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Original Article

Cancer Drug Pricing in the United States

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Abstract

Cancer drug pricing in the United States is widely criticized as being excessively profit-oriented and not related to the cost of production, but rather, related to arbitrary pricing tactics that ensure maximal revenues. Drug development is undoubtedly an expensive endeavor but cur-rent research shows not only that the advertised costs of cancer drug production are significantly inflated, but also that revenues that pharmaceutical companies make outweigh production costs by a substantial margin. The price of cancer drugs are intimately related to the cost of drug production as well as the market dominance of pharmaceutical companies, and it is becoming ap-parent that rising prices are not due to the difficulty of discovering and marketing oncology drugs rather prices increase due to overstating the true cost of drug development and price-setting on this premise, significant negotiation leverage of pharmaceutical companies, extensive policy related factors that create conducive market environments for designer drug companies, and a market structure that inherently eliminates competitors from retaining market power. The combination of all these factors result in ever-increasing cancer medication prices that place a significant toll on patients, insurers, and the government while allowing pharmaceutical firms to proliferate with extensive price-setting freedom and negotiation power.

Introduction

Over the past three decades an important pattern regarding the cost of cancer treatment has arisen the medical costs of cancer have nearly doubled, with the price of patented cancer drugs experiencing a 5 to 10-fold increase between 2000 and 2014 itself [1]. In response to the trend that cancer drugs are becoming synonymized with extremely high almost prohibitive cost [2] it is important to examine the relationship between the cost of producing an oncology drug and its subsequent effect on price, the shifters that impact cost, and the regulatory factors that are at play in cancer drug pricing.

Differentiating Cost and Price

In order to investigate the rising expense of cancer drugs, it is imperative to highlight the difference between price and cost of a cancer drug and examine the relationship between price and cost to come to a conclusion about the appropriateness of drug pricing. Price refers to the amount of money a payer expends in exchange for the cancer drug, whereas the cost refers to all expenses included in the production of the drug. The price on the consumer-side is reflective not only of the cost to produce the drug, but also on the market power of the pharmaceutical companies that sell it. Therefore, the sum of costs and market power factors behind oncology drug production primarily dictate drug price.

The cost factors that pharmaceutical companies must account for include research and development, regulatory studies (i.e. phase I,II, and III clinical trials), material costs, manufacturing costs, intellectual property, marketing costs, and patent-related expenditures [3]. Primarily, pharmaceutical companies justify their pricing of cancer drugs as being compensation for the high cost of bringing oncology medication to FDA approval [4]. The cost of approval, which can add up to $1 billion per drug, is calculated by dividing the total costs of research and development by the number of drugs that become FDA approved [5]. In addition to research and development costs and the complexity of the cancer treatment being tested, it is no surprise that costs of cancer drug development are so high. Additionally, the market power of a pharmaceutical company contributes to the price of oncology drugs market power refers to the ability of a firm to raise the price of a drug beyond the marginal cost. Many large pharmaceutical companies focus on patenting newly discovered compounds in order to capitalize

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on the returns of providing the drug with little, if any, competition. Therefore, the price that payers are met with is a combination of the costs of developing the cancer drug in addition to the market power and price-setting behaviors of the pharmaceutical company.

Positive Question: What is the cost of cancer drugs?

Drug Development: Research and Development

"The enormous cost of drug development is a key component of the current debates over prescription drug prices" [6] due to the drug production pipeline being such a financially aggressive process after research and development (R&D). The cost of drug development primarily relates to the predicted expenditures a firm will pay for a drug that enters human clinical trials, [7] and the expenditures allocated to clinical trials can outweigh expenditures related to R&D. In 2008 pharmaceutical companies allocated $50 billion in aggregate on research and development [8] and this cost can decrease if pharmaceutical firms offset R&D costs by contracting universities, research organizations, biotechnology companies and manufacturing organizations to identify potential compounds [9], with the cost of R&D alone can varying between $178.2 million to $1.95 billion for an individual company [10]. Once a target compound is identified through R&D, individual firms can spend anywhere between $500 million to $2 billion [11] in the clinical trial phase of drug deployment. Additionally, factors other than R&D, such as manufacturing, diagnostic tests, costs of materials, and other direct costs that are difficult to enumerate add to the total cost of developing oncology drugs preclinical trial [12].

