MK and I affirm Resolved: The United States Federal Government should impose price controls on the pharmaceutical industry.

Contention 1 is Insulin

The lack of price controls enables pharmaceutical companies to constantly hike up prices on insulin.

Tridgell of the Washington Post in 2017

> A recent paper in the Journal of the American Medical Association found that **insulin nearly tripled in cost from 2002 to 2013** [while the inflation rate was 2.38%]

However, McCall of Medscape in 2018 finds

> **Cost issues related to insulin use prevent a full quarter of patients with diabetes taking insulin as prescribed**, and this is associated with poorer glycemic control, shows a new study

The American Diabetes Association finds that

> **Approximately 6 million Americans use insulin** [29.1 million Americans have diabetes, and it] Diabetes remains the 7th leading cause of death in the United States in 2015,[contributing to more than **and diabetes leads to 250,000 deaths per year**] with 79,535 death certificates listing it as the underlying cause of death, and a total of 252,806 death certificates listing diabetes as an underlying or contributing cause of death.

Price controls would help ensure that patients would be able to afford life-saving insulin.

Contention 2 is Insurance

Chan of Medium in 2016

Premiums. As with car insurance, **we** all **pay a "premium" or a regular fee to be covered by health insurance. When drug prices go up, payers pay more, and thus make less money.** When payers make less money, they **[causing them to] boost premiums.**

Chan furthers that

There are other factors contributing to why **health premiums have risen by nearly 20–40% in the past few years;** however, **rising drug prices is a substantial [factor]** one. Insurance may continue to cover our drug costs, but we make up for it daily by paying skyrocketing premiums and rising taxes. **These issues will only become more pressing if rising drug costs continue unabated.** Up next on this blog, I'll discuss what our 2016 presidential candidates are proposing to tackle this issue.

The Impact of slowing the rise in health insurance cost is increasing insurance affordability

First is increasing available family income

https://www.rand.org/pubs/research_briefs/RB9605.html

Auerbach of the RAND Corporation in 2011

Had health care costs tracked the rise in the Consumer Price Index, rather than outpacing it, an average American family would have had an additional $450 per month to spend.

The Urban Institute in 2010 found that just a 9% increase in premiums for large firms alone would cause 3.3 million Americans to become uninsured.

A Harvard Medical School report in 2009 found

Uninsured, working-age Americans have 40 percent higher death risk than privately insured counterparts

Contention 3 is Going Global

The American College of Cardiology estimates that

> **Cardiovascular disease accounted for one-third of all deaths [globally] in 2015.**

Unfortunately, US companies hold onto pharmaceutical patents for as long as possible using a phenomenon known as "patent evergreening," as Amin 2018 finds that

> The strategy is called "evergreening": **drug makers add on new patents to prolong a drug's exclusivity, even when the additions aren't fundamentally new**, non-obvious, and useful as the law requires. One of the most expensive cancer drugs on the market, Revlimid®, is a case in point: priced at over $125,000 per year of treatment, For example **Celgene has sought 105 patents on Revlimid**®, many of which have been granted, extending its monopoly until the end of 2036. That gives the Revlimid **[giving the] patent portfolio a lifespan of 40 years**, which is being used to block or deter generic competitors from entering the market.

However, high drug prices in the US disincentivize companies from selling these patented drugs at lower prices in developing countries for two reasons.

First is parallel importation

Schweitzer 2011 from Health Affairs writes that

> Parallel trade can make **manufacturers [are] reluctant to [sell products at] lower prices** too much for products sold **in less-developed countries** because **[for fears that] those products can be resold to more-developed countries [like the United States]**—including the one where they were

manufactured—**undercutting the prices charged there.** This concern applies primarily to drugs that are still patented because generic drug prices vary less across countries.

