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# Sustainability and Quality of Care Drug Formularies

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## Sustainability and Quality of Care

### Drug Formularies

#### Introduction:

The house always wins. A common saying about casinos, but it's not just a saying, it's a necessity. If the house lost, then sooner or later the casino would go out of business. The money coming in must always exceed the money going out. This same concept can be applied to insurance companies, since insurance is similar to a very large scale casino. The way it works is that a person pays their premium each month which is akin to placing down a bet each month. The bet is whether or not you will either get in a car accident for auto insurance, get sick for health insurance, have damage done to your house for home insurance, and so on. So what happens if the amount you pay out begins to increase faster than the amount of money coming into the business? The answer is that you run the risk of becoming insolvent and going bankrupt; for an insurance company, this can be very bad news for all those depending on

the coverage. Another similarity to casinos is that the largest payouts go to a very small percentage of all the players. In casinos, it's the one who wins the jackpot. In insurance it's the one who is injured the most. The simplest solution to trying to prevent insolvency would be to eliminate those taking out the most money. This is where health insurance is far different than casinos and all other forms of insurance.

It's quite possible to go through life without ever getting in a car accident requiring filing of a claim such that your insurance carrier may never have to make a payout. The same cannot be said about getting injured or sick. Even if it's merely by old age, everyone will eventually need health care. Not only that, the health of people is valued greatly in our society. This can be seen in the fact that many countries have their health care run by the government for the benefit of all, and recently in the United States of America the passing of the Patient Protection and Affordable Health Care Act.

The true challenge lies in trying to strike a balance between two different objectives of Health Insurance. The first is the objective of sustainability and profit, which is the insurance companies need to keep the amount of money being paid in greater than that of the money they must pay out to those insured. The second objective is providing affordable and

quality care given to patients. The common element here is in maintaining cost. One of the major cost areas in health insurance is prescription drugs.

The consumption of prescription drugs is increasing at an alarming rate with the rate at which new and more expensive drugs are coming out. The Health Insurance industry needs to plan on how to manage these costs while still allowing for the best care to patients.

This paper will show the current method in place to combat the rising consumption of prescription drugs, and how this current method marginalizes those who need the most expensive drugs for the sake of containing costs.

There are changes that can be taken to effectively cut cost, and some of these methods can lower cost without singling out any one group of prescription drugs consumers.

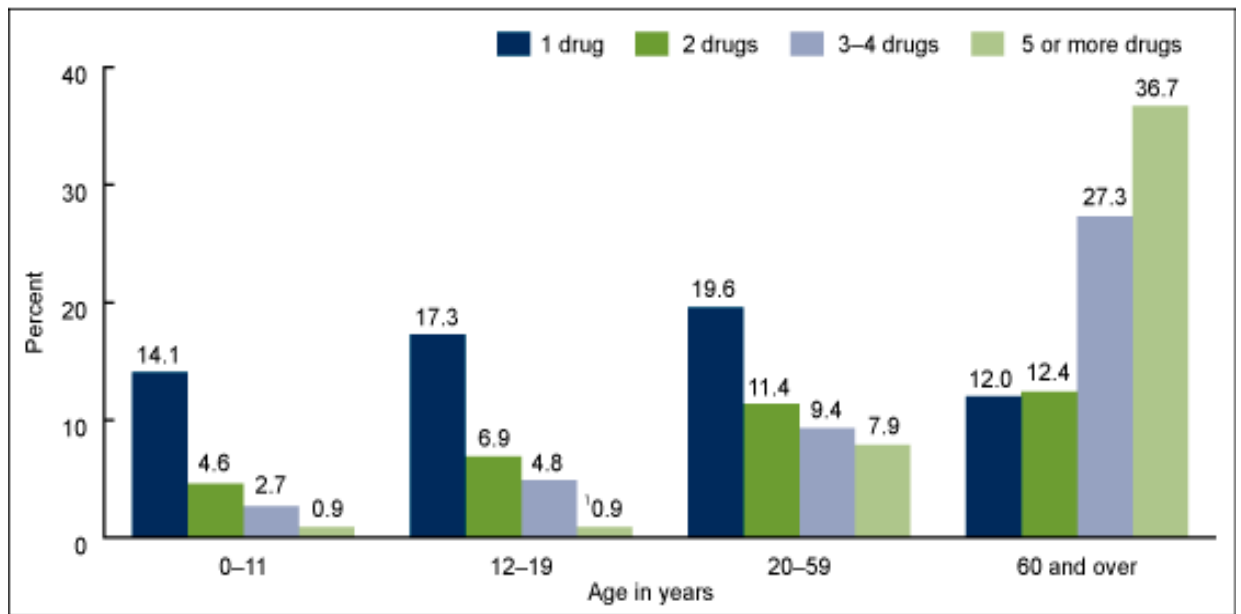
#### The Problem:

