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The Affordable Prescription Drugs Act: A Solution for Today's High Prescription Drug Prices

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THE AFFORDABLE PRESCRIPTION DRUGS ACT: A SOLUTION FOR TODAY'S HIGH PRESCRIPTION DRUG PRICES

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I. INTRODUCTION

As we move forward into a new millennium, a large number of Americans, especially senior citizens or those without insurance, will find it increasingly difficult to obtain prescription drugs because of rising prices. International price increases have had the most severe consequences in third world countries where sixty percent of the population does not have regular access to essential drugs.¹ While this paper focuses on domestic prescription drug prices, many analogies may be drawn between the problems created by high prescription drug prices in the United States and those in third world countries.

Many have attributed rising prescription drug prices to the *laissez-faire* attitude of the U.S. federal government. As a result, Congress has introduced new proposals to combat both these criticisms and prices. Many of these proposals reduce the amount of protection granted to a patent holder of a newly developed prescription drug. Large pharmaceutical companies are lobbying against these proposals, claiming that implementing such "price controls" will hinder the research and development of new and important drugs.² They argue that the patent protection offered to pharmaceutical companies allows them to recoup and profit from their monetary investments on recently introduced drugs, and in turn, allows them to produce new essential drugs.³ Using this argument as a catalyst, the pharmaceutical

¹Website of Essential Information, *A Healthy Drug Policy for the Third World*, at http://www.essential.org/monitor/hyper/issues/1992/12/mm1292_09.htm (website expired).

²Carl B. Feldbaum, *Loosening Patent Protection Hurts Drug Companies*, PLAIN DEALER, Oct. 17, 1999, at 4G.

³*Id.*

industry has pushed for the adoption of a style patent protection regime internationally.⁴ Ultimately, the Pharmaceutical Manufacturers Association (PMA) of the U.S. appealed successfully to the government to take retaliatory trade measures against third world countries that did not change existing national legislation, which provided no protection to pharmaceutical products.⁵

High prescription drug prices must be reduced through a proposal that allows new drugs to be more accessible and affordable to those who need them, while maintaining the drug companies' ability to profit and reinvest in new essential drugs.

This article will discuss a recently proposed bill, The Affordable Prescription Drugs Act (APDA),⁶ and how it will attempt to strike a balance between reducing prices to make essential drugs more available and affordable, and working with pharmaceutical companies to make sure they profit and reinvest their money into research and development of new essential drugs. It argues that the APDA increases competition in the market place, thus reducing the price of prescription drugs, while still allowing pharmaceutical companies to profit from their inventions. In reaching this conclusion this article examines the bill itself, how to define an essential drug, whether current prices are fair, Congress' attitude towards these prices, the drug industry's justifications for high prices, and presents a rebuttal argument against those justifications.

II. THE AFFORDABLE PRESCRIPTION DRUGS ACT

Representative Sherrod Brown⁷ introduced APDA in the House of Representatives on September 23, 1999.⁸ The bill favors "good old fashioned American competition" by reducing the amount of patent protection granted to pharmaceutical companies.⁹ The APDA would allow the government to force price competition for drugs that provide a substantial health benefit, but carry an excessive price tag.¹⁰ It would accomplish this by issuing a compulsory license to a drug

⁴Website of Essential Information, *supra* note 1 ("It is only the pharmaceutical industry that has been trying to force the entire world to adopt U.S. style patent laws.")

⁵*Id.* (stating that the PMA has been successful in getting Third World countries such as Brazil, Chile, Indonesia, Korea, Mexico, Thailand and Venezuela to change their patent laws to resemble those of the United States).

⁶H.R. 2927, 106th Cong. (1st Sess. 1999).

⁷Sherrod Brown is an Ohio Democrat currently serving his fourth term as Representative of Ohio's 13th Congressional District; he is the ranking member of the House Commerce Committee's Health and Environment Subcommittee, at <http://www.house.gov/sherrodbrown/bionew.htm>.

⁸H.R. 2927, *supra* note 6.

⁹National Journal, American Health Line, *Medicare RX: House Committee Navigates Crowded Field*, Oct. 5, 1999, § Politics and Policy, at http://nationaljournal.com/cgi-bin/ifech4?ENG+AMERICAN_HEALTHLINE+7-ahindex+1052542-REVERSE+0+0+26178+F+1+1+rx%&3a+AND+house+AND+navigates+AND+crowded+AND+field+AND+PD%2f10%2f05%2f1999%2d%3e10%2f05%2f1999.

¹⁰National Journal, American Health Line, *Prescription Drugs: Two More Bills Would Lower Costs*, Sept. 24, 1999, § Politics and Policy, at http://nationaljournal.com/cgi-bin/ifech4?ENG+AMERICAN_HEALTHLINE-_-POLL_TRACK-_-AD_SPOT_LIGHT+7-

manufacturer to produce a generic version of a brand name drug which is still protected under patent.¹¹

Certain steps must be taken and requirements met before a compulsory license is granted. The bill requires three important elements to be satisfied. First, the Secretary of Health must determine “[s]uch compulsory license is necessary to alleviate health or safety needs which are not adequately satisfied by the patent holder, contractor, licensee, or assignee.”¹² This first element determines whether the drug should be considered essential or non-essential. If the drug has been determined to be essential or one that provides a “substantial health benefit,” the first requirement has been met.¹³

The second element requires, “[t]he patented material is priced higher than may be reasonably expected based on criteria developed by the Secretary of Commerce.”¹⁴ This determines whether a drug’s price is so excessive that it bears no semblance to pricing norms for other industries.¹⁵ To help make this determination drug companies would be required to provide audited, detailed information on the expenses accumulated while developing the drug.¹⁶ Companies that fail to disclose such information would be ineligible to participate in federal health care programs.¹⁷ After this information has been gathered and analyzed, if the selling price of the drug is determined to be “exorbitantly costly,” the bill’s second element has been met.¹⁸

The third and final element states: “The patent holder, contractor, licensee, or assignee . . . has not taken or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in a field of use.”¹⁹ This element functions as an “escape clause,” allowing the drug company to work with the government in voluntarily lowering prices.²⁰ Thus, many drug companies could avoid a compulsory license if they decide to voluntarily lower their prices below an excessive price rate as determined by the Secretary of Commerce.

If these elements are satisfied it will be determined that a compulsory license is necessary to reduce the price of the drug to make it more accessible and affordable to those who need it. A generic manufacturer would then be granted a compulsory license to manufacture the drug while it is still under patent protection.²¹ During the

ahlindex+1021382_REVERSE+0+0+-1+F+9+13+1+prescription+AND+drugs
%3atAND+two+AND+more+AND+bills+AND+WDuld+AND+lower+AND+costs.

¹¹*Medicare RX: House Committee Navigates Crowded Field*, *supra* note 9.

¹²H.R. 2927, *supra* note 6.

¹³*Prescription Drugs: Two More Bills Would Lower Costs*, *supra* note 10.

¹⁴H.R. 2927, *supra* note 6.

¹⁵106 CONG. REC. H10754 (daily ed. Oct. 25, 1999) (statement of Rep. Brown).

¹⁶*Id.*

¹⁷*Prescription Drugs: Two More Bills Would Lower Costs*, *supra* note 10.

¹⁸*Medicare RX: House Committee Navigates Crowded Field*, *supra* note 9.

¹⁹H.R. 2927, *supra* note 6.

²⁰106 CONG. REC. H10754, *supra* note 15.

²¹*Medicare RX: House Committee Navigates Crowded Field*, *supra* note 9.

period that the generic drug is on the market, the generic manufacturer would pay royalties to the original manufacturer.²² These royalties would help “amply reward” the patent holder for being the first on the market, while “Americans would benefit from competitively driven prices.”²³

It is important to note that the APDA does not use price controls to reduce prescription drug prices.²⁴ Instead, the bill reduces drug industry monopoly power, while increasing consumer buying power by subjecting the drug industry to market-driven competitive forces.²⁵ The bill is a means of moderating prices that are too high without inadvertently setting prices too low.