Drug Development: Clinical Trial Pipeline

Clinical trials are typically 3 to 4 phase processes that ensure potential compounds are safe and efficacious for patients. Phase I of the pipeline involves information acquisition regarding dosage, absorption, metabolic effects, excretion, and toxicity of a new chemical entity (NCEs) through administration on a small sample of healthy volunteers [13]. A typical phase I trial lasts between 1 to 2 years, where up to 25% NCEs are deemed as unsuitable compounds. If the NCE is accepted as safe for administration, Phase II trials are conducted on patients who are afflicted with the target disease/condition to obtain preliminary evidence and data on safety and efficacy, or effectiveness in a clinical setting [14]. If the NCE passes Phase II trials, it continues to Phase III where a larger sample size and more robust trials are implemented to firmly establish efficacy and highlight side effects of the compound.15 Only after passing all three phases can a compound be submitted for approval by the Food and Drug Administration (FDA), and eventually appear on the drug market. The entire clinical trial process can take upwards of [15] years per drug, [16] and this is a major contributor to the high cost of drug development.

Drug Development: Market Power and Price Setting

In order to recapitulate expenditures attributed to R&D, approval, and other development related costs, pharmaceutical firms are given incentives to accept the large upfront 'sunk costs' of the development process. These incentives are provided by the government and relate to market protections such as marketing and patent exclusivity [17]. The result of these incentives is significant market power which allocates freedom to the firm in terms of setting prices without considerations relating to competition. Since product exclusivity through patent protection eliminates bioequivalent competitors from the drug market until the patent expires, pharmaceutical firms are given the opportunity to absorb the cost of cancer drug production through revenue. Though this opens an avenue for monopolistic profit-maximizing price setting, studies by Di Masi et al. and Grabowski et al. suggest that the "internal rate of return of pharmaceutical companies is close to the industry cost-of-capital" [18] for randomly selected drugs. For cancer drugs, however, the opposite behavior is observed -- the profit margins of patent-protected cancer drugs can range anywhere between 7-fold to 10-fold higher than R&D spending [19].

Normative Question: Why are cancer drug costs high?

When comparing the price of cancer drugs to their costs, it becomes apparent that the common $1.3 billion estimate to bring a cancer drug to market is heavily inflated [20]. Pharmaceutical firms, however, attribute the high pricing of cancer drugs to the additional health benefits of the cancer drug in addition to the high research and approval costs [21]. Furthermore, proponents of cancer drug pricing assert that free market forces eventually cause prices to settle at reasonable levels [22]. However, current research suggests that the aforementioned reasons do not justify the high price of cancer medication.

True Research Costs

Current research shows that pharmaceutical companies marketing patented cancer drugs participate in a market spiraling strategy where prices on the previous year's drugs are continually increased and the price of the newly developed drug is set higher than that of the previous year [23]. Light et al. suggest this is the direct reason for escalating cancer drug prices, in addition to significant inflation of the true cost of cancer drug production. Firstly, the $1.3 billion drug re-search cost is an estimate of the profits a pharmaceutical company would have made if they did not invest in research they are effectively adding the foregone profits onto drug research costs to arrive at $1.3 billion, so the true cost comes down to $650 million after correction [24]. Addition-ally, pharmaceutical firms do not make public the fact that half of company research is subsidized through deductions due to taxpayer subsidies once this is accounted for, the average cost to get a drug to market is $325 million [25].

Furthermore, 84% of new drug discovery comes from basic research conducted by the public (i.e. universities, National Cancer Institute) and pharmaceutical firms rely on pre-established basic research and allocate the rest of their revenues towards testing and improving the drug [26]. This brings the median net cost of bringing a drug to market down to $125 million in addition to variable costs attributed to basic research [27] which calls to doubt the axiom that 'drug development to market costs $1 billion'. Considering the volume of publicly available cancer research in addition to clinical trial funding via the National Cancer Institute, research suggests that "there is no credible evidence that the net costs of the major companies for cancer research are not lower than research costs for other drugs" [28].