Left to their own market forces the cost of prescriptions drugs increases exponentially.<sup>1</sup> During a 5 year period between 1995 and 2000 the money spent on prescription drugs by Americans doubled from 60 to roughly 120 billion dollars.<sup>1</sup> Now before trying to make an effort to solve the problem it's important to

understand it first. In the article, Understanding Health Care Cost Drivers by the National Institute of Health Policy it discusses many of the cost drivers.

The first reason offered is our ever increasing elderly population.<sup>2</sup> The following graph shows the amount of drugs used by each age group.<sup>4</sup>

Figure 2. Percentage of prescription drugs used in the past month, by age: United States, 2007–2008



<sup>1</sup>Estimate is unstable; the relative standard error is greater than 30%.  
SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey.

As seen in the graph, as people get older the odds of them being on at least 1 prescription drug increases to roughly 90%.<sup>4</sup>

The next reason offered is Direct-to-consumer advertising.<sup>2</sup> This refers to the advertising shown on television, radio, and

the web.<sup>2</sup> The stringent "warning labels" are much more lax when it comes to these ads as of the FDA creating the rules for these ads and finalizing them in 1999.<sup>2</sup> This led to consumers doing as the commercials say and "asking their doctor if drug X is right for them!" With the addition of the internet it is very easy for people to discover new drugs that they can then seek out, as opposed to doctors being the ones giving out information on prescription drugs.<sup>2</sup>

Another important driver to the increasing prescription costs is the amount of drugs being introduced that are merely incrementally modified versions of previous drugs.<sup>2</sup> This can be seen by that fact that the amount of new drugs that have new therapeutic value increased by only 10% from 1995 to 2000 while the amount of drugs that were just modified versions of older drugs increased by 81%.<sup>2</sup>

In an article by the Star Tribune a doctor speaks about how easy a solution taking a pill for heartburn is as compared to a change in lifestyle to fix the illness.<sup>8</sup> A doctor had even mentioned that during his residency "I was told it was a quick and easy answer to everything, and it had no side effects, and insurance was willing to pay for it."<sup>8</sup> Fixing the underlying problems is the better solution for many patients, but as the article says people would rather take the path of least

resistance, and that comes in pill form.<sup>8</sup> The problem lies in the fact that these drugs have a purpose to cure an illness, but are rather being used so people can maintain their bad lifestyle choices.

Furthermore, in the Star Tribune article the focus is on the over-prescription of drugs by doctors.<sup>8</sup> Doctors often give the person the drug just to see if they improve with no real medical reason for prescribing it.<sup>8</sup> One doctor is quoted as saying "What's the downside? I might make you feel better. I'm saving you an invasive test. And if it works, I'm a hero." The downside comes twofold. First from the fact that the article claims that up to 69% of acid-suppressing drugs are for inappropriate reasons, which means a lot of wasted money that need not be spent.<sup>8</sup> The second is from what is mentioned as the "Rebound Effect." Once someone is on the drug if they stop taking the drug their acid production system kicks into overdrive.<sup>8</sup>

#### Drug Formularies Explained:

A drug formulary is essentially a categorization of prescription drugs with each category representing a different amount that the patient needs to pay before health insurance

will cover the remaining amount. This definition applies to both private health insurance and Medicare part D. The way a formulary is set up is well shown through how Medicaid handles it. A formulary must be established by a pharmacy and therapeutic (P&T) committee which includes a majority of practicing physicians and/or pharmacists.<sup>5</sup> In developing and reviewing the formulary, the committee must make clinical decisions based on "the strength of scientific evidence and standards of practice" and, when determining which drugs should be included in the formulary, the committee must consider whether certain covered drugs provide "therapeutic advantages in terms of safety and efficacy."<sup>5</sup> While the effectiveness of a drug is taken into account, the cost seems to be a largest determining factor as well.