Passing price controls reduces companies' fear of parallel importation, as the low costs in the US mean there is less potential profit loss
Schweitzer furthers

Parallel trade can make manufacturers reluctant to lower prices too much for products sold in less-developed countries because those products can be resold to more-developed countries—including the one where they were manufactured— undercutting the prices charged there. This concern applies primarily to drugs that are still patented because generic **[when] drug prices vary less across countries [manufacturers are not as concerned about reimportation].**

It is important for prices to lower now, as Wurtz from Boston University in 2016 writes

The HAI/WHO standardized survey results in over 70 countries also provided relevant information on affordability of cardiovascular medicines. While the prices of government-procured generic medicines varied from 1.5- to 3-times international reference prices, the same generic products sold to patients cost about 15-times international reference prices in the public sector and about 30-times international reference prices in the private sector.37 Treatment for CVD in general was not affordable in the majority of countries, particularly in low-income countries.35 In the public sector, a 1-month supply of one generic CVD medicine cost on average 2.0 days wages and one originator brand CVD costs on average 8.3 days wages for the lowest paid government worker. Atenolol was the most affordable of all cardiovascular medicines studied (1.1 days wage). Combination therapy for CVD is largely unaffordable. Since the publication of the 2009 Cameron, et al article, nine peer-review publications reporting 20 additional surveys have demonstrated similar findings.34 Importantly, post-manufacture costs are generally borne by patients and include duties, taxes, markups, and additional charges. A recent study evaluated the affordability of **combination therapy [for cardiovascular disease]** (aspirin, beta-blocker, ACE inhibitor, and statin) for the secondary prevention of CVD using a threshold of 20% of a household's capacity-to-pay. **In** lower-middle- and **low-income countries,** a 4-drug combination **was not affordable for** 33% and **60% of households respectively**.38 The patent status of a medicine impacts access due to effects on affordability. Medicines that are protected by patents are on average more expensive and less affordable than off-patent medicines since patented medicines generally lack market competition

Furthermore,

To measure availability of medicines, Health Action International (HAI) together with the WHO has conducted standardized surveys in over 70 countries. The HAI/WHO methodology assesses availability during facility inspections noting whether a medicine that should be in stock is or is not physically present.34 A meta-analysis of surveys from 36 countries assessed access to five cardiovascular medicines of different classes: atenolol, captopril, hydrochlorothiazide, losartan, and nifedipine.35 The authors found **cardiovascular medicines were only available in in 26% of public** and 57% of private **facilities**.35 In general, availability of generic medicines for acute conditions was higher than for chronic condition s in both public and private sectors. For the public sector, availability was 54% for a basket of generic medicines for acute conditions and 36% for generic medicines for chronic conditions (p=0.001). For the private sector, availability was 66% for generics for acute conditions and 54% for generics for chronic conditions.36

Fortunately, Bollyky of the Center for Global Development in 2009 concludes that

This suggests there may be a trend towards more effective international differential **drug pricing** between developed and developing countries and for a much larger range of products. If so, U.S. health care **reform may** be driving the trend. The direct effect of that reform, which the WSJ article notes, is that **[cause] drug firms** are **[to] look**ing **to emerging markets to make up for the expected loss in U.S. revenues**. **The** indirect **effect of reform may be that drug firms are less concerned about the risks of parallel importation** and reference pricing **in a world in which**

on-patent **drug prices in the U.S.,** which has represented roughly 50 percent of world drug market, **are no longer** expected to remain as anomalously **high.**

There is historical precedence for this.

The Wall Street Journal finds that

> **[In 2009] The Obama administration and Congress's attempt to pass legislation** overhauling the health-care system, including provisions **that could lower the cost of medicine**, could **[potentially] put drug makers' U.S. businesses under further pressure. As a result, developing countries** like Venezuela have **beg[a]n to look more attractive to the industry [as a way to make up for lost revenue].**

For example, Bollyky found Pfizer began selling the cardiovascular drug Lipitor in Venezuela after healthcare reform threatened to lower the price of Lipitor in the US.

The impact is saving lives.
Cardiovisual finds that

> **13 million [cardiovascular] deaths occurred in low-income and middle-income countries.**

Thus, we proudly affirm.

