WINTER 2015 WINNER

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INSTRUCTOR'S FOREWORD

On a campus with many students whose lives, inside and outside the classroom, revolve around technological innovation, our *Thinking Matters* course "Bioethical Challenges of New Technology" prompts students to critically assess how such technologies can reflect or conflict with our values. In the final paper for the course, we ask students to choose one of the issues we have discussed in the quarter and write a research paper about how we as a society ought to address it. For his paper, Eli chose to focus on an important systemic problem with the US health care system: the fact that new pharmaceutical drugs often come with astronomically high price tags. Eli argues for a specific practical solution: allowing the US government to negotiate drug prices with pharmaceutical companies, a practice that is now forbidden by the laws governing Medicare's prescription drug program (Medicare Part D).

One of the most impressive features of Eli's paper is how even-handedly it treats the reasons both for and against his proposal. In addition to the thoughtful points he makes about how the current system fails to improve health and drives up costs, he identifies reasonable points opponents could make about how his proposal could, for instance, negatively affect lower-income countries. For the topic of health care reform in particular, Eli's non-doctrinaire approach is a refreshing change of pace to the typical mode of discourse. Additionally, Eli's paper exhibits both good judgment and independent thinking in his focus on Medicare Part D, a program only briefly addressed in the assigned readings for class. Through his additional research for the paper and ability to distill a complex set of arguments into their essential components, Eli presents a well-informed and tightly organized picture of what's at stake with this issue. From all this, he draws a carefully reasoned conclusion that creatively addresses his opponent's concerns.

—Nate Olson

On the Ethics of Negotiating Drug Prices through Medicare Part D

Eli Shayer

The United States health care system is one of the mostly costly in the world, and yet the country as a whole has no better health outcomes than other less expensive countries by a range of health care metrics (Gawande 2009; Davis, 2014). There are many sources of this increased cost of health care, ranging from perverse incentive structures that encourage costly procedures, the threat of litigation encouraging doctors to over-prescribe unnecessary drugs, and the American health care ethic of all patients receiving the best possible care regardless of cost. One particularly egregious source of increased cost in the United States health care system is the lack of downward pressure on drug prices due to government non-negotiation. Medicare, a government program that primarily insures Americans age 65 and older, is bound by law to purchase any drug shown to be clinically effective under Medicare Part D (Medicare, 2003). Moreover, Medicare is required to purchase these drugs regardless of cost and without negotiation of price. This non-negotiation policy is ethically inferior to a policy that features negotiation and the possibility of certain drugs being unavailable, because a policy featuring negotiation creates a larger net positive result in terms of health care outcomes and the few negative consequences of such a policy can be mitigated through policy reform in other realms. This paper will discuss both sides of this policy with both consequentialist and deontological approaches, and propose that the policy be changed to feature negotiation with corresponding policy changes to mitigate negative second-order effects.

The economics of the drug marketplace are significantly affected by Medicare's lack of negotiation. Pharmaceutical companies act in a market that is nominally

guided by free market principles, but in reality includes almost no downward pressure on prices. As noted by Hall, the only pressure holding down drug prices is "headline risk," or the desire to avoid negative publicity. (Hall, 2013) It is established that negotiation does lower prices when it is implemented in healthcare, so negotiation would provide the missing downward pressure (Tang et. al, 2011). Pharmaceutical companies, like all other private businesses, have a fiduciary obligation to seek profit. Therefore it is expected that a lack of negotiation leads to increased prices, and thus higher costs for the health care system. The fiduciary obligation also manifests itself in manipulating exactly which drugs pharmaceutical companies seek to develop. In pursuing low-risk investments, pharmaceutical companies enter a cycle of focusing on drugs that provide only incremental benefits but are sold for extravagant prices (Lage, 2011).