Plan sponsors must inform patients about the formulary and "appropriate" notice must be given before a drug may be removed from the formulary or before a drug's preferred status is changed.<sup>5</sup> This gives the companies a wide range of power to change how much each drug will cost the patients even if it can only be done annually.<sup>5</sup> An example of this can be show in Saltzman v. Independence Blue Cross where the drug Plavix was moved from a preferred tier 2 drug, which appeared on the formulary, to a tier 3 non-preferred drug, which in this case



meant any brand name not referred to on the formulary.<sup>12</sup> In the case, the plaintiffs sued with the argument that since there was no substitute for Plavix on the formulary, removing it from their formulary they did not meet the "highest level of coverage" that the contract mentioned the company would take into account for placing drugs in their formulary.<sup>12</sup> The court found that the contract allowed for them to alter their formulary, and that at the statement made in the contract was one of the insurance company's opinion of the quality of the plan and not a concrete commitment to include certain drug coverages.<sup>12</sup>

Into which tier a drug falls in a formulary depends on the company, a general overview helps to understand what each tier of drug means for the patients.

Tier 1 drugs are generally drugs that have since lost their patent and are now generic drugs.<sup>10</sup> All drugs will eventually find their way down to these lower tiers, since as drugs come off their patents the cost paid for the drug is no longer affected by research and development costs.

Tier 2 drugs are generally preferred brand name drugs. Often this means that the insurance company has bargained a good price with the company that owns the drug.<sup>10</sup> In the absence of

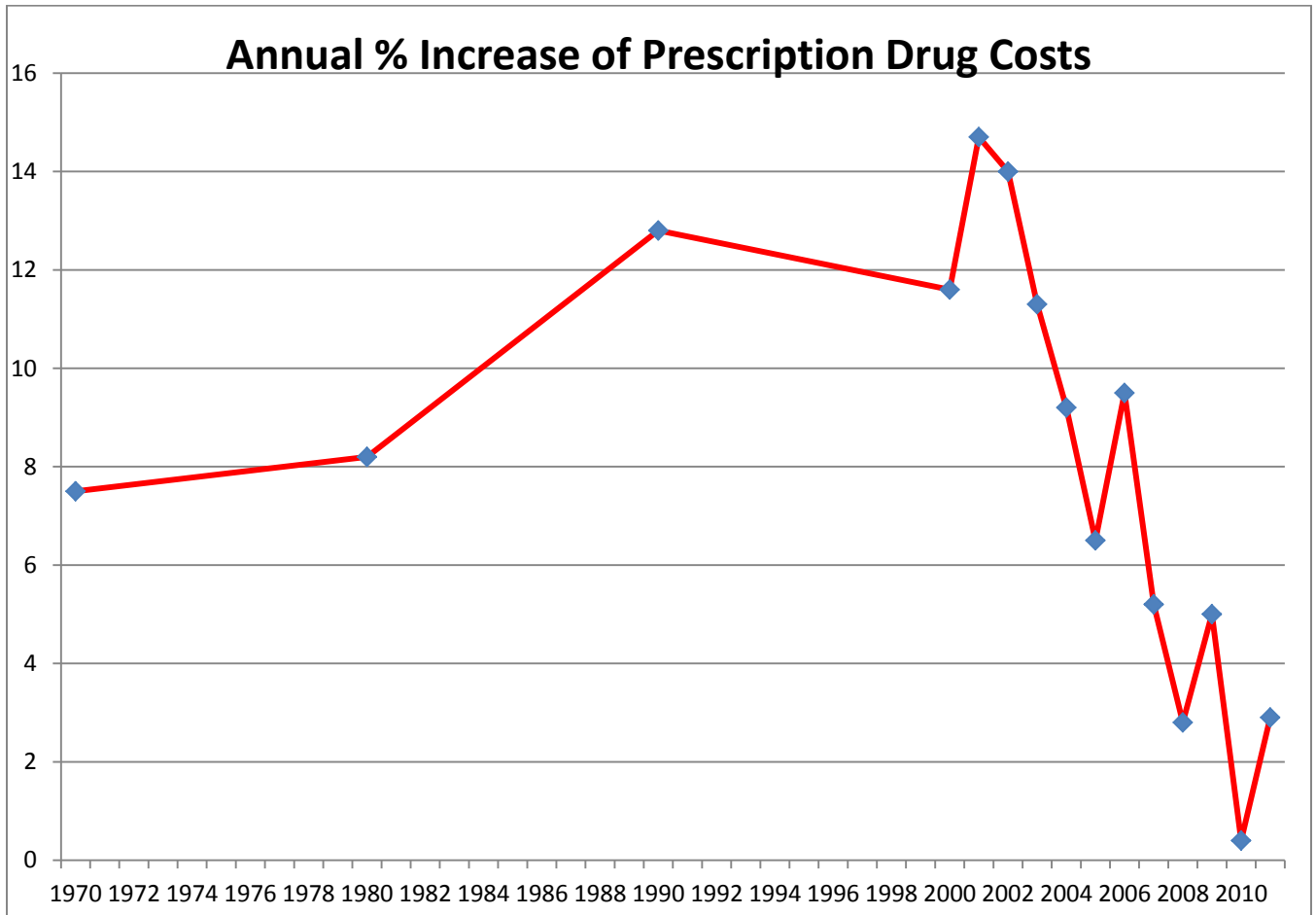
this bargaining many tier 2 drugs in one companies formulary may appear as tier 3 drugs in another insurance companies formulary.