III. HOW TO DEFINE AN ESSENTIAL DRUG AND EXCESSIVE PRICING

An important and difficult element to determine is whether a drug should be considered essential. Most would agree that life-saving drugs should be considered essential. However, there are many drugs that fall into a gray area, such as the anti-depressant Prozac whose determination as an essential drug will be difficult.

The difficulty of this determination is compounded by the fact “that there is no established systematic process, either in our regulatory or medical structures, to establish criteria for identifying and prioritizing the most important drugs...”²⁶ So how will the Secretary of Health determine whether a drug is essential or non-essential? Some possible criteria include the volume of use of the drug, the number of people the drug will impact, the severity of the condition for which the drug is prescribed, or if the drug is used only to treat a life-threatening condition.²⁷

Such criteria lead to an array of difficult choices in determining what is an essential drug. For example, proponents of treatments for rare life-threatening diseases view certain drugs as essential, even though these drugs may ultimately be used on a relatively small amount of the general population.²⁸ In contrast, drugs used to treat medical conditions such as ulcers, while not a life-threatening disease, would be more widely prescribed and impact a larger portion of the population.²⁹

Determining how an essential drug is defined is a complex issue. Yet, developing a definition and process for identifying essential drugs is imperative for the success of the APDA. Possible models that can be examined in order to determine whether a drug is essential or non-essential are those used by many third world countries that have already produced an essential drug list.³⁰ According to the

²²*Prescription Drugs: Two More Bills Would Lower Costs*, *supra* note 10.

²³106 CONG. REC. H10754, *supra* note 15.

²⁴*Id.*

²⁵*Id.*

²⁶Jeffrey L. Blumer, *Essential Drugs for Infants and Children: North American Perspective*, PEDIATRICS, Sept. 1999, at 603.

²⁷*Id.*

²⁸*Id.*

²⁹*Id.*

³⁰Michael R. Reich, *The Global Drug Gap*, SCIENCE, Mar. 17, 2000, available at http://www.biotech-info.net/drug_gap.html.

World Health Organization (WHO), more than sixty countries have operationalized essential drug programs, with thirty more in the process of drafting such programs.³¹ These essential drug lists were initiated in poorer countries in order to ensure a reasonable level of health care for as many people as possible.³²

The WHO has been a large promoter of the concept of essential drugs “to advance health equity through expanded access to basic medicines for poor people in poor countries.”³³ Currently, the WHO’s Tenth Model list of essential drugs contains 306 active drugs.³⁴ Such a list allows a country to focus its efforts on supplying the most important drugs to a population that is unable to gain access to them.

Experts have argued that using the WHO’s Model List as a basis will prove to be largely ineffective “[b]ecause of the great differences between countries, the preparation of a drug list of uniform, general applicability is not feasible or possible. Therefore each country has the direct responsibility of evaluating and adopting a list of essential drugs, according to its own policy in the field of health.”³⁵ This argument is countered by recent studies of various essential drug lists from different countries, which have shown surprisingly small variations of drugs determined to be essential.³⁶ The theory behind this lack of diversity is that diseases normally transcend national boundaries in symptoms and cures.³⁷

While an essential drug list developed in America should be broadly based on the WHO’s Eleventh Model List, it should also incorporate the specific criteria that will make it more suited to the economic and medical needs of Americans.

Another problematic element is the determination of when a drug’s price should be considered excessive. This requirement poses the problem of determining what financial statistics are relevant. The drug industry will inevitably argue that the cost of research and development of drugs that failed to reach the market should be included in this calculation. The industry argues that “[o]f every 5,000 medicines tested, on average, only five are tested in clinical trials and only one of those is approved for patient use. Revenues from successful medicines must cover the costs of the dry holes.”³⁸ Furthermore, only three of every ten prescription drugs available in America generates revenues that meet or exceed average research and

³¹Dzulkifli Abdu Razak & Pusat Racun Negara, *National Essential Drug List Hailed*, NEW STRAITS TIMES, (Mar. 2, 1996) at 11, at <http://www.prn.usm.my/edl/nedl.html>.

³²*Id.*

³³*Id.*

³⁴*Id.*

³⁵*Id.*

³⁶Razak, *supra* note 31.

³⁷*Id.*

³⁸PhRMA, *Why Do Medicines Cost So Much?* at <http://www.Pharma.org/publications/brochure/questions/>.

development costs.³⁹ The industry average for bringing just one new medicine to the market is \$500 million.⁴⁰

To determine what is an excessive price, the Secretary of Commerce most accurately determine how much was spent to develop the drug. As will be discussed later, a complication in determining the amount spent on a new drug is that a large portion of research and development costs are not paid by the pharmaceutical industry. Thus, for an accurate determination of an excessive price only those research and development expenditures paid by the company should be considered relevant.

IV. THE RISING COSTS OF PRESCRIPTION DRUGS

Soaring drug prices represent a health crisis that is sweeping this nation.⁴¹ Currently, the prices of prescription drugs are rising twice as fast as the inflation rate.⁴² Hardest hit by these price increases are senior citizens and the uninsured. Recent statistics indicate “[a] third of all seniors, over 10 million seniors, lack drug coverage; millions more are barely insured; employers are dropping their retiree coverage and private health insurers are cutting back their prescription drug benefits.”⁴³ Since senior citizens consume one-third of all prescriptions and many live on low fixed incomes, such actions have made them the most vulnerable segment of the American population to rising prescription drug prices.⁴⁴

Much like senior citizens, those without insurance coverage have also found it difficult to obtain much needed prescription drugs. Uninsured families are often charged two or three times more for prescription drugs than those who are insured.⁴⁵ The pharmaceutical industry agrees with these figures stating that private insurance companies pay drug prices thirty to thirty-nine percent lower than those charged to individuals without prescription drug insurance.⁴⁶ Higher costs for the uninsured are attributed to the uninsured having no one to negotiate lower prices on their behalf.⁴⁷

In both instances higher drug prices have lead to many difficult decisions for those who cannot afford them. People are making decisions that put their health in jeopardy, often choosing between purchasing food and purchasing medicine for themselves or their families.⁴⁸ A seventy-one-year-old widow from Sheffield Lake, Ohio, reported that since United Health Care pulled out of her county she has little

³⁹*Id.*

⁴⁰*Id.*

⁴¹John Freeman, *Cutting Drug Prices and Saving Lives*, METRO TIMES, July 5, 2000, available at <http://www.metrotimes.com/20/40/features/newcutting.htm>.

⁴²*Id.*

⁴³146 CONG. REC. H1127 (daily ed. Mar. 21, 2000) (statement of Rep. Brown).

⁴⁴Freeman, *supra* note 41.

⁴⁵*Id.*

⁴⁶*Id.*

⁴⁷*Id.*

⁴⁸*Id.*

drug coverage left.⁴⁹ The coverage she does have is absorbed by just one of her medications.⁵⁰ This seventy-one-year-old woman was forced to take a part time job in order to subsidize her low fixed income and help pay for her prescription drugs. A seventy-six-year-old woman from Elyria, Ohio stated, “I desperately need prescription drug help. Up until two weeks ago I worked three jobs, now I am working two jobs. Without working I can not [*sic*] afford to live. I don’t know how much longer I will be able to work.”⁵¹ The elderly are not the only group feeling the effects of high prescription drug prices. The middle-aged also have found it difficult to afford prescription drugs as reported by a man from Medina, Ohio: “Not only does [*sic*] high prescription (prices) affect senior citizens (but it also affects the) middle-age as well. When you take (into account) maintenance medication (*i.e.* [*sic*] high blood pressure, estrogen replacement, ... etc.) the cost effects us too. [A] decision has to be made – Do you eat or buy medication?”⁵²

On a larger international scale, citizens of third world countries face severe consequences because of accessibility problems, and mirror many of the dilemmas faced by America’s senior citizens and uninsured. An example of this is the AIDS epidemic in Africa and the excessive price of the drug AZT. As the AIDS epidemic continues to rage out of control in Africa, families that must care for a member infected with the virus often deplete monetary resources, which would otherwise be used for necessities, such as healthy food, or as an investment in their children’s futures.⁵³

V. ARE CURRENT PRICES FAIR?

This leads us to the question of whether current drug prices are fair?⁵⁴ Comparisons of prescription drug prices in other industrialized nations and prices for veterinary medicines, with average prices Americans pay demonstrate they are not.

