mexico correspondent for The Economist since 2010. The title of that interview: 'Narconomics': How The Drug Cartels Operate Like Wal-Mart And McDonald's.[72]

Walmart has successfully evaded allegations of predatory pricing.[73] Why have the courts given Walmart monospony power? In doing so, they’ve crowning the Waltons as America’s richest family.[74] Royalties for American royalty.

CVS Caremark and Target are teaming up to compete with Walmart.[75] CVS is the nation's biggest retailer of prescription drugs and second-largest pharmacy benefits manager.[76] In June 2015, CVS acquired big-box retailer Target's pharmacy and clinic business for $1.9 billion. The ink had just dried on the $12.7 billion acquisition of Omnicare by CVS to expand its presence in the senior care market.[77] (Just a year before that, the DOJ hand slapped Omnicare with $4.19 Million fines to resolve False Claims Act Allegations of Kickbacks.[78] An inauspicious start…)

CVS uses increased consolidation for greater negotiating power. CVS also has the largest CEO-to-worker pay disparity among top companies.[79] At a ratio of 422:1, CEO Larry J Merlo's salary, bonus and non-stock compensation was $12,112,603, while the average employee earned $28,700. IMS Health says the shareholder is "king," but shareholders need affordable health care—both for themselves and the Americans who purchase it. The real kings are executives commanding grotesquely enormous incomes.

The Editorial Board of USA Today[80] says Medicare should use its purchasing clout to negotiate better deals with pharmaceutical companies.

Co-sponsor and pass S.31, the Medicare Prescription Drug Price Negotiation Act of 2015[81]

What role does the concept of ''value'' play in this debate, and how should an innovative therapy's value be represented in its price?

As defined by the WHO[82], "Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford."

"Value" cannot be ascribed to essential drugs that demand rationing if they are unaffordable.

It's important that this committee address how taxes are spent to subsidize drugs for the very poorest. However, essential ordinary medicines like insulin are in danger of becoming unaffordable to the middle class. That's particularly true when investors price drugs by what the market will bear—whether it's for drugs to treat cancer, hepatitis C, diabetes or Wilson's disease.[83]

Valeant[84] became one of Wall Street's most popular health stocks by buying up existing drugs and aggressively raising prices. The price of Cuprimine, which treats Willson's disease, spiked last summer. Neither Medicare ($35,000 monthly) nor the patient ($1,800 monthly) can afford the drug.

Is this just maximizing profit out of each drug in the interest of shareholders? No. This is price gouging. Shareholders can claim a fiduciary breach only if they can demonstrate fraud, illegality, waste conflict of interest and negligence.[85] PhRMA exacts high prices through valuing drugs as profit-makers. Until Congress establishes essential medicines as a public good, drug companies will get away with murder.

Reintroduce and pass S.1782,[86] the American Health Security Act of 2013:A bill to provide for health care for every American and to control the cost and enhance the quality of the health care system through a Medicare-for-All type single payer health care system

What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?

IMS[87] (and other big data aggregators) claim they protect "individual patient privacy and only utilize anonymous healthcare data to deliver real-world disease and treatment insights." This is not true. They mine patient information without notice and consent to help set high drug prices.

This is a classic example of information asymmetry. In 2001, Joseph Stiglitz won the Nobel Prize[88] in Economics, recognizing that "problems of information are central to understanding not only market economics but also political economy." Like a sharecropping contract, Medicaid is a tax-financed insurance for the poor, where pharma-lords rebate[89] the government for excessively priced drugs.

Gilead, Turing Pharmaceuticals and Valeant put a face on PhRMA price gouging.[90] But Wall St. and global finance capital transformed the pharmaceutical industry gaining excess profits at the expense of consumers and even other companies over the past few decades. They do this through a complex web[91] that includes pharmacy benefit managers, acting as "king-makers." PBMs have paid $371.9 million[92] in damages over the past decade for allegations of fraud; misrepresentation to plans, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards.

Who can really make sense of the average wholesale price, the pharmacy discount price, the wholesale acquisition cost, the average manufacturer price, the best price, the 340 B(PHS) price, the federal upper limit price, the state maximum allowable cost, the acquisition cost and the ADAP Supplemental Discount/Rebate[93]?

Congress should amend HIPAA to address conflicts of interests that arise with big data aggregators.

The Universities Allied for Essential Medicines[94] and the American Medical Student Association[95] are student-oriented groups that lead the Make Medicines for People Not for Profit[96] and Just Medicine[97] campaigns. The Senate Finance Committee should heed their recommendations.

The UAEM calls upon the World Health Organisation (WHO) to negotiate a much overdue global research and development (R&D) agreement to ensure innovation and access to affordable vaccines, medicines and life-saving technologies for all. Mechanisms being used that show great potential including prize funds, patent pools, and open collaborative approaches. AMSA's Just Medicine Campaign comprehensively addresses conflicts of interest, legislative solutions, medical curriculum and more.

Solicit recommendations from the Universities Allied for Essential Medicines and the American Medical Student Association.

These recommendations are a stretch because of all the money in politics. In response to Citizens United, a cloture motion of the DISCLOSE Act failed by one vote in September 2010.[98] S.J.Res.19 was similarly rejected in 2014.[99] Sen. McConnell was accurate in pointing out that the DISCLOSE Act is "pure politics."[100] It's pure politics that corporations brand Congress and rig the system to their advantage. Best to keep that price transparency opaque?

Jeanne Whalen writing for the WSJ points out[101]: "Drug prices in the U.S. are shrouded in mystery, obscured by confidential rebates, multiple middlemen and the strict guarding of trade secrets. The state-run health systems in Norway and many other developed countries drive hard bargains with drug companies: setting price caps, demanding proof of new drugs' value in comparison to existing ones and sometimes refusing to cover medicines they doubt are worth the cost."

An individual cannot evaluate an insurance plan when prices are obfuscated. This is the antithesis of a marketplace. The real problem is thinking that health care should be a delivered in competitive marketplace.

A few years ago Steven Brill pulled back the curtains on the hospital "chargemaster."[102] Earlier this week, CMS Acting Administrator Andy Slavitt invited those attending the Federation of American Hospitals annual meeting on Monday to submit ideas about the "retailization"[103] of health care. He hears from "hospitals and physicians who want to lead the charge so there are no more consumer surprises in their hospitals." The "retailization" of pharmaceuticals and health care delivery began with deregulations of the industry in the 1980s when hospitals[104] and insurance companies[105] shed their non-profit status.

Trade secret protections for negotiated prices of pharmaceuticals are a charade to enhance profits. Transparency of pricing will be a means for physician/"knights" to understand their role in helping to manipulate and sacrifice patient/"pawns" for the shareholder/"king." Awareness of price gouging is step one toward a health care delivery system that puts people over profits.

Eliminate trade secret protections for pharmaceutical price negotiations.

What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

Co-sponsor and pass S.1364 – Medicaid Generic Drug Price Fairness Act of 2015[106]

Co-sponsor and pass S.2023 - Prescription Drug Affordability Act of 2015[107]

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