FL: Generics solve global access over time
Amin 2018

The strategy is called "evergreening": **drug makers add on new patents to prolong a drug's exclusivity, even when the additions aren't fundamentally new**, non-obvious, and useful as the law requires. One of the most expensive cancer drugs on the market, Revlimid®, is a case in point: priced at over $125,000 per year of treatment, For example **Celgene has sought 105 patents on Revlimid**®, many of which have been granted, extending its monopoly until the end of 2036. That gives the Revlimid **[giving the] patent portfolio a lifespan of 40 years**, which is being used to block or deter generic competitors from entering the market.

Extension:
Drug companies lack incentives in the status quo to sell drug s in other countries because

A. **US companies fear drugs can be imported back undercutting profits**
B. **US companies fear price differentials cause consumers to pressure them to lower prices**

However, Bollyky says price controls remove these disincentives because prices are more similar in the US and other countries now, and companies will expand to broaden their consumer base. This is why Pfizer introduced Lipitor to the Venezuelan poor when price controls threatened them.

FL: Cardiovascular drugs are ineffective

European Heart Journal in 2017

Combination pills containing aspirin, multiple blood pressure (BP) lowering drugs, and a statin have demonstrated safety, substantial risk factor reductions, and improved medication adherence in the prevention of cardiovascular disease (CVD). The individual medications in combination pills are already recommended for use together in secondary CVD prevention. Therefore, current information on their pharmacokinetics, impact on the risk factors, and tolerability should be sufficient to persuade regulators and clinicians to use fixed-dose combination pills in high-risk individuals, such as in secondary prevention. Long-term use of these medicines, in a polypill or otherwise, **is expected to reduce CVD risk by at least 50–60%** in such groups. This risk reduction needs confirmation in prospective randomized trials for populations for whom concomitant use of the medications is not currently recommended (e.g. primary prevention). Given their additive benefits, the combined estimated relative risk reduction (RRR) in CVD from both lifestyle modification and a combination pill is expected to be 70–80%. The first of several barriers to the widespread use of combination therapy in CVD prevention is physician reluctance to use combination pills. This reluctance may originate from the belief that lifestyle modification should take precedence, and that medications should be introduced one drug at a time, instead of regarding combination pills and lifestyle modification as complementary and additive. Second, widespread availability of combination pills is also impeded by the reluctance of large pharmaceutical companies to invest in development of novel co-formulations of generic (or 'mature') drugs. A business model based on 'mass approaches' to drug production, packaging, marketing, and distribution could make the combination pill available at an affordable price, while at the same time providing a viable profit for the manufacturers. A third barrier is regulatory approval for novel multidrug combination pills, as there are few precedents for the approval of combination products with four or more components for CVD. Acceptance of combination therapy in other settings suggests that with concerted efforts by academics, international health agencies, research funding bodies, governments, regulators, and pharmaceutical manufacturers, combination pills for prevention of CVD in those with disease or at high risk (e.g. those with multiple risk factors) can be made available worldwide at affordable prices. It is anticipated that widespread use of combination pills with lifestyle modifications can lead to substantial risk reductions (as much as an 80% estimated RRR) in CVD. Heath care systems need to deploy these strategies widely, effectively, and efficiently. If implemented, these strategies could avoid several millions of fatal and non-fatal CVD events every year worldwide.

Drug companies don't want to expand to developing markets because they fear that reimportation of these cheap drugs will cut into their high US profits. Bollyky says that when price controls are implemented, that disincentive goes away plus they have to now expand their consumer based, which is why Pfizer introduced Lipitor to the Venezuelan working class when they thought price controls would limit US prices.

FL: Co already introducing
Wirtz, most can't afford

Probably non-patented but patent evergreening means most current drugs won't be available for like 40 yrs

FL: Other barriers to access
Bollyky says main barrier is reimportation, Lipitor did it so clearly the main barrier is reimportation

FL: Reimportation illegal
AARP
Although the Food, Drug and Cosmetic Act prohibits re-importation, the federal government has not strictly enforced the law in the past. The FDA has used discretion in dealing with reimportation or importation of prescription drugs for personal use. Many American citizens have been able to cross the Canadian border, purchase a limited supply of prescription drugs, and bring them home. Earlier this year, in recognition of the increase in both Internet-based pharmacies selling drugs from abroad and organized busloads of older persons traveling to Canada to buy medicine, the FDA announced that it plans to enforce the law more rigorously by bringing civil or criminal charges against third party groups that help Americans import drugs from Canada.