A recent survey shows that on average U.S. citizens are charged 205 percent more than their Canadian neighbors for the same prescription drugs.⁵⁵ For example, the medication Cipro, which is used to treat infections, has an average wholesale price of \$171.59 in Canada.⁵⁶ The same medication sold in the U.S., by the same manufacturer, in the same dosage and quantity of pills, has a wholesale price of \$399.63, which represents a 233 percent increase from the Canadian price.⁵⁷ Other

⁴⁹Statement of Representative Sherrod Brown, *The Affordable Prescription Drugs Act*, at <http://www.house.gov.sherrodbrown/afpda.htm>.

⁵⁰Representative Sherrod Brown, *Prescription Drug Stories From Seniors*, at <http://www.house.gov.sherrodbrown/rxstories.htm>.

⁵¹*Id.*

⁵²*Id.*

⁵³Website of CNN, *AIDS Leaves Africa’s Economic Future in Doubt*, at <http://www.cnn.com/SPECIALS/2000/aids/stories/economic.impact.htm>.

⁵⁴146 CONG. REC. H1127, *supra* note 43.

⁵⁵Senator Byron Dorgan, *Rising Drug Costs are a Pain*, at <http://www.senate.gov/~dorgan/prescriptioncosts.html>.

⁵⁶*Id.*

⁵⁷*Id.*

examples of such price discrepancies include Zocor, a cholesterol reducing medication, and Tamoxifen, which is used to treat breast cancer. In Canada, sixty tablets of Zocor costs \$44; in the U.S. the same dosage of Zocor costs \$102.⁵⁸ Remarkably, a month supply of Tamoxifen sells for \$156 in the U.S. and only \$12 in Canada.⁵⁹ Not only do these discrepancies exist between Canada and the U.S., they also exist between the U.S. and other industrialized nations such as Germany, Sweden, United Kingdom, Canada, France, and Italy.⁶⁰

Why are the U.S. drug prices disproportionate when compared to other industrialized nations? It is because the U.S. does not demand that drug manufacturers reduce their prices.⁶¹ Instead of using the collective purchasing power of thirty-eight million senior citizens to demand fairly priced drugs, the U.S. simply retreats when drug manufacturers warn that any such action may stifle research and development of new drugs.⁶²

A comparison of medicines used by both animals and humans also demonstrates that current drug prices are unequal and inherently unfair. Manufacturers charge an average of 106 percent to 151 percent more for prescription drugs used by humans compared to the price of the same drug when used by animals.⁶³ A recent study shows that a group of drugs manufactured by the same company in the same dosage and form, used by both people and pets, costs on average 131 percent more when the drug is intended for human rather than animal use.⁶⁴

A good example of the price disparity between veterinary medicines and human medicines is the price of the drug Lanoxin, used in the treatment of heart failure.⁶⁵ A human purchasing Lanoxin will pay \$25.65, however, make that exact same purchase, in the same dosage and form for your pet and you only pay \$6.36.⁶⁶ Another example of these price differentials can be found in the frequently prescribed antibiotic Augmentin.⁶⁷ A manufacturer selling Augmentin for animal use charges \$18.00 for a one-month supply.⁶⁸ When the same manufacturer sells a one-month supply of the drug for human consumption the price skyrockets to

⁵⁸145 CONG. REC. H11148 (daily ed. Nov. 1, 1999) (statement of Rep. Brown).

⁵⁹*Id.*

⁶⁰For every U.S. dollar spent on prescription drugs on average Germany only pays seventy-one cents, Sweden sixty-eight cents, U.K. sixty-five cents, Canada sixty-four cents, France fifty-seven cents, and Italy fifty-one cents, Dorgan, *supra* note 55.

⁶¹146 Cong. Rec. H1127, *supra* note 43.

⁶²*Id.*

⁶³Website of Sherrod Brown, *Study Shows that Drug Manufacturers' Prices are More than Double for Humans than for Animals*, available at <http://www.house.gov/sherrodbrown/drugm31.htm>.

⁶⁴*Id.*

⁶⁵Freeman, *supra* note 41.

⁶⁶*Id.*

⁶⁷*Study Shows that Drug Manufacturers' Prices are More than Double for Humans than for Animals*, *supra* note 63.

⁶⁸*Id.*

\$56.40.⁶⁹ By subtracting the manufacturer's price increase paid by humans for popular drugs such as these, consumers would pay an average of 25 percent to 38 percent less at the pharmacy per year.

The pharmaceutical industry attempts to explain this discrepancy by reasoning that veterinary drug prices cost less because of lower research and development costs, and less restrictive testing standards that are less restrictive which lead to less expensive production costs.⁷⁰ However, lower research and development costs do not justify the cost discrepancies. As stated by Dr. Alan Sager, an industry expert: "The observed price differences cannot be explained by differences in research costs. Research is a fixed or sunk cost. Manufacturers do not set their prices based on recovery of these costs. Instead, they set their prices as high as possible in order to maximize revenue and profit."⁷¹ Higher production costs due to more restrictive safety standards also fails to account for these price differentials. The Food and Drug Administration's (FDA) "good manufacturing practice requirements," codified in 21 C.F.R. part 211, which are designed to ensure drug quality and consistency, are applied to both human and animal drugs.⁷² According to the FDA, "The methods, facilities, and controls under which animal drugs are manufactured, processed, packaged, or held for sale must conform to the requirements of the regulations for Current Good Manufacturing Practices in the drug industry generally."⁷³

These price differentials demonstrate the price-gouging attitude of many large pharmaceutical companies. The vulnerability of today's U.S. senior citizens and uninsured has allowed these companies to place the burden of paying high prices for necessary drugs on these segments of the U.S. public. The continuation of such a burden will no doubt result in an elderly society saturated with sickness, and without the ability to pay for drugs that will help.

VI. CONGRESSIONAL *Laissez-Faire* APPROACH

While drug prices continue to increase to the point where millions of U.S. citizens cannot afford the high costs of prescription drugs, the majority in Congress refuses to take action to help reduce these prices.⁷⁴ This *laissez-faire* attitude that Congress has taken can be attributed to the drug industry's lobbying power and constant threat that money for "research and development will dry up."⁷⁵

⁶⁹*Id.*

⁷⁰PhRMA, *Prescription Drugs: Are Fido and Fluffy Getting a Better Deal?*, at <http://www.phrma.org/publications/documents/backgrounders/2000.phtm>.

⁷¹Representative Elijah E. Cummings, *Prescription Drug Price Discrimination: Drug Manufacturer Prices Are Higher for Humans than for Animals*, at <http://www.house.gov/cummings/drugrpt3/comprpt8.htm>.

⁷²*Id.*

⁷³*Id.*

⁷⁴145 CONG. REC. H10754 (daily ed. Oct. 25, 2000) (statement of Rep. Brown).

⁷⁵Representative Sherrod Brown, Statement at House Subcommittee on Health and the Environment Hearing (Sept. 28, 1999), available at <http://www.house.gov/sherrodbrown/medpresdrg920.htm>.

