AFF:

Smoke and Mirrors

The overwhelming refrain from the Pharmaceutical Industry which will no doubt be parroted by the Con side is, drug prices need to be high to support the exorbitant cost of research and development of new drugs. They say, that while price controls can lower prices, price controls ultimately harm public health by limiting development of new and better pharmaceuticals. There may be some truth to these claims, but the only way to be sure is through industry transparency. What are the real costs, versus what the industry is telling us and what about those products which already exist and have been sold on the market for many years? Why do they cost so much?

Berman, et al

Berman A, Lee T, Pan A, Rizvi Z, Thomas, A, Curbing Unfair Drug Prices: A Primer for States, Global Health Justice Partnership of the Yale Law School and the Yale School of Public Health, National Physicians Alliance, Universal Health Care Foundation of Connecticut. https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf

Drug manufacturers sometimes justify their exorbitant prices based on the costs of research and development and the difficulty of introducing a new drug. However, evidence suggests that drug prices today generally are not set with reference to the cost of innovation. Furthermore, these costs can be accounted for if drug manufacturers provide information regarding public funding of R&D costs (including tax benefits) and granular data by clinical trial phase. More information about R&D costs, as well as public investments in R&D and other influences on pricing will help inform both fair prices for particular drugs and future legislative approaches to drug pricing. [7]

Market Domination

It is well documented that free and fair competition can be effective in controlling prices. However, many companies, acting in the best interests of their investors and share-holders will take steps to reduce or eliminate competitors. The old model of buying out competitors and shutting them down is being replaced with a new model: buy the rights to a particular product and take advantage of the fact it is no longer sold competitively.

Derse, et al 2016:

Derse AR, Soverson S, Drachenberg J, Spektor D, Kusterbeck S, Drastic Surge in Drug Prices: 'Unethical and Immoral', Relias Media, Medical Ethics Advisro, November 1, 2016. https://www.reliasmedia.com/articles/139464-drastic-surge-in-drug-prices-unethical-and-immoralS

A new business model is emerging in which pharmaceutical companies buy the rights to a drug, then raise the price dramatically. Often, the drugs are produced by one manufacturer, with few or no alternatives.
“It is one thing to charge high prices in order to recoup costs associated with the research and development of a drug,” says Jonathan D. Alpern, MD, co-author of a recent paper on the topic. Alpern is an infectious disease fellow at University of Minnesota.
Companies are not recouping research and development costs, however, because the drugs already exist on the market. Craig M. Klugman, PhD, a professor in the Department of Health Sciences at Chicago-based DePaul University, says, “They are very simply trying to maximize the profit on their purchase of these drugs. The motivation is nothing more or less than greed.”
The 'new' business model, hits underprivileged populations particularly hard and forces patients to seek alternative treatment from 'unregulated' sources.

The impact of these latest trends in market dominance effects the well-being of vulnerable populations and forces some to seek treatment from unregulated sources.

Derse, et al 2016:
Derse AR, Soverson S, Drachenberg J, Spektor D, Kusterbeck S, Drastic Surge in Drug Prices: ‘Unethical and Immoral’, Relias Media, Medical Ethics Advisro, November 1, 2016. https://www.reliasmedia.com/articles/139464-drastic-surge-in-drug-prices-unethical-and-immoralS

Alpern notes the activity has been especially prominent in markets dominated by economically disadvantaged patient populations. Thus, access to life-saving drugs is being limited for patients who can’t afford them. “This has now become a common scenario, with outcomes that I think are unacceptable,” Alpern says.
Patients are going without treatment, receiving second-line therapy, or acquiring the drug from overseas or the internet. “This places clinicians in ethically difficult positions,” says Alpern. “Do you allow your patient to go without therapy, or support them in acquiring the drug from an unregulated source?”

The Regulatory Commission

One proposed model for controlling prices in the pharmaceutical industry is the same employed by local and federal governments to manage monopolies by public utilities.

Arak & Tschinkel 2017:
Arak M, Tschinkel S, The Conversation, Why the ‘free market’ for drugs doesn’t work and what we can do about it, January 19, 2017. http://theconversation.com/why-the-free-market-for-drugs-doesnt-work-and-what-we-can-do-about-it-70007

A better approach is to start with a public utilities method, which is frequently used when there is a natural monopoly in production, such as for water or power. In these cases, state and local governments typically allow a company to have a monopoly over the market but also establish regulatory commissions to determine “fair” prices. Such prices take into account current costs,

the need for investment in production facilities and the need to earn a rate of return on capital invested.
A wrinkle with drug developers is that they can incur substantial costs in their quest for new medications, including dead-end ideas and extensive testing. A 2014 report put the cost to develop a new drug at $2.6 billion, while others put it at around half that.
Under our proposal, an independent federal panel consisting of scientists, medical professionals, public health experts and economists – perhaps working as part of the FDA approval process and called on when the price of a drug is above a specific threshold – would determine the maximum price a government buyer such as Medicare or Medicaid could pay for a new drug. It could also do the same for existing treatments – for example, it could have turned down Turing's huge Daraprim price hike.
A key element of this idea is that the panel would develop methods to identify and set maximum prices for existing and prospective drugs that cure a serious illness, improve the quality of life, limit contagion or otherwise provide large benefits to society. These procedures would need to make sure that producers of these important new drugs are sufficiently rewarded for those costly efforts.