On a worldwide scale, there is great variety in price for identical drugs, driven by values and implementation of drug purchasing policy. In the United Kingdom and Australia, for example, the government sets a minimum value for quality-adjusted life year, and negotiates with drug companies (Brock, 2010; Lopert et. al 2007). The United States, on the other hand, emphasizes the value of individual choice (Lage, 2011). This difference in value systems is a primary reason that the landscape of drug prices varies significantly from country to country (Lopert et. al, 2007). Additionally, the policy of non-negotiation by the United States through Medicare has effects reaching throughout the world. The United States pays more for identical drugs than other countries. Essentially, the United States' non-negotiation policy subsidizes the drug prices of other countries worldwide. Pharmaceutical companies, knowing they can rely upon the huge profit generated by the United States government, can afford to provide the same drugs in other countries at a reduced rate while still maintaining a profit.

Turning to the ethical issues related to the policy of non-negotiation, there are several positive results stemming from the policy. The foremost consequentialist benefit is that all patients on Medicare have access to the medicine and treatments they desire. This focus on individual decision and open access matches with the American health care ethic of individual choice. Additionally, as just discussed, the high prices paid to pharmaceutical companies in the United States allows other, less fortunate countries to access drugs at a relatively lower cost. Applying the principle of helping the least fortunate on an international scale suggests that this consequence is especially positive. (Brock, 2010) Additionally, the high probability of profit for pharmaceutical companies generates an incentive to produce more drugs. As more drugs become available to consumers, the range of drug choices afforded to patients increases.

There are also negative consequences for non-negotiation, however. The United States health care system as a whole is the most costly in the world, with approximately $8,508 spent per year per capita as of 2010 (Davis, 2014). The lack of negotiation is one contributing factor to this outsized spending figure. This has negative consequences for the United States because the money that is spent on health care is, in a macro scale, directly taken away from other valuable programs and initiatives. This implies that the money could be more efficiently allocated, which in turn suggests that America is inside the curve of production possibilities, because the same money could be spent to get better results. There is also a negative consequence in the incentives for pharmaceutical companies, as they have an incentive to produce any drug that is clinically effective. Those drugs are sold for the same prices as novel, breakthrough drugs but are a less risky investment. This risk-aversion, stemming from drug prices not reflecting drug effectiveness, leads to fewer breakthrough drugs even being attempted to be developed. In health care, there is a notion of *Justum Pretium*, or "fair price," which dictates that the price should reflect value (Kantarjian, 2013). A change to using negotiation has the potential to lead to more risky research and development investment decisions due to this match between drug price and drug effectiveness, and thus better health outcomes through better drugs being available.

There are also elements on both sides of the deontological debate over drug price negotiation. Starting with the positives, the policy encourages autonomy. Any patient served by Medicare has the ability to purchase the drugs that they and their doctor feel will best support their health. There is value in allowing patients to do what they desire as part of a system supporting patient rights. The principle of non-maleficence also applies to this discussion. A health care system that makes all desired drugs available for patients avoids the possibility of patients not getting a drug they desire. There is a non-maleficence argument to be made for not changing the system as well. American patients are accustomed to the current system of drug availability, and there is a risk of damaging a patient's medical status if that availability is taken away. Similarly, other countries are used to their current drug prices that are reduced as a product of high drug prices in the United States. There is a potential cost to countries that rely on America's high prices to keep their own lower, and under the principle of non-maleficence there is value in not disrupting that balance.

The potential benefit to health outcomes with a mind for distributive justice is the primary deontological argument for negotiation. The money that would be saved from negotiations could be reallocated in ways that improve health outcomes. Moreover, the reallocation would ideally be done to support those who have the

most need, as fitting with the principle of helping those who are least fortunate (Brock, 2010). The government is willing to spend a large amount of money on health care as a means of reaching our society's ideal distribution of justice. As a society, we believe that those who are less fortunate, whether it be socioeconomic status or the misfortune of bad health, don't deserve to live a worse life because of their circumstances. Thus our society uses a significant portion of its money to help those who are least fortunate, and one of the major avenues through which this aid is administered is through the health care system. Thus, any potential reallocation of money to better serve those who are least fortunate is a good change, and moves our utilization of resources towards our society's ideal distribution of justice.