Even when Congress has taken action against high drug prices, strong lobbying by the drug industry has led to watered down measures. An excellent example is the recently approved Agriculture Appropriations Conference Report.⁷⁶ Originally, this legislation would have established drug re-importation from other countries by eliminating a federal law that gives manufacturers a monopoly over drug imports.⁷⁷ It ultimately would have allowed the same drugs that are being sold at a lower price in countries such as Canada to be brought back into the U.S. and sold at a lower price here.⁷⁸ In order to fight off these measures, the pharmaceutical industry spent millions of dollars on television, radio and newspaper ads in an attempt to expunge the provisions during committee meetings.⁷⁹ This effort by the pharmaceutical industry led to a final law, which included language filled with various pharmaceutical industry backed loopholes, making the provisions largely ineffective.⁸⁰ “Specifically the provisions limit where prescription drugs can be imported from, allows the pharmaceutical industry to force foreign wholesalers to sell products at the inflated American price, and revokes the bill after five years.”⁸¹

Another excellent example of Congress’ reluctance to take action against prescription drug prices is the recently proposed “Sanders Amendment.”⁸² The Sanders Amendment was proposed specifically in order to enforce the already existing Bayh-Dole provisions, which require the reasonable pricing of prescription drugs.⁸³ The mere fact that Congress must attempt to enact legislation in order to enforce already existing legislation to lower drug prices leads to the inevitable conclusion that the pharmaceutical industries lobbying power has succeeded.

VII. CONGRESSIONAL EXTENSIONS OF PATENT PROTECTION

Not only has the majority of Congress opposed new laws which would help reduce the price of prescription drugs, but they have also passed legislation to extend the length of patent protection granted to these drugs. The pharmaceutical industry gained a major extension in its patent term when Congress enacted the Patent Term Extension to the Waxman-Hatch Act.⁸⁴ Section 155 of the Act states, “the term of a patent . . . shall be extended if such composition or process has been subjected to a regulatory review by the Federal Food and Drug Administration pursuant to the

⁷⁶Representative Sherrod Brown, *Brown: The Gop Forsakes Seniors for Drug Companies*, at <http://www.house.gov/sherrodbrwn/drugo11.html>.

⁷⁷*Id.*

⁷⁸Asad Jaleel, *Congress Finally Acts to Cover Prescription Price*, JOURNAL FOR PRE HEALTH AFFILIATED STUDENTS, available at http://icaius.cc.uic.edu/orgs/jphas/fall2001/invitedopinion_ol.html.

⁷⁹*Brown: The Gop Forsakes Seniors for Drug Companies*, *supra* note 76.

⁸⁰*Id.*

⁸¹*Id.*

⁸²*Id.*

⁸³*Id.*

⁸⁴35 U.S.C. §155 (2001).

Federal Food, Drug and Cosmetic Act.”⁸⁵ Section 155 effectively allowed the drug industry to gain up to five years of added protection for any drug subjected to the FDA’s regulatory procedures.⁸⁶ The pharmaceutical industry has taken full advantage of this provision extending patent protection and higher prices of many important prescription drugs.⁸⁷

Once again in 1995, many pharmaceutical companies gained an extension on their patents. Pharmaceutical companies benefited from a ruling on the General Agreement on Tariffs and Trade which extended many prescription drug patents from seventeen years to twenty years.⁸⁸ This ruling allowed prescription drugs such as Zantac, an ulcer medication, whose patent protection was about to expire, to reap the monopolistic benefits of patent protection for three more years.⁸⁹ According to the Prime Institute at the University of Minnesota, an institution that does research on pharmaceutical economics and public policy issues, this extension has cost consumers an extra 6.2 billion dollars in spending on prescription drugs.⁹⁰

Another recent attempt by Congress to extend the patent protection of prescription drugs occurred in 1998. A proposed rider to the 1998 Agriculture Appropriations bill would have allowed manufacturers of seven prescription drugs to petition the Patent and Trademark Office (PTO) for additional patent term extensions beyond those allowed by the Hatch-Waxman Act.⁹¹ One drug that would have benefited from this extension was the top anti-arthritis drug Relafen that had already grossed sales of \$419 million.⁹² The availability of a generic version of Relafen would save consumers \$268 to \$535 a year while total annual savings to all health care payers would range from \$126 million to \$252 million.⁹³ Fortunately, for senior citizens, the rider did not go through; however, this is an excellent example of how costly a “second bite at the patent apple” can be for seniors citizens on a fixed income.⁹⁴

VIII. PHARMACEUTICAL COMPANIES EXTEND PATENT PROTECTION

Despite Congressional patent extensions, pharmaceutical companies have used unscrupulous methods to unfairly extend their drug patents in order to reap the benefits of a patent monopoly. One method used by large pharmaceutical companies

⁸⁵*Id.*

⁸⁶Franklin Pierce Law Center’s “IP Mall,” at <http://www.ipmall.fplc.edu/ipcorner/bp97/eval2.htm#Returnto> 23.

⁸⁷*Id.*

⁸⁸Barbara Sullivan, *New Drug Patent hard to Swallow; FDA Ruling Will Delay Launch Of Generic Products*, CHI. TRIB., May 31, 1995, at Business 1.

⁸⁹*Id.*

⁹⁰*Bad Medicine*, at http://www.commoncause.org/publications/pocket_book2.htm.

⁹¹*Sneak Prescription Drug Patent Extension In Appropriations Rider Would Increase Drug Prices for Seniors*, PUBLIC CITIZEN, at <http://www.citizen.org/Press/pr-sid14.htm>.

⁹²*Id.*

⁹³*Id.*

⁹⁴*Id.*

to extend their patent protection is to keep generic drugs from the market by paying off manufacturers to refrain from producing the generic version for a limited time.⁹⁵

In *FTC v. Hoechst Marion Roussel, Inc.*,⁹⁶ a large pharmaceutical company, Hoechst, attempted to delay the introduction of a generic version of the brand name hypertension and angina drug, Cardizem CD, that they produce.⁹⁷ Hoechst and Andrx, generic drug manufacturers, entered into an agreement in which Hoechst agreed to pay Andrx millions of dollars, and in return Andrx would not enter the market with the generic version of the drug during the term of the agreement.⁹⁸

Another similar conspiracy involved Abbott and Geneva Laboratories. Abbott Laboratories develops, manufactures and sells a variety of health care products and services including a drug called Hytrin, which is used to treat two chronic conditions that affect millions of Americans, particularly senior citizens, high blood pressure and enlarged prostate.⁹⁹ Abbott Laboratories conspired with Geneva, one of the leading generic drug manufacturers in the U.S., to delay the sale of a generic version of Hytrin, terazosin HCL.¹⁰⁰ The agreement between Abbott and Geneva was that Abbott would pay Geneva \$4.5 million dollars per month and in return Geneva would not offer HCL in competition with Hytrin for a limited time.¹⁰¹ "Without a lower-priced generic alternative, consumers, government agencies, health plans, pharmacies, hospitals, wholesalers, and others were forced to purchase Abbott's more expensive Hytrin product."¹⁰²

Such conspiracies are in direct conflict with the Hatch-Waxman Act, which facilitates the entry of generic drugs into the market while maintaining incentives for pharmaceutical companies to invest in new drugs.¹⁰³ These conspiracies have a direct and substantial effect on consumer savings.¹⁰⁴ The entry of generic drugs into the market plays a key role in lowering prices of prescription drugs. Generic drugs usually have an immediate impact on the market place; pharmacists generally select lower priced drugs for their brand name substitute, and third party payers of prescription drugs, such as Medicaid programs, encourage or insist upon the use of

⁹⁵*Skull-Druggery Patients' Access to Drugs Must be Ensured*, COLUMBUS DISPATCH, Aug. 15, 2000, at 8a.