Tier 3 drugs are the non-preferred name brand drugs that an insurance company does not want to encourage people taking.<sup>10</sup> Even though drugs in this category are not ones that an insurance company would prefer their patients to take, it does not guarantee that a cheaper equivalent exists on a lower tier.

Tier 4 is different from all other tiers. This tier does not generally have a maximum co-pay for the drugs, but rather is based on a percentage of the total retail price. This price can range between 30 to 70 percent. This tier is for the most expensive drugs on the market. This tier came about in 2003 with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.<sup>5</sup>

Drug Formularies effect on Health Care Costs:

The following graph shows the percentage increase in total health care costs over the previous years.<sup>3</sup>

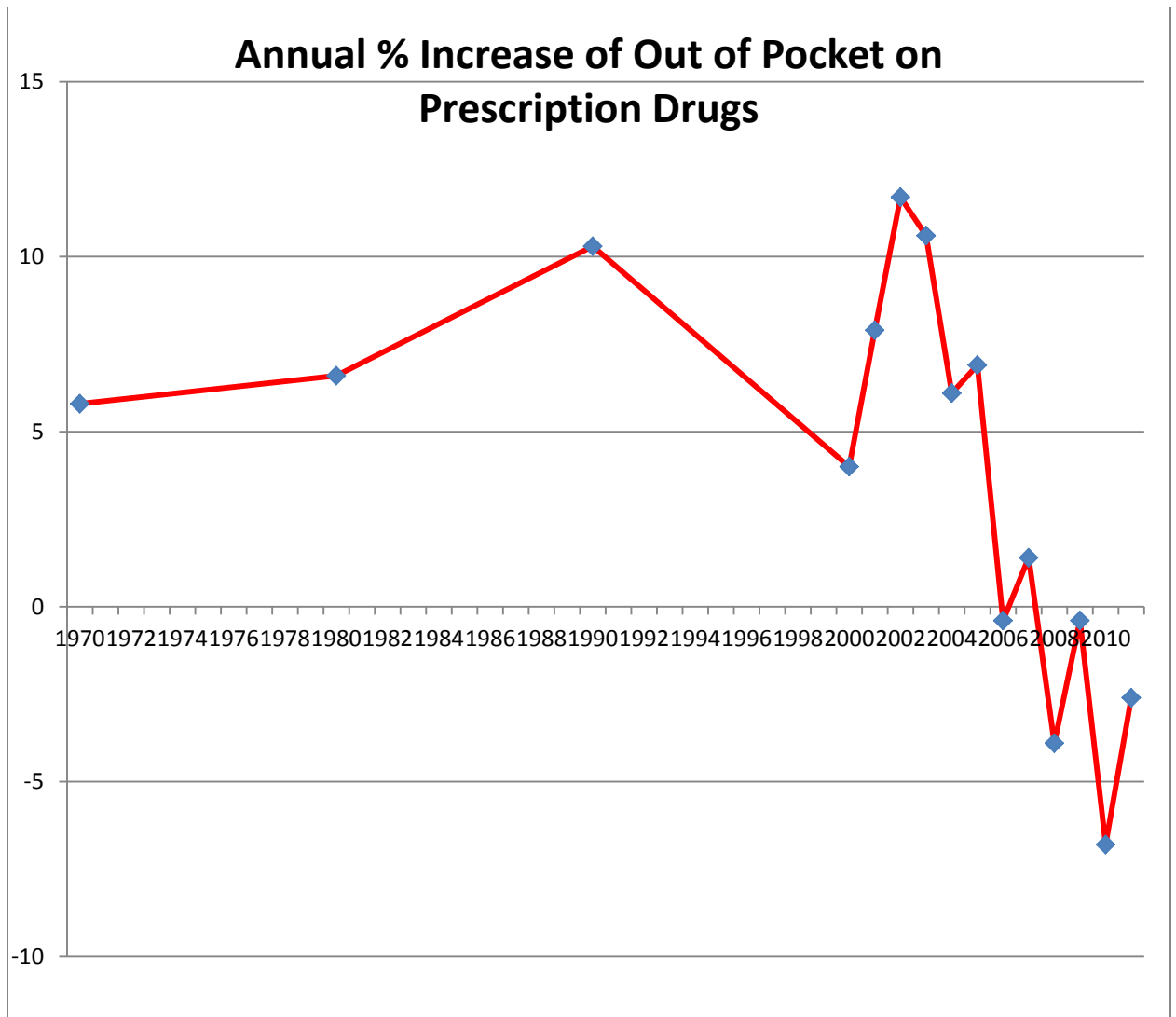


The key point to look at is 2003, where the downturn begins. This point is important because this is when the Medicare Prescription Drug, Improvement, and Modernization Act was implemented.<sup>3</sup> This act had two effects that led to this sudden decline in our every increasing health care costs. The first

was the creation of Medicare Part D, which created a formulary for Medicare usage.<sup>5</sup> The second part was the fact that it also allowed Insurance companies to create the cost cutter that is tier 4 drugs.<sup>1</sup> Before we bring out the party poppers to celebrate this marked slowdown in the cost of health care, there is something else to consider. This method did wonders when it comes to reducing prescription drug expenditures, the moral question that then must be then asked is how did this change affect the quality of the care given to the patients.

The New York Times wrote an article discussing the affect this change had on patients on an individual level.<sup>11</sup> The first story they tell is of women named Robin Steinward who has multiple sclerosis.<sup>11</sup> Prior to the creation of tier 4 in drug formularies, her co-payment for Copaxone was 20 dollars a month.<sup>11</sup> After the change, her bill jumped to 325 dollars a month, which is equal to 25% of the drugs cost.<sup>11</sup> Suddenly, she now questions that with the additional cost will she be able to pay for her son's tuition or pay for her own retirement?<sup>11</sup> While the story is heartbreaking, the fact that she is continuing to get the drug means that her quality of care has not gone down. Another situation mentioned in the article however is troubling when it comes to quality.<sup>11</sup> Mr. Banning is in need of a drug called Sprycel, which costs \$13,500 for a 90-day supply.<sup>11</sup> With

the new drug tier system he is currently not on the drug despite the fact that he should be on it for the remainder of his life.<sup>11</sup> The reason this story is more troubling is the fact that Mr. Banning isn't receiving quality care any longer, he is in fact not receiving any care at all. The question that then must be asked is, which situation is the normal as of 2003? The following graph answers just that question.<sup>3</sup>