Other studies suggest that the cost to develop one cancer drug lies between the conservative $125 million estimate and the inflated multi-billion dollar estimate, at approximately $648 million as of 2017 [29]. Despite differences in estimates of what the true cost of bringing a cancer drug to market is, research shows that the advertised cost of bringing a cancer drug to market is heavily inflated, which places a heavy price burden on payers. This directly impacts the price of cancer medication, as artificial cost inflation acts as justification for high prices.

Regulation and Policy: Economic shifters

Regulation

In a free market there is an expectation that the price of a drug will settle based on its actual benefit but there seems to be little correlation between a cancer drug's price and benefit due to escalating costs outside the scope of pharmaceutical companies [30]. The National Institute of Health, National Cancer Institute, Food and Drug Administration, and Office of Human Research Protection have imposed increasing regulatory burdens on drug companies which lead to in-creased development costs [31]. These regulations, such as initiating a Cancer Therapy Evaluation Program are instituted to protect the health and safety of patients, but also lead to fewer patients entering clinical trials such regulations not only lead to significant delays in the drug production pipeline but also "obstruct cancer research and increase costs while adding little to patient protection" [32]. This is certainly a contributing factor to the rising costs of cancer drug development which impact the rising prices if regulatory burdens are creating delays in the drug production pipeline, or making it data acquisition more difficult through tending to the interests of patients, the drug companies are the entities which absorb the cost and risk of regulatory interference. In order to recapitulate on lost revenues and additional expenditures attributed to regulatory delays, pharmaceutical firms could increase prices to ensure reimbursement.

Policy

In addition to regulation, policy changes can act as economic shifters to drive the price of cancer drugs up. Legislation such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 prevents Medicare from negotiating drug prices [33]. This legislation was not arbitrary, but rather "encouraged or guided by interest groups" [34] (i.e. pharmaceutical lobbyists) and resulted in an almost immediate increase in the profits of pharmaceutical companies [35]. Dean Baker's analysis suggests that eliminating the Medicare Prescription Drug, Improvement, and Modernization act could allow Medicare to negotiate drug prices, which would result in annual savings between $50 billion to $80 billion [36] but by eliminating the option for Medicare to negotiate prices, pharmaceutical firms establish a position of control over the prices they set for medication. By actively shaping policy and taking proactive measures to make sure the negotiation leverage is in the hands of pharmaceutical companies, drug producers eliminate the risk of political regulation from placing restrictions on their pricing behaviors. Such a practice not only al-lows for greater market power via lessened government control, but also allows for more aggressive price setting which guarantees substantial revenues.

International Policy

Cancer drug prices in the United States seem to follow their own economic frameworks that are not priced according to cost of research development and production, value to patients, or effectiveness [37]. In Canada, the Middle East, Far East, and most European nations, drug prices are actively negotiated between governments and pharmaceutical companies which places limits on the cost and subsequent price of drugs [38]. For example, Tyrosine Kinase Inhibitors (TKIs) used as therapy for Leukemia are priced at 50-75% lower than prices in the United States, albeit at a similar cost of development and production [39]. This is a clear exhibit of profit maximizing price setting that is placing strain on the American healthcare system and placing patients in a position of choosing between bankruptcy and death. The same drug (TKIs) being priced differently in Europe and in America displays a distinct "crossing of a moral line between reasonable profits and profiteering" [40] and adds evidence to the claim that cancer drugs are priced too high. By drawing a comparison between the same medication being offered in the United States and abroad, it becomes clear that price setting behaviors function far differently in America. Without involved government regulation with entities that establish negotiation power comparable to pharmaceutical industries, cancer medication prices in the United States are not priced based on what is beneficial to the economy and affordable to the patient, but rather prices are based on arbitrary profit maximizing tactics.