⁹⁶Website of Federal Trade Commission, *Conduct Involving Health Care Services and Products*, available at <http://www.ftc.gov/bc.hcindex/conduct.htm>.

⁹⁷No. D9293 (FTC complaint issued Mar. 16, 2000).

⁹⁸*Id.* ("Because of Hatch-Waxman provisions which grant the initial generic manufacturer a 180 day market exclusivity period, the complaint alleges the effect of the agreement was to ensure that no other company's generic drug could obtain FDA approval and enter the market during the term of the agreement.").

⁹⁹Website of Federal Trade Commission, *Analysis to Aid Public Comment*, available at <http://www.ftc.gov/os/2000/05.abbottgenevaanalysis.htm>.

¹⁰⁰*Id.*

¹⁰¹*Id.*

¹⁰²*Id.*

¹⁰³*Id.*

¹⁰⁴*Analysis to Aid Public Comment*, *supra* note 99.

generic drugs.¹⁰⁵ Studies have shown that generic drugs sell for thirty to sixty percent less than brand name drugs.¹⁰⁶ Furthermore, estimates by the Congressional Budget Office Report have shown that lower prices from generic drugs have saved consumers \$8-10 billion per year on prescriptions at retail pharmacies.¹⁰⁷

Pharmaceutical companies have also unfairly extended their patent protection by double patenting the same drug. In order for a company to acquire a drug patent the PTO must find its claim to be novel, useful, and non-obvious.¹⁰⁸ As a result, if a company attempts to extend a patent of an existing patented drug by bringing in a new claim for a drug patent that is similar to the already patented drug, the claim should fail because of obviousness.¹⁰⁹ To simplify, by claiming a second invention, the pharmaceutical company is simply looking to extend the underlying first patent. Such attempted extensions of patent protection by pharmaceutical companies are illegal under the doctrine of obviousness-type double patenting.¹¹⁰ “The doctrine of obviousness-type double patenting prohibits a party from securing an unjustified extension of its exclusive rights through claims in a later patent that are not patentably distinct from earlier claims.”¹¹¹ Obviousness-type double patenting requires the court to take a two-step analysis.¹¹² First, the court must determine whether the second claim encompasses the subject matter of the first claim.¹¹³ Second, the court must determine if the second claim is patentably distinct from earlier claims.¹¹⁴

In *Eli Lilly Co. v. Barr Laboratories, Inc.*,¹¹⁵ the Court of Appeals for the Federal Circuit held that Barr Laboratories’ attempt to manufacture a generic version of Prozac did not infringe upon an existing Eli Lilly patent because of obviousness-type double patenting.¹¹⁶ In 1977, Eli Lilly patented claim ‘895 for the marketing of fluoxetine hydrochloride to be used as an anti-depressant in humans.¹¹⁷ This patent was set to expire in 1994.¹¹⁸ In 1984, Eli Lilly patented claim ‘549 for the marketing

¹⁰⁵*Id.*

¹⁰⁶*Sneak Prescription Drug Patent Extension In Appropriations Rider Would Increase Drug Prices for Seniors*, *supra* note 91.

¹⁰⁷*Id.*

¹⁰⁸MICHAEL H. DAVIS, *INTELLECTUAL PROPERTY; PATENTS, TRADEMARKS, AND COPYRIGHT IN A NUTSHELL*, 36 (3d ed., 2000).

¹⁰⁹Brief of Amici Curiae Intellectual Property Owners Association, at 6, *Eli Lilly Co. v. Barr Laboratories, Inc.*, 222 F.3d 973 (Fed. Cir. 2000).

¹¹⁰*Id.*

¹¹¹*Id.*

¹¹²*Id.*

¹¹³*Id.*

¹¹⁴Brief of Amici Curiae Intellectual Property Owners Association, *supra* note 109, at 6.

¹¹⁵222 F.3d 973 (Fed. Cir. 2000), *vacated* 251 F.3d 955 (2001).

¹¹⁶*Id.* at 975 (Newman, J., dissenting).

¹¹⁷*Id.* at 989.

¹¹⁸*Id.*

of fluoxetine hydrochloride to be used in the treatment of serotonin uptake in animals.¹¹⁹ This patent was set to expire in 2003.¹²⁰ In 1995, Barr Laboratories filed an Abbreviated New Drug Application under the Hatch-Waxman Act to market fluoxetine hydrochloride as an anti-depressant. On April 10, 1996 Eli Lilly brought an infringement action against Barr for infringement of claim '549, which had yet to expire.¹²¹

Applying the two-step analysis, the Federal Circuit first determined that the later claim encompassed the same subject matter of the previous claim.¹²² The court then attempted to determine "whether the differences in subject matter between the two claims are patentably distinct."¹²³ The court found that the only discernible difference between the two patents was that the earlier patent addressed the treatment of depression in humans while the later patent addressed the treatment of serotonin uptake in animals.¹²⁴ Relying upon previous case law, the Federal Circuit held that the use of fluoxetine hydrochloride in two different species was not enough to make the two separate claims patentably distinct.¹²⁵

Generic drug manufacturers have also played a role in keeping prescription drug prices high. In a case that was scheduled to be ready for trial early this year, Mylan Laboratories, the second largest U.S. generic drug manufacturer, was accused of cornering the market on raw materials for two popular drugs lorazepam and chlorazepate.¹²⁶ Mylan attempted to restrain competition from other generic drug manufacturers by acquiring exclusive licensing arrangements for the supply of the raw materials necessary to produce both of the generic drugs, thereby allowing Mylan laboratories to dramatically increase the price of both lorazepam and chlorazepate.¹²⁷ Mylan Laboratories has agreed to pay \$147 million in order to settle these charges.¹²⁸

Such actions taken by the pharmaceutical industry increases the amount of patent protection beyond the limits deemed appropriate by Congress. These patent/monopoly extensions have had and will continue to have a detrimental effect on the accessibility and affordability of prescription drugs. By the time of patent expiration, United States consumers have more than compensated the drug industry for its innovative expenditures, and are being cheated out of lower priced generic drugs by the unscrupulous patent extensions of a spoiled industry.

¹¹⁹*Id.* at 988.

¹²⁰*Eli Lilly Co.*, 222 F.3d 973.

¹²¹*Id.* at 975.

¹²²*Id.* at 985.

¹²³*Id.*

¹²⁴*Id.* at 988.

¹²⁵*Eli Lilly Co.*, 222 F.3d at 988.

¹²⁶*Conduct Involving Health Care Services and Products*, *supra* note 96.

¹²⁷*Id.*

¹²⁸*Skull-Druggery Patients' Access to Drugs Must be Ensured*, *supra* note 95.

IX. DRUG INDUSTRY'S JUSTIFICATION FOR HIGHER PRICES

Repeatedly, drug companies have made the same threat: "If you don't leave drug prices alone, we won't produce any new drugs."¹²⁹ They argue that any type of action taken by the government to reduce the price of prescription drugs will inevitably lead to a decrease in the profits necessary to fund research and development of new life-saving drugs.¹³⁰ This threat has not only led to a reluctance on the part of the government to interject regulatory policies, but it has also made many essential prescription drugs unavailable to the elderly and uninsured.