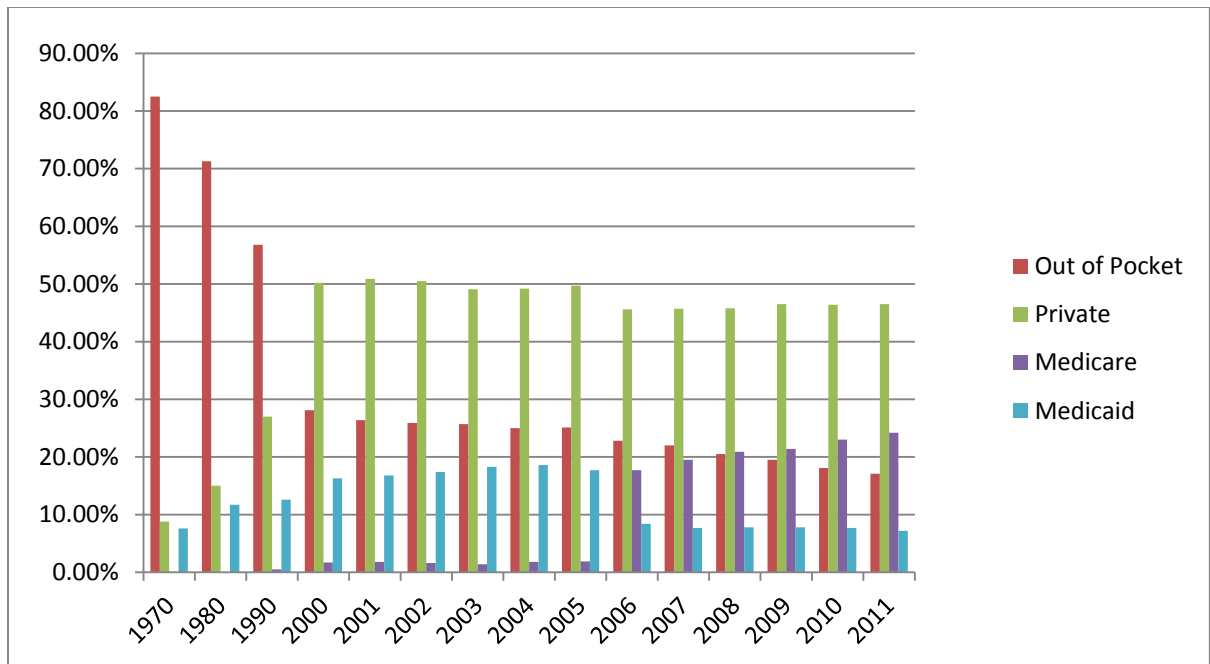


To interpret this graph we must ask what would happen to out of pocket expenses if patients continued to receive the same level of care? What would happen to out of pocket expenses if people no longer could afford to obtain prescription drugs?<sup>3</sup> If the benefit to the patients had remained the same it would mean that a majority of people would act like Robin Steinward, who made sacrifices in her own life to continue to pay for her medication

which should cause an increase in the amount of out of pocket expenditures. If people were stopping treatment due to the increased cost of the drugs, we would expect out of pocket expenses to decrease since where before they had obtained the drug after paying the co-pay, now they would simply forego getting treatment and their out of pocket expenditures would be at zero.

As we see in the graph above, the truth of the matter is out of pocket expenses decreased after 2003. Since we have this decrease, it is possible the reasons are for those expressed in the prior paragraph. Those who cannot afford to pay the high cost of tier 4 prescription drugs simply drop off leaving only those who pay less out of pocket to be included in the data.

Looking at the graph in another context could also further show that even though out of pocket expenditures have decreased, it has not been by a noteworthy amount.



This graph shows where the money comes from that actually pays for prescription drugs.<sup>3</sup> While the graph showing out of pocket expenses annual change shows a very large decline, this graph more shows that the percentage of out of pocket hasn't changed by a large amount.

Formulary Solution:

When measured up to the two objectives set forth at the beginning of the paper, the current drug formularies, in particular the drugs classified at tier 4 or higher, sacrifices the patients that cost the most to the health insurance industry in favor of a more sustainable system for the rest of the population. This is not to say that I am not impressed by the



marked change in how quickly the spending on prescriptions drugs have dropped. The problem is that after examining all the problems that lead to the increasing costs, there are safeguards already in place but not in use, that could be used to prevent drugs from being unavailable to anyone through high tier formularies.

The method which is already currently implemented, but is mostly a guard dog with no teeth is the "The Nondiscrimination Criterion." This allows for a formulary to be rejected if it has a discriminatory effect of trying to drive away those who are ill.<sup>9</sup> The reason this has no bite to it is the fact that the rules are so vague that it leaves a very large grey area as to what is and what is not permitted.<sup>9</sup> So long as you stay within the most basic guidelines most levels of percentage based co-pays are allowed.<sup>9</sup> The way in which this could be fixed would be using the data collected since the introduction of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to see if patients are being pushed out of the market. At the introduction of the Act vague rules could be expected as they had nothing to go on as to what would and what would not constitute abuse. Since then, even with the small amount of data examined that if enough people are unable to obtain drug that

are in tier 4 such that it has a large effect on out-of-pocket expenses it is worth looking into.