Pay-for-Delay

Pharmaceutical companies partake in 'pay-for-delay' deals where firms with branded/ patented drugs which are close to expiry offer monetary incentives for companies to delay introduction of the generic version to the drug market [41]. The motive behind this behavior is the fact that generic drug manufacturers have very little market power relative to branded drug manufacturers due to competition within the drug market [42]. 'Pay-for-delay' deals allow branded drug manufacturers to continue reaping the monetary revenues of products without the risk of patients switching to generic bio-equivalents or therapeutic equivalents by delaying the introduction of generics to the drug market a structure that has led to $1.06 trillion in expenses over the last decade [43]. By creating a delay in generic cancer medication from hitting the market, pharmaceutical companies effectively 'renew' their patent privileges for a limited period of time, and continue pricing at the status quo for the drug. Since the entrance of generic competitors would de-crease the demand for branded cancer medications, eliminating competitors through 'pay-for-de-lay' deals for a limited period of time allows the persistence of market power and subsequently, aggressive price setting behavior which ensures substantial revenues. Such systems have a direct impact on the patient because it limits, if not eliminates, the options for more affordable medication 'pay-for-delay' schemes solidify the demand for branded cancer medications through minimizing generic competition and allow the persistence of price-setting behavior.

Generic Drugs

Upon introduction of a generic bioequivalent to a branded drug, a

significant price drop is observed [44] where drug firms would set prices very close to marginal costs in order to stay competitive [45]. This behavior is observed by rehashing the definition of pricethe sum of the cost of production and the market power of the firm. The cost of producing generic bio-equivalents is significantly reduced in comparison to producing a branded drug because there are no prohibitive R&D and clinical trial costs. Furthermore, due to competition, the market power of a generic drug manufacturer is also significantly less than the market power of a branded drug manufacturer. As a matter of fact, "the free-market economy may have worked too well" for generic drugs, because upon entering the market, "they result in a significant drop of the drug price to a bottom value that may discourage generic companies from competing for the particular drug market" [46]. This causes an exodus of generic cancer drugs from the market, leaving a paucity of companies competing to produce the drug [47] the scarcity of potential generic drug producers in conjunction with "strict FDA regulations, aging manufacturing facilities, shortage of raw materials, and market manipulation by intermediary distributorships, contributes to increasing drug shortages" [48] Additionally for older cancer drugs, competition and the availability of newer alternatives forces prices to be set low in conjunction with potentially small patient populations, these factors provide very little incentive for generic drug manufacturers to continue producing oncology drugs, thus drug shortages occur as they leave the market [49]. Though this is not directly related to designer pharmaceutical companies, the difficulty of producing generic cancer medication while staying solvent presents a substantial barrier for providing affordable medication effectively the competition eliminates itself until there are very few generic companies that are able to pro-duce medications while funding their operations, and this indirectly allows for a greater market presence of designer drug companies.

What can be done about the cancer drug pricing issue

Based on the evidence presented, it is clear that the estimated cost of producing a cancer drug is significantly lower than the established costs, with estimates ranging anywhere between $125 million to $648 million instead of the commonly assumed $1 billion to $2 billion. Granted, cancer drug development is an expensive process, but perhaps it is not as expensive as prices suggest they are. It is unanimously agreed upon that the cancer medication pricing scheme needs to be addressed due primarily to the financial toll aggressive price-setting takes on patients, but also due to unnecessary expenditures on behalf of the government and insurers.

Restrict Monopolies

Monopolistic behavior by branded pharmaceutical companies has shown to result in price setting that is excessive. In order to address this issue, there are several approaches which could place controls on price setting. The first option is to subject cancer drugs which operate under a monopoly environment to price controls or even competition [50]. If a pharmaceutical firm creates a drug which addresses a specific cancer for which there is no alternative treatment or competitor, the approved drug should undergo price control through legal mandates which controls the price which the pharmaceutical companies can set the drug [51]. By creating a panel of healthcare professionals with no conflicts, interests, or relations with the success of the drug, a fair pricing system which is less of a burden to the patient, yet still incentivizes the pharmaceutical firm could be developed and implemented. This could act as a system of checks and balances that allows pharmaceutical companies the freedom to price drugs in a manner that provides incentives, but places controls and limits on how much they are allowed to incentivize themselves. Similar to how legislative bodies in Europe and Canada are able to negotiate prices with drug companies, this approach increases regulation and provides the opportunity for a pricing scheme that is beneficial to both payers and producers'.