Many pharmaceutical companies have taken up arms against the APDA in an effort to keep the bill from becoming a law. They have projected that research-based pharmaceutical companies will invest an estimated \$24 billion dollars in research and development of new medicines.¹³¹ They argue that the APDA will be detrimental to any hope for new cures, and will jeopardize the current development of new drugs by forcing companies to reduce their patent protection to new breakthrough drugs.¹³² Alan F. Homer President of the Pharmaceutical Research and Manufacturers of America (PhMRA³) has stated:

We couldn't keep up the current, pro-patient research momentum if Representative Brown's bill were enacted into law. More investment dollars instead would flow to other products that have intellectual property protection, instead of to medicines. If we want to continue the remarkable strides in health, we need to keep strong intellectual property protection for medicines in place.¹³³

Domestic biotechnology companies are also investing large amounts of money to lobby against the APDA. The U.S. biotechnology industry leads the world in health-care innovation.¹³⁴ These cutting edge companies are developing drugs for many debilitating illnesses, such as Alzheimer's disease, various cancers and heart disease.¹³⁵ Many biotechnology companies argue that patents provide a limited amount of market protection from competitors, and this protection gives these innovative companies the opportunity to recoup their enormous investments in new drugs. Furthermore, they argue that without patent protection private investors have no incentive for risking their capital.¹³⁶

Carl B. Feldbaum, President of Biotechnology Industry Organization, has taken a strong opposition against the APDA, and any other regulatory action that will reduce

¹²⁹*Id.*

¹³⁰*Id.*

¹³¹PhMRA, *Rep. Brown's Plan Would Hurts Patients Hoping for Cures & Harm a Model U.S. Industry, says Phrma*, at www.phrma.org/press/newsreleases//1999-09-23.27.phtml.

¹³²*Id.*

¹³³ *The Affordable Prescription Drugs Act Statement of Congressman Sherrod Brown*, *supra* note 49.

¹³⁴*Id.*

¹³⁵Feldbaum, *supra* note 3.

¹³⁶*Id.*

the price of drugs. In a recent interview, Feldbaum stated “we will aggressively oppose any legislation that undermines innovation through either overt or covert disguised government imposed drug price controls. Anything that artificially lowers reimbursement rates and keeps our companies from bringing new drugs to market and to patients.”¹³⁷ Feldbaum points to the record twenty-one drugs produced by biotech companies and approved by the FDA in 1998.¹³⁸ He argues that biotech companies, that produce new innovative drugs, could not have done so under a system of regulatory price controls.¹³⁹ Speaking specifically of the APDA, Feldbaum stated, “[i]nstead of helping seniors and other patients, Brown’s legislation clearly would hurt them by impeding new drug development. Many biotech drugs and vaccines under development are aimed at diseases, such as Alzheimer’s, where no treatments are available.”¹⁴⁰ Biotech industry representatives are quick to note the majority of their drugs are still in the research stage, and their continued development relies upon the venture capital obtained by drugs already on the market.¹⁴¹

Pharmaceutical companies also argue that higher prices are justified since today’s drugs do considerably more than drugs from the past.¹⁴² Examples include recently introduced drugs that reduce cholesterol, lower blood pressure, treat depression, battle cancer, and improve patients’ quality of life.¹⁴³ The drug industry explains that not only do prescription drugs offer the most ideal therapeutic option, they are also the most feasible economic alternatives.¹⁴⁴ An example of the possible economic benefits of prescription drugs are the cost savings of purchasing new prescription drugs compared to patient hospitalization. One week of hospitalization in the U.S. for a patient with schizophrenia costs nearly the same as a full year of treatment with a newer antipsychotic drug, such as Zyprexa.¹⁴⁵

However, the fact that a drug offers additional benefits cannot be a viable economic rationale for higher drug prices. The only justifiable argument for higher prices is recoupment of research and development costs, not the public benefit that a drug affords.

The drug industry proclaims that the best way to ensure the accessibility of new drugs is to avoid governmental price controls and focus more on adopting a Medicare modernization position.¹⁴⁶ Such a position would allow drug companies to

¹³⁷Interview by WaBio.com with Carl Feldbaum, C.E.O. Biotechnology Industry Organization, at <http://www.wabio.com/ind/anrpt/ceo905F/feldbaum.htm>.

¹³⁸*Id.*

¹³⁹*Id.*

¹⁴⁰*Id.*

¹⁴¹*Id.*

¹⁴²*Eli Lilly and Co., 1999 Annual Report: Are Drug Prices Fair*, available at http://www.lilly.com.about.investro.99report/english/at_prices.html.

¹⁴³*Id.*

¹⁴⁴*Id.*

¹⁴⁵*Id.*

¹⁴⁶Feldbaum Interview, *supra* note 137.

continue to charge monopolistic prices, while, allegedly, making prescription drugs more available and affordable to the public.

X. REBUTTAL ARGUMENT

The drug industry's threat that any action by the government to reduce prescription drug prices would ultimately decrease the industry's ability to create new drugs has been very effective. However, consumers and Congress should be wary of the truth behind such a threat.

While research and development of new drugs is as important to health care as availability and lower prices, the pharmaceutical industries threat has no merit when we determine who really pays for the research and development of new drugs. What the drug industry does not reveal is that they do not bear the major burden of funding research and development of new drugs.¹⁴⁷ Presently, the federal government funds all of the basic research and development of new drugs through the National Institutes of Health (NIH).¹⁴⁸ In fact, through the NIH, U.S. taxpayers finance 42 percent of the research and development that produces new drugs.¹⁴⁹ Furthermore, private foundations, state and local governments, and other non-industry sources represent eleven percent of the funding for research and development of new drugs.¹⁵⁰ The pharmaceutical companies are usually only involved in funding the clinical testing of new compounds for safety and effectiveness in order to gain regulatory approval for applications of the new drug.¹⁵¹ "The NIH and independent scientists working with NIH grants, generally do the hard part and take the biggest risks, yet there is no system for sharing the drug companies' subsequent profits with the public treasury or for setting moderate prices that don't gouge consumers."¹⁵²

Furthermore, the drug industry's threat that research and development of new drugs will be chilled by any actions taken to lower prescription drug prices is less effective when we examine the large tax breaks given to pharmaceutical companies for their research and development expenditures. Congress bestowed these generous tax breaks upon drug companies in order to give them an incentive to invest more of their time and effort into the research and development of new essential drugs.¹⁵³ The tax breaks are enormous. Drug manufacturers pay an effective tax rate of ten percentage points lower than the average for all major industries.¹⁵⁴ These tax breaks diminish the drug industry's argument that profits from high drug prices are the

¹⁴⁷*E-Drug Affordable Prescription Drugs Act*, available at <http://www.healthnet.org/programs/e-drug-hma/e-drug.199910/msg00025.html>.

¹⁴⁸William Greider, *If Politics Got Real*, NATION MAGAZINE, available at <http://www.thirdworldtraveler.com/Greider/IfPoliticsGotReal.html>.

¹⁴⁹*The Affordable Prescription Drugs Act Statement of Congressman Sherrod Brown*, *supra* note 49.

¹⁵⁰*Id.*

¹⁵¹Greider, *supra* note 148.

¹⁵²*Id.*

¹⁵³145 CONG. REC. H10754, *supra* note 74.

¹⁵⁴146 CONG. REC. H1127, *supra* note 43.

driving force behind the research and development of new drugs, and that Congress will chill that research and development by tampering with prices.

The enormous amount of profitability and success of the drug industry is yet another indicator that lower drug prices will do little to affect the research and development of new drugs. Currently, drug companies' profits are greater than those of any other industry by at least five percent.¹⁵⁵ These profits are expected to grow by 16-18 percent over the next four years.¹⁵⁶ This growth rate is about three times greater than that of the average profit growth rate for any other Fortune 500 company.¹⁵⁷ Drug industry revenues have reached a staggering \$106 billion dollars per year.¹⁵⁸ These large profit margins have created an enormous amount of financial security for these companies and their representatives. In 1999, Bristol-Meyers Squibb paid its CEO a \$1.2 million salary, a \$1.9 million bonus, and \$30.4 million in stock options.¹⁵⁹ Such expenditures and large profits should make it difficult for the U.S. public to believe that high prescription drug prices are necessary in order for drug companies to prosper and invest more in research and development. It seems as if their cup is already full.