Solution - Drug tier reform:

When trying to come with a solution that will directly affect the way the pricing system for prescription drugs will work there are two path we can take. I like to call these paths, the path of Revolution and the path of Evolution.

The path of Revolution would be to create a solution that complete destroys the current pricing scheme in an attempt to replace it with a more efficient one. This would be admirable as a long term goal, it would be nearly impossible to create one that could be effectively implemented. Implementing it would require Congress to agree on a solution.

The path of Evolution would be to build upon what is already in place. This is a much simpler solution since leverages much of what already exists and attempt to isolate the flaws within the current system. This seems to be a more reasonable approach that my solution would fall under.

My solution is simple in form at least, and that is for each drug to be able to exist across multiple tiers depending on the purpose. To understand we must refer back to the article by

Maura Lerner of the Star Tribune which discusses over-prescribing and improperly prescribing a drug called Nexium for GERD (gastro esophageal reflux disease) despite the fact that patients had not been diagnosed with GERD.<sup>8</sup> The drug was highly advertised and as a result made it one of the highest selling prescription pills in the country.<sup>8</sup> Now, this is not to say that the drug was not useful since upon its release it was hailed as a miracle drug that boasted a 90% success rate of resolving GERD.<sup>8</sup> The problem arises in the fact that the healing was originally planned over an 8 week period, and once the drug received FDA approval doctors were prescribing it for a lot longer.<sup>8</sup> Some people remained on the drug for years and are likely going to be on it for the rest of their lives.<sup>8</sup> To get someone off the drug they need to be weaned.<sup>8</sup> This is due to the rebound effect mentioned earlier; to take someone who has grown accustomed to the drug, off of the drug, can result in a sudden surge of acid production.<sup>8</sup> The drug is also prescribed to many people who had not been diagnosed with GERD and whose heartburn doesn't warrant the possible side effects of Nexium.<sup>8</sup> The end result of all this is many people spending unnecessary money of their own along with the money of health insurance companies on a drug that is given as a knee jerk reaction to heartburn.

Currently in formularies, the effectiveness of a drug is taken in account in its placement on the list.<sup>5</sup> However, Nexium could be seen as defying that purpose, because its effectiveness is based on the shorter treatment cycles for treating GERD.<sup>7</sup> This is where my solution comes as previously stated it is to alter the current tier system to make it so a single drug can actually appear across multiple drug tiers depending on why they were prescribed. An example of what I mean is that currently in many formularies Nexium is considered a tier 3 drug, but that tier should be based on the fact that they have been diagnosed for GERD, and that they are only taking it for a limited time as is necessary to cure the illness.<sup>10</sup> Should they want to take the drug for simple heartburn that could be solved without Nexium, the drug would be in a higher tier so that they would pay a premium. This gives an incentive to prescribe drugs for a specific illness as opposed to a catchall approach so that the patient can get a lower cost on the drugs. A catchall approach might look at the symptom of heart burn and say that while many things cause it, varying from eating too late at night to being afflicted with GERD, the drug Nexium would have a positive effect either way. The problem with that is that side effects, the duration at which the patient remains on the drug, and the alternatives will vary depending on what the patient actually

has. The incentive is to get away from sweeping prescriptions and more towards directed solutions.

Even if a patient forgoes an invasive test to just see if the drugs will improve their condition it will work to better patient care regardless of whether the drug works or not. If it succeeds then you can move towards a diagnosis, since the test is now more worthwhile with a higher chance of it proving what is actually the cause of the heartburn. If the drug does not help, then you would stop taking the drug, so that even if you paid a premium it would only be for a short time. When looking to how people describe expensive drugs are, they often look to the annual cost it will put on a patient. If the drug isn't helping there wouldn't be an annual cost since you would not remain on a drug that had no positive benefit for over a year.

Another benefit to this solution would be that it is self-policing. For example, imagine a Doctor that gives diagnoses with each prescription so that the patient will get the drug at the drug's lowest price. The doctor would become open to suit from health insurance companies for lying to obtain cheaper prices, and they would open themselves up to medical malpractice if it turns out the phony diagnosis is wrong and their only reasoning for coming to that diagnosis was to get the patient a cheaper drug. So a doctor has an incentive to not defraud the

system since if he does, he runs the risk of suit from both the party he would be trying to help and the party he is defrauding. Now, there is the opposite danger which is if a doctor misdiagnosis an illness and is accused of trying to cheat the system. The solution would be that for an insurance company to win they would need to show a trend of diagnosis that can only have the purpose of defrauding insurance companies. For a patient to sue for malpractice would not be burdened with these problems, since a patient would know whether or not the doctor is purposely misdiagnosing them which is clearly below the standard of care.