Many ethicists agree, the regulation of pricing should be done at the federal level. It is the best way to prevent unfair practises by companies which end up dominating the market and cutting out competition.

Derse, et al 2016:
Derse AR, Soverson S, Drachenberg J, Spektor D, Kusterbeck S, Drastic Surge in Drug Prices: 'Unethical and Immoral', Relias Media, Medical Ethics Advisro, November 1, 2016. https://www.reliasmedia.com/articles/139464-drastic-surge-in-drug-prices-unethical-and-immoralS

Klugman says bioethicists should encourage Congress to regulate the drug industry, and require review of all corporate sales of drug licenses and patents to ensure that the new owners will not seek excessive profits and high charges.
"Utilities and insurers already have to submit requests for price increases for government approval," notes Klugman. Similarly, insurance companies and large corporations need to be reviewed by the FTC to be sure that changes do not cause monopolies or impose a price burden on consumers.
"Drug companies should have to do the same — whether the entire company is being acquired, or merely a few drugs are being sold," says Klugman.

Price Control Compendium

Scott Kneor, Chief Pharmacy Officer at the Cleveland Clinic, views the current trends in pharmaceutical industry pricing an immoral act that transcends politics because not only are those who need the products affected, everyone is affected by unjustifiably high prices. Knoer provides a compendium of solutions which can be employed to regain some control over the problem.

Knoer 2016:

Knoer SJ, How to Stop Immoral Drug Price Increases, Time, September 7, 2016, Knoer is the Chief Pharmacy Officer at the Cleveland Clinic. http://time.com/4475970/stop-immoral-drug-prices/

Ban direct-to-consumer advertising. Why do drug companies spend so much more on marketing than they do on research and development? Because advertising works. The American Medical Association and the American Society of Health-System Pharmacists have endorsed banning direct-to-consumer advertising because it leads to the over-prescribing of expensive drugs when more cost-effective options often exist. (Only two countries allow direct-to-consumer advertising—the U.S. and New Zealand, whose residents happen to take significantly more prescription drugs than those in comparable countries.) Drug companies spent $5.4 billion on direct-to-consumer ads in 2015, an increase of 19 percent over 2014. In fact, five of the ten fastest-growing ad spenders in 2015 were pharma companies, according to Ad Age. Valeant spent $441 million on advertising in 2015 on drugs like Jublia, a $500-per-bottle drug for toenail fungus that has a total course-of-treatment cost of $20,000. Direct-to-consumer drug advertising is not a constitutional right. We haven't always had drug ads. FDA relaxed the rules in 1999 creating the deluge of ads we see today. These regulations should be rescinded in light of the negative cost impact to society.

Eliminate "pay-to-delay" payments. When a brand-name drug's patent is about to expire, competing manufacturers begin to consider making a generic alternative, which will cost less than the brand-name drug and cut into its profits. To stop that from happening, the manufacturers of brand-name drugs will pay the generic manufacturers to not produce a generic version. It should not be legal to crush competition and manipulate the market in this way.

Pass the Creating And Restoring Equal Access To Equivalent Samples Act Act of 2016. Competition in the marketplace is a critical part of managing drug prices. However, competition has been stifled by the holders of certain patent-protected drugs. The CREATES Act requires manufacturers of brand-name drugs to provide the required samples of their products to generic manufacturers, allowing them to conduct studies demonstrating the equivalence of the generic version. This would allow generic versions of these drugs to get to market faster after the patent protection ends, creating a competitive market.

Allow some drug imports when companies egregiously raise prices. This is another means of creating competition—and it can still require the FDA to allow drug importation to hospitals through existing supply chains, as long as FDA's quality standards are met.

Eliminate patient assistance co-pay cards. Pharmaceutical companies offer these cards to patients to help reduce their out-of-pocket expenses. While this may sound like a good thing, the real purpose is to direct patients to higher-cost branded drugs as opposed to using much cheaper alternatives. Eliminating a co-pay saves patients' money but shifts the payment burden to insurance companies, which is eventually passed on to consumers.

Conclusion

It is perhaps indisputable, there is a high cost associated with the development, testing, and approval of new drugs and treatments in the United States. However, there is a great deal of opacity preventing the government and consumers from seeing the real costs in a unbiased way. It is not unreasonable for a corporation to expect to recuperate its expenditures incurred prior to offering the product for sale to the public. Nevertheless, there is a huge public health risk to not striking the correct balance between pricing for recuperation of expenses and pricing for excess profit. There is a point when reasonable profits become unreasonable and expected prices become price-gouging. Pro contends, the bright-line should not be set by the industry itself, but rather the USFG with an interest in providing for the general well-being of the citizens. Clearly pharmaceutical companies must have incentive to continue marking new products, but there can be no excuse for "immoral" price-gouging to satisfy the financial interests of investors. Perhaps one such solution is convert the pharma to a non-profit industry. But until that happens, the USFG has a fiduciary responsibility to protect the public health by imposing price controls.

For all these reasons and more, we urge a Pro ballot.

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