Furthermore, the drug industry's search for profitable drugs has had a detrimental effect on the research and development of less profitable drugs for rare life threatening diseases. In 1983, Congress recognized this danger and attempted to stimulate drug development in this area by enacting into law the Orphan Drug Act (ODA).¹⁶⁰ The intent of the Act is to offer an incentive to the pharmaceutical industry to produce drugs which, without governmental assistance, would be unprofitable.¹⁶¹

The ODA is applicable upon the FDA's determination that absent the ODA's granting of exclusive rights, and financial assistance, a rare disease would not receive the attention necessary to produce a cure.¹⁶² If such a determination is made that an exclusive seven-year right to market a drug is necessary to treat the disease will be granted to a manufacturer willing to research and develop the drug.¹⁶³ Public monies through a variety of research grants, tax credits, and other subsidies subsidize these drugs' research and development.¹⁶⁴ In order to receive these incentives it must

¹⁵⁵*E-Drug Affordable Prescription Drugs Act, supra* note 147.

¹⁵⁶*The Affordable Prescription Drugs Act Statement of Congressman Sherrod Brown, supra* note 49.

¹⁵⁷*Id.*

¹⁵⁸Greider, *supra* note 148.

¹⁵⁹*The Affordable Prescription Drugs Act Statement of Congressman Sherrod Brown, supra* note 49.

¹⁶⁰Peter Arno, et al., *Rare Diseases, Drug Development, and AIDS: The Impact of the Orphan Drug Act*, MILBANK Q. VOL. 73, No. 2, at 231 (June 22, 1995), available at <http://www.house.gov/waxman/phar/Orpahn/Orlinks/062295MQ/62295mz.html>.

¹⁶¹*Id.*

¹⁶²DAVIS, *supra* note 108, at 35.

¹⁶³*Id.*

¹⁶⁴Arno, *supra* note 160.

be proven that the disease affects less than 200,000 people.¹⁶⁵ While there is no actual patent granted by the ODA, “the effects of its exclusive right often are indistinguishable from those of a patent.”¹⁶⁶ Arguably, the Act suffers from a serious constitutional defect in that the exclusive rights granted offer the same amount of protection that a patent offers, yet the patent requirements of novelty, non-obviousness, and distinctiveness are not required.¹⁶⁷

Regardless of its constitutionality, the ODA is an example of the drug industry’s exploitation of legislation enacted for the public good, to gain larger profits. However, in many respects the ODA has been a success. Ten years before it was enacted, only ten ‘orphan drugs’ that were used to treat rare debilitating diseases were developed without governmental assistance.¹⁶⁸ After ten years as law, 513 drugs were determined to be ‘orphan drugs,’ and the FDA licensed eighty-seven of those for sale.¹⁶⁹ Yet, the drug industry has taken full advantage of the seven-year exclusive market right by charging extraordinarily high prices for ‘orphan drugs’ that are almost completely subsidized by public monies.¹⁷⁰

The development of drugs for AIDS highlights the industry’s attempt to manipulate the ODA to gain larger profits. When the epidemic first began, the reluctance of the drug industry to research and develop in this area was linked to a lack of potential profit.¹⁷¹ Realizing how beneficial the ODA could be for profitability, companies, such as Burroughs Wellcome, were able to develop new drugs, such as AZT, through public funds and subsequently charge an exorbitantly high price for it due to the seven-year market right granted via the ODA.¹⁷²

High prices of orphan drugs are an example of pharmaceutical companies taking advantage of an inherent flaw in the ODA; “Although the act presumes limited profitability, it does not require that it be demonstrated. Absent that requirement, the ODA has often been used to increase the marketing advantages of a drug that would have enjoyed sufficient potential profitability from its patent exclusivity alone.”¹⁷³ The drug industries manipulation of the ODA is another example of the lengths the industry will go for profits.

Many drug companies would have Americans believe that the majority of their profits go towards research and development of new drugs. However, since the FDA has allowed direct-to-the-consumer advertising campaigns the majority of their profits have gone towards the marketing of new drugs. The pharmaceutical industry has decided to gradually shift the core of its spending away from creating new drugs

¹⁶⁵DAVIS, *supra* note 108.

¹⁶⁶*Id.*

¹⁶⁷*Id.*

¹⁶⁸Arno, *supra* note 160.

¹⁶⁹*Id.*

¹⁷⁰*Id.*

¹⁷¹*Id.*

¹⁷²*Id.*

¹⁷³Arno, *supra* note 160.

and towards the steadier business of marketing them.¹⁷⁴ A recent study by the National Institute for Health Care (NIHC) shows that 25 of the most heavily advertised drugs accounted for more than 40 percent of the increase in retail drug spending last year.¹⁷⁵ Between 1998 and 1999 the amount of money spent on consumer advertising increased from \$1.3 billion dollars to \$1.8 billion dollars.¹⁷⁶ The analysis further shows that consumer advertising could be responsible for 10-25% of the recent increase in prescription drug prices.¹⁷⁷ Just one example of the enormous amount of advertising spent on a prescription drug is that of the allergy medication Clariton. Clariton is one of the most heavily advertised drugs in the U.S..¹⁷⁸ In 1999, Schering-Plough, the manufacturer of Clariton, spent over \$137 million in advertising the drug.¹⁷⁹

Another type of advertising large pharmaceutical companies sink major investments into are donations made to political groups to increase their lobbying power. Companies such as Pfizer and Bristol-Myers Squibb lead the pack with totals of \$1,683,433 and \$1,648,668, respectively.¹⁸⁰ In both cases about 84 percent of these donations were made to the Republican Party.¹⁸¹

Contrary to what the drug industry would like the American public to believe, the large profits made from high prescription drug prices are not used to extensively research and develop new drugs. Rather, the majority of these profits are used for advertising and lobbying. This is yet another reason why the drug industry's threat that research and development will dry up without the high prices charged to Americans is without merit.

Another excellent indicator that the drug industry's threat is idle is the success of past legislative actions that regulate the industry. Congress proposed legislation to pave the way for a stronger generic drug industry in 1983.¹⁸² Under the Hatch-Waxman Act generic competitors would be allowed to enter the market and compete with brand-name drugs in a more reasonable fashion.¹⁸³ Much like the present scenario, when the Hatch-Waxman Act was proposed, brand-name drug manufacturers claimed that competition from generic drug producers that would result in lower drug prices would have a significant chilling effect on research and development of new drugs.¹⁸⁴ Ignoring this threat, Congress enacted the Hatch-

¹⁷⁴*Prescription Drugs and the Cost of Advertising Them*, at <http://www.therubins.com/geninfo/advertise.htm>.

¹⁷⁵*Id.*

¹⁷⁶*Id.*

¹⁷⁷*Id.*

¹⁷⁸*Id.*

¹⁷⁹*Prescription Drugs and the Cost of Advertising Them*, *supra* note 174.

¹⁸⁰*Id.*

¹⁸¹*Id.*

¹⁸²*See* 35 U.S.C. § 155 (1999).

¹⁸³*Id.*

¹⁸⁴*Id.*

Waxman Act, and the generic drug industry now manufactures nearly fifty percent of all drugs dispensed in the U.S.¹⁸⁵ Yet, even with this increase in competition, the drug industry's own estimates of the amount of research and development conducted increased dramatically.¹⁸⁶ The past success of the Hatch-Waxman Act in increasing competition and lowering prices, while not dampening research and development of new drugs, should be an excellent indicator that lower drug prices and increased competition do not necessarily lead to a reduction in new drugs.