FL: Price will never be low enough
WSJ
Lipitor introduced in the poorest Venezuelan slums
Second is political pressure

The Economist explains in 2001

Drug firms fear that if their products are sold at low prices in poor countries, smugglers may buy crate-loads and ship them back to rich countries, where they could undercut legitimate sales. This is possible, but safeguards in rich countries are stringent. A far worse worry is the **[it will lead to] mounting pressure in the drug companies' most important markets, notably America, for cheaper drugs.** American pharmaceutical companies have just come through a big row about the relatively cheaper cost of drugs in Canada. **If consumers learn that pills that cost $10,000 a year in America cost only $700 in Africa, they will demand similar discounts.** That would be going too far. For the rich to steal from the rich is inexcusable.

Contention 2 Rural Hospitals

Drug Costs are skyrocketing in the status quo as the Argus institute A recent analysis shows thousands of generic drug prices have increased. **over the past several years**, Almost **400** generic **drugs [studied] grew in price by more than 1,000%, and** approximately **3,500** generic **drugs grew in price by more than 100%.**

As a result, **Saporito of Time Magazine furthers in 2014** that hospitals are being hurt by rising drug prices. When a price spikes hospitals are unable to receive accurate rebates, which decrease their spending on drugs, and insurance companies cannot help with the payment as the list price remains the same.

For this reason, Ascension Hospitals' drug costs rose by $36 million in one year

Stempniak of H&HN quantifies in 2016 that 90% of hospitals have been impacted by high drug prices on their budget[1]

Rural hospitals in particular are at risk as **Weber of the Huffington Post writes in 2017** rural hospitals most absorb the costs from uninsured patients

Warshaw of the AAMC explains in 2017[2] that rural americans are more likely to be uninsured

Thus, **Hu of the Business Insider finds in 2018** that 20% of hospitals in the US are at risk of closure

Fortunately, price controls solve as **Lo of PT finds in 2018** that studies have shown prices controls in South Africa reduced prescription drug prices by 22% in the first year.

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The impact is creating hospital deserts

Ostroff of CNN writes in 2017 that since 2008 81 rural hospitals have shut down and another 673 are vulnerable to shutting down. When hospitals close they force people to seek treatment far away. For this reason, **Ostroff furthers** the rate of accidental deaths was 50% higher in rural areas than urban areas.

Contention Two is Going Global

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However, high drug prices in the US disincentivize companies from selling these patented drugs at lower prices in developing countries because

drug companies fear that US consumers will import low-priced drugs, cutting into their profits.

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> Parallel trade can make **manufacturers [are] reluctant to [sell products at] lower prices** too much for products sold **in less-developed countries** because **[for fears that] those products can be resold to more-developed countries [like the United States]**—including the one where they were manufactured**—undercutting the prices charged there.** This concern applies primarily to drugs that are still patented because generic drug prices vary less across countries. **[However, when] drug prices vary less across countries [companies have less fear of profit loss, which is why companies have already introduced drugs in developed countries].**

This is because passing price controls disincentivizes importation, as US patients can obtain low-price drugs domestically.

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> **[for treating cardiovascular diseases] was not affordable for** 33% and **60% of households** respectively.38 The patent status of a medicine impacts access due to effects on affordability. Medicines that are protected by patents are on average more expensive and less affordable than off-patent medicines since patented medicines generally lack market competition

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For example, Pfizer began selling the cardiovascular drug Lipitor in Venezuela after healthcare reform threatened to lower the price of Lipitor in the US.

Implementing price controls would thus accelerate this process by increasing revenue pressure.

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