Given these ethical considerations, the implications of a change in policy to negotiating for drug prices can now be analyzed. First off, as discussed above, such a change would save money for the health care system, which could either be reallocated within the health care system or to other government spending. Either way, the money would have the positive effect of improving the distribution of justice in the country. Additionally, such a policy has been undertaken in other countries without negative impacts to healthcare outcomes. The United States ranks 11th in health care outcomes among the 11 nations studied in the Commonwealth Fund report, ranking behind each nation studied that negotiates for drug prices at the cost of fewer drugs being available (Davis, 2014). Thus in the aggregate, a health care system with negotiations provides identical care for less money, which is to say that the health care system both becomes more efficient and has no downside in health outcomes. This shows that there are purely positive outcomes consequentially on the macro scale. A final positive consideration based on a change to negotiating drug prices is that the price of drugs will reflect their value. Having price match value is important in providing the proper incentives to drug companies, as well as being more fair to consumers and insurance companies that pay for the drugs.

There are important negative consequences, however. On a micro level, the United States has a deep-rooted fear of rationing (Ubel, 1998; Gawande, 2009). There is no net negative consequence on a macro level, but individuals are certainly afraid of their own ability to access the health care solutions they desire being compromised (Ubel, 1998). While this fear of rationing primarily applies to concerns about not having access to doctors, rather than access to drugs, it is nonetheless an issue that must be overcome for drug price negotiation to sit well with the general public. Additionally, there is the potential to hurt countries that would need to bear more of the cost of drugs as a result of the United States bearing less of the cost of drugs. Considering that many of those countries that could potentially be hurt

by such a change are less fortunate than the United States, such a change would violate the principle of helping the least fortunate. One final potential downside to a change in negotiation policy would be pharmaceutical companies pursuing less risky projects due to smaller profit margins. Although this is at least partially counteracted by the increased correlation between price and value, there is evidence that pharmaceutical companies respond to less profit by taking on projects that are lower risk in order to maintain a high probability of profitability (Lage, 2011).

To counteract these effects, a change in policy to negotiating for drug prices can be accompanied by corresponding policy changes that mitigate the negatives of such a change. To deal with the fear of rationing, the government would benefit from a large public information campaign that informs the public as to why such a change is occurring, and how the net result of the policy is positive. As part of the campaign, the public would be assured that all drugs that are shown to be clinically effective and worth their price will still be available, which is the enormous majority of drugs that are in use. The concern for other countries is a valid and humanitarian consideration. However, overpaying for drugs is by no means the most efficient way to support countries that are not as fortunate as our own. Instead, the United States can make up for the likely increase in worldwide drug prices by providing corresponding additional foreign aid to practice non-maleficence, keeping the drug prices at or near their original level for disadvantaged countries. To mitigate the potential for less innovative research and development by pharmaceutical companies, the government could provide targeted subsidies that reduce the risk in pursuing an ambitious project. This would counteract the effect of risk-aversion, and lead to more innovative and breakthrough drugs becoming available for usage. Rather than money being spent globally through non-negotiation, the last two policies of targeted foreign aid and targeted subsidies would spend only a portion of the money saved and achieve the same ethical positives.

The United States and the greater global community would benefit from a change in Medicare Part D to allow for negotiation over drug prices. By reallocating funds towards sources that will better produce a favorable result in terms of distributive justice, negotiation benefits the country by bringing it closer to its ideal distribution, which doesn't punish people for the misfortune of getting sick. By matching a change in negotiation policy with the mitigating policies outlined above, the negative effects of a change would be mitigated while expending only a portion of the money that is saved by negotiating for drug prices. Moreover, the change to the negotiation policy would satisfy deontological considerations of working towards a better distribution of justice and helping those that are least fortunate on a national scale and an international scale.

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