XI. ARGUMENT IN FAVOR OF THE APDA

Lowering the price of prescription drugs is vital to the health and well being of our nation. These drugs are not luxury items, for which consumers can shop elsewhere for lower prices.¹⁸⁷ Instead, these drugs are a necessity to millions of Americans who often cannot live without them.¹⁸⁸ Strong patent protection of new essential drugs has allowed many drug companies to acquire a monopoly power over the market, effectively eliminating any price competition. Thus far, Congress' "hands off approach" towards prescription drug prices has done nothing to help reduce these costs.¹⁸⁹

With public concern over high drug prices increasing many members of Congress have been making efforts to make prescription drugs more accessible and affordable for Americans.¹⁹⁰ The APDA was introduced in order to lower drug prices through competition not price controls.¹⁹¹ The bill states, "[u]nder certain conditions, if a prescription drug provides a substantial public health benefit and is unreasonably priced, as determined by the Secretary of Health, the federal government may require drug manufacturers to license their patent to generic drug companies."¹⁹² This would allow competitors to market new drugs before patent expiration, while paying the original inventor royalties for that right.¹⁹³

By reducing the drug industry's power and increasing consumer power the APDA decreases the cost of prescription drug prices by subjecting pharmaceutical companies to competitive forces. The bill itself is based upon, and draws from, intellectual property laws already established in the U.S., such as those dealing with pollution control devices, in which accessibility is an issue.¹⁹⁴ The success of these

¹⁸⁵*Id.*

¹⁸⁶*Id.*

¹⁸⁷*E-Drug Affordable Prescription Drugs Act, supra* note 147.

¹⁸⁸*Id.*

¹⁸⁹*Factors Affecting the Growth of Prescription Drug Expenditures, available at* <http://216.239.51.100/search?q=cache:1-fms-qPeDAC:www.nihcm.org/FinalText3.PDF+Pres.>

¹⁹⁰*E-Drug Affordable Prescription Drugs Act, supra* note 147.

¹⁹¹*Id.*

¹⁹²*Id.*

¹⁹³*Id.*

¹⁹⁴*Id.*

programs is an excellent indicator of how effective the APDA will be in making prescription drugs more accessible and affordable.

Drug companies are in business to maximize profits in order to prosper and create new drugs. Therefore, it is important not to take away any incentive these companies have for being innovative and aspiring to be the first to enter the market. The APDA is a proposal that would do just that by bringing down prices without taking away the drug companies incentive to act like an industry.¹⁹⁵ This balancing act would be accomplished by the APDA rewarding the patent holder for being the first to create and market a new drug with the royalties paid to that company.¹⁹⁶ Still, it would, through competitive forces, moderate prices that are too high and make many life saving drugs more readily available to consumers who need them.¹⁹⁷ Furthermore, the APDA allows pharmaceutical companies the option to work together with the government and avoid a compulsory license by voluntarily reducing the price to a reasonable amount that would allow the company to profit from the drug, while still making it more accessible and affordable to the American public.¹⁹⁸

An important policy issue that must be resolved in order for the APDA to be effective is the determination of what constitutes an essential drug. It is imperative that a systematic process be established so that the APDA is effective. Many borderline determinations of essential or non-essential drugs will prove to be less problematic if a set of criteria to help make these determinations is already in place. The optimal choice for the APDA is to focus on the guidelines and precedent set by the WHO and its Eleventh Model List of essential drugs. Using the same criteria as the WHO is ideal since the original goal of the list parallels that of the APDA's goal. This goal is "to advance health equity through expanded access to basic medicines."¹⁹⁹ More specifically, the WHO has broadly defined essential drugs as "those that satisfy the health needs of the majority of the population and should therefore be available at all times in adequate amounts and in appropriate dosage forms."²⁰⁰ Using such a broad definition as a basis for developing a more precise set of criteria to create a systematic process for determining what is an essential drug will prove to be beneficial to the success of the APDA.

Industry threats that any type of governmental intervention to reduce the price of drugs would inevitably hinder the research and development of new life-saving drugs has consistently destroyed any hope of lower prices. While profits from already existing drugs are vital to the research and development of new drugs, the threat does not hold true when one examines the underlying facts.

First, the amount of research and development funded by the drug company itself has been exaggerated to lead many to believe that all of the money spent on research and development is coming directly from the company. However, in actuality, over

¹⁹⁵*E-Drug Affordable Prescription Drugs Act*, *supra* note 147.

¹⁹⁶*Id.*

¹⁹⁷*Id.*

¹⁹⁸145 CONG. REC. H10754, *supra* note 74.

¹⁹⁹Razak, *supra* note 31.

²⁰⁰Reich, *supra* note 30.

fifty percent of the funding for research and development often comes from public sources such as the NIH. Furthermore, the government currently provides a major incentive to drug companies to invest more into research and development through large tax breaks given to those companies that invest the most. Both of these points are relevant to show that what small amount of profits that maybe lost due to the promotion of competition, through the APDA, will in no way have a detrimental effect on the research and development of new drugs.

Second, the drug industry is one of the most profitable industries in the world. Its average profit growth rate is three times greater than any other industry and the industry's revenues have reached a staggering \$106 billion dollars per year. Such success has resulted in a spoiled and greedy industry, which focuses more on profits than it does on relieving the pain and suffering of those in need. The profits currently generated from prescription sales currently show no signs of weakening. This helps disprove the industry's argument that government induced competition would deter any further research and development because of loss of profits.

Third, since the FDA has approved direct-to-the-consumer advertising the majority of new drug profits go towards advertising expenses rather than towards research and development. A recent study conducted by the NIHC has revealed that twenty-five of the most heavily advertised drugs have accounted for more than 40 percent of the increase in retail drug spending.²⁰¹ These advertising expenditures are in direct conflict with the drug industry's argument that a reduction in profits due to reduced market protection will lead to fewer innovative drugs. Furthermore, the economic policy of patent protection should not be used to pay for marketing expenditures, but rather to reinvest into research and development of new drugs.

The drug industry argues that in order to relieve the financial burden of high drug prices from America's senior citizens a Medicare modernization or private insurance enrollment plan would be the most effective measure. More specifically the drug industry has argued the best way to make drugs more accessible and affordable for the elderly is "to make prescription drugs affordable for seniors by enrolling all 38 million in private health insurance plans."²⁰² This argument makes the faulty assumption that enrollment in private health insurance or expanding Medicare coverage, alone, will make prescription drugs more accessible and affordable to senior citizens while allowing prices to remain the same. Enrollment in private health insurers alone will do little to solve the accessibility and affordability of prescription drugs especially during a period where private insurers are cutting back their prescription drug benefits.²⁰³ In any event, such an argument represents a dramatic departure from the industry's original argument for a free market system. Such a departure indicates that the bottom line to drug companies is not what economic theory will make prescription drugs more available to Americans, but rather what is the most expedient method to increase profits.

Congress is currently debating whether the Medicare program should offer prescription drug coverage. While amending current Medicare coverage would help alleviate some of the financial burden on the elderly, without lower prices its long-

²⁰¹ Prescription Drugs and the Cost of Advertising Them, *supra* note 174.

²⁰² 146 CONG. REC. H1127, *supra* note 43.

²⁰³ *Id.*

term solvency will be damaged.²⁰⁴ This is not to say that Medicare should not be expanded to cover prescription drugs, it should; however, this alone will not solve the problems caused by high drug prices. Expansion of Medicare to provide prescription drug coverage along with the availability of lower priced drugs provided via the APDA would allow Medicare the ability to cover senior citizens while not putting its long-term solvency at risk.

America can no longer stand idly by and allow an already spoiled industry to regulate prescription drug prices by limiting competition through patent protection. Congress must not back down from the constant threat that any intrusion or restraints placed upon the industry will inevitably lead to a reduction in innovative prescription drugs. The APDA is the optimal implementation plan, which will allow the government to increase the level of competition in the prescription drug market and thus reduce prescription drug prices without chilling research and development of new essential drugs. Governmental assistance has never been more necessary in order to provide the American public with affordable and accessible drugs.

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²⁰⁴*Id.*