The next part of the solution that needs to be examined is how exactly this will lower cost. The answer is that it depends on how people react to the solution. The way the solution incentives work, we would lower cost by making it unappealing for people to get prescription drugs if they want it for a lifestyle purpose as opposed to getting it at a cheaper price for a necessity purpose. Lifestyle choice being when an alternative to taking the drug is changes in things such as eating habits, exercise, etc. A necessity purpose would be one where you have an illness that a prescription drug has the main purpose of curing such as Nexium curing GERD. This would result in a drop in money spent on prescription drugs and lower the

cost overall. The other side of the coin is that if this solution was implemented and all patients simply paid the higher cost and continued to take the prescription drugs for all purposes it would have a cost-shifting effect. This means that the actual expenditures on prescription drugs would remain the same, but patients would bear a larger portion of the cost. This would still be beneficial since the patients that would make up this increase in patient costs would be people who are taking the drug for lifestyle purposes, and the health care system itself would have lower expenses.

The result on cost will likely be somewhere in between lowered expenditures and cost-shifting onto some patients. This result can be seen in a findings brief of an experiment where a two tiered drug formulary was turned into a three tier drug formulary.<sup>13</sup> The structure for the part of the experiment that is most similar to what occurred within Medicare part D was a formulary that originally had a 7 dollar co-payment for all generic and brand name drugs turned into a three tier system. This new system had an 8 dollar co-pay for tier 1 generic drugs, a 15 dollar co-pay for tier 2 preferred drugs, and a 30 dollar co-pay for tier 3 non-preferred drugs.<sup>13</sup> The result was two-fold, a noticeable switching or stoppage from tier 3 drugs.<sup>13</sup> There was also a marked drop in the cost to the health care plan, but

accompanied by an increase in the cost onto the employees. My solution would avoid the pitfall of increasing the cost on everyone, to increasing cost mostly to those who are taking drugs for lifestyle purposes.

#### Solution - New or Improved?:

As previously stated when discussing what drives up the cost of prescription drugs I mentioned the types of drugs that are being created. Only 10% are newly developed drugs, while 81% are improvements on existing drugs.<sup>2</sup> Within the current system of improved drugs, a drug company is able to market an adjusted form of a current drug to obtain a new patent and prolong their monopoly. The problem arises when you ask the question "How big an improvement should warrant not letting the drug become generic?" To answer this would be difficult especially on a drug by drug basis. Since if a drug has a 2% increase in effectiveness, it would likely look like it hasn't improved enough to warrant a new patent. However, if that drug was a cancer drug that increased a patient's survival rate, or the duration they might live by that amount, suddenly 2% means the world.



To effectively lower cost through denial of patents to slightly improved drugs a general of improvement could not be imposed since what defines a significant improvement will vary from drug to drug. The actual solution would be to give a right to challenge patents on all improved drugs to private companies. If the improvement is minimal, it would be worth it for a generic brand company to challenge a patent to be able to produce the drug themselves. It would also give incentive to drug companies to not strive for a direct percentage point of improvement, but rather the ability to argue a significant improvement within their own drug. This would be a two-fold benefit since not only would it decrease the number of minutely improved drugs from getting patents, but the cost of it would be paid by companies seeking their own best interests.

Conclusion:

By applying this to the current formulary system we achieve both the objective of health insurance. The system would help to stifle cost by eliminating much of the knee jerk response to prescribing drugs without a clear reason, while at the same time not requiring an entire overhaul of the formulary system. With stronger enforcement of the Nondiscrimination Criterion, we would avoid those who are most sick from being abandoned for the

sake of cost. Finally, we can reduce the amount of drugs that come onto the market that are minor improvements on already existing drugs. There will still be cost shifting onto some patients, but it will be spread over people who won't bear the cost for long period or people who have alternative solutions, as opposed to all the costs being shifted to those in need of the most expensive drugs. Prior to Medicare Prescription Drug Improvement and Modernization Act, the cost was spiraling out of control, and if the patient never has to bear any of the cost they will never have an incentive to move away from the current growth of consuming of prescription drugs.

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