Control Negotiations

Due to the Medicare Prescription, Drug, Improvement, and Modernization Act of 2003, pharmaceutical companies effectively prevented Medicare from negotiating prices lower than what the firm set. Eliminating such legislation would not only decrease the price payers face [52] but also potentially increase transparency in the price-setting behavior it would truly "enhance the capacity of market forces to produce more reasonable cancer drug prices" [53]. Furthermore, prohibiting pay-for-delay strategies would allow earlier introduction of generic medication into the drug market, allowing for significantly decreased prices in relation to patented cancer medication. Research shows that from 1994 to 2004, prohibiting pay-for-delay negotiations and rejecting the Medicare Reform Act of 2003 would have saved about $1.4 trillion - $1.8 trillion, and this is a valuable avenue to pursue if the cancer drug pricing issue is to be alleviated [54].

Additionally, it is not possible to import foreign prescription medications in the United States due to patient safety reasons put forth by the pharmaceutical lobby [55]. Estimates by the Canadian Patented Medicine Prices Review Board suggested that American consumers pay 100% more for branded drugs compared to what consumers from other countries pay [56] for ex-ample Imatinib, a chronic leukemia drug is priced at $29,000 in Mexico, $46,000 in Canada, but $92,000 in the United States [57]. Such price setting from designer pharmaceutical companies is creating a monetary barrier for patients to receive treatment on severe conditions. The unnecessarily high prices place an insolvency risk on Medicare, increase the annual expenditures of the United States healthcare system, and raise health insurance premiums. The shockwaves of prescription drug pricing in general are being felt throughout the healthcare system, and prescription cancer drug price changes present the opportunity for balancing the system.

Lobbying

The method by which legislation such as the Medicare Reform Act get approved is through significant lobbying efforts on behalf of the pharmaceutical industry. As a matter of fact, the expenditures allocated towards aerospace, defense, gas, and oil are all outweighed by pharmaceutical lobby expenditures, which were estimated at $306 million in 2012 [58]. Lobbyists assert that their price setting behaviors do not affect consumers because insurers are the ones who pay for medical expenses, but in reality, insurance corrects for this by increasing insurance premiums, increasing cost-sharing with the patients, and increasing out-of-pocket expenses, which places patients in a difficult

financial situation. Though it is not illegal to lobby by any means, it is imperative to look at the impact lobbying is having on the United States healthcare system and establish measures to consider lobbyist's appeals from all angles. Like mentioned before, a panel of health care professionals with no vested interest or conflicts in the success of pharmaceutical firms could act as liaisons for patients who currently receive little representation against pharmaceutical companies. Lobbying is a vital method of company representation, but implementing a system of healthcare professionals who can predict the ramifications of lobbying efforts and educate the public about potential risks allows for foresight in policy-related decision making.

Discussion

Cancer drugs are priced based on what the market will tolerate. Constantly rising oncology drug prices are creating shockwaves in the United States healthcare industry, putting patients under tremendous financial stress and contributing to rising healthcare expenditures. The prices pharmaceutical companies set for patented cancer drugs do not reflect true costs, but rather reflect monopolistic behavior that significantly inflates the price of the drug over the true cost. Though patent protection incentivizes pharmaceutical firms to innovate and tackle challenging problems, it leaves opportunity for exploitation and profiteering.

The financial toll of research and development and the clinical approval process have been touted as the reasons for the high price of cancer drugs, but current research shows that the expenses of the drug development and approval process are significantly inflated. Pharmaceutical companies are exercising their market power by not only setting prices of treatment prohibitively high, but also by changing legislation and lobbying congress to guarantee increasing revenues. In an age where the United States is aiming to control healthcare expenditures, it is imperative to address the patented cancer drug price setting behaviors of pharmaceutical companies not only to create a more efficient health care system, but most importantly to allow patients to afford essential cancer medication and not have to choose between death and bankruptcy.

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