

Statement of Families USA
by William Vaughan
Before the Subcommittee on Human Rights and Wellness
Committee on Government Reform
U.S. House of Representatives
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Mr. Chairman, Members of the Committee:

Thank you for inviting Families USA to testify on the important issue of “The Economics of the Pharmaceutical Industry in the United States.”

Families USA is a national non-profit health consumer advocacy organization. It has issued numerous reports over the past decade on drug pricing, the need for more generics, and collusive practices in the industry. Since 1999, we’ve released reports on the rate of inflation in the 50 prescription drugs most commonly used by seniors. Our next report is due about July 7th, but I regret that we don’t have the new data ready yet.

It appears that the numbers will show that the growth in the cost of prescriptions used by Medicare seniors and people with disabilities continues to far exceed the growth in the Consumer Price Index. It will once again show why so many seniors are crying for help: we have the highest retail pharmaceutical prices in the world, and those prices keep rising faster than inflation.

Your hearing is extremely timely. We are pleased that Congress appears to be about to pass a major Medicare prescription drug bill. But during the next decade, CBO predicts Medicare beneficiaries will use about \$1.84 trillion worth of prescriptions. With a budget limit of \$400 billion, there is no way that Congress can provide as much help as people want or need. It is absolutely certain that Congress will be asked to revisit the issue of pharmaceuticals—repeatedly.

Because of the gaps—or donut holes—in both Chambers’ bills, Medicare beneficiaries will be exposed to significant out-of-pocket costs at a time of illness. They will want a better Medicare benefit, and they will want drug price moderation. The Medicare program will need to get the best price for pharmaceuticals if it is to have any hope of expanding the benefit—or avoiding financial crisis.

With deficits facing us, it will be hard to fill in the gaps in the new law, and the question will come up repeatedly, can we get a better price for the pharmaceuticals we buy, without killing the Golden Goose of pharmaceutical research?

Families USA thinks we can.

On the Subcommittee’s question: Why do Americans pay higher retail prices than residents of Canada and Europe? An excellent question. Former Oregon Governor Kitzhaber was quoted as saying, in effect, that the Medicare prescription drug debate is

kind of a distraction: the real debate should be on why the price of prescriptions is so high!

Reasons for differences between U.S. and OECD prices

There are a many reasons for the difference between us and other societies. But basically, everything in the world of health is more expensive in the United States than other advanced industrial societies. Americans spend about 60 percent more than the OECD median nation for hospitals and doctors. Yet, we get fewer services, fewer doctor visits, and fewer days in the hospitals, and we generally do not get better outcomes. We have a lot of high tech equipment compared to other societies, but some countries are even ahead of us in things like CAT and MRI scanners.¹ And again, for 4 points of our GDP---about \$400 billion per year---we do not get much additional value in health outcomes over other nations, yet we still have 41 million uninsured on any one day. Families USA recently reported that in a two-year period, nearly one out of three of us below age 65 had a period of un-insurance. And as the Institute of Medicine reported last week, having those many people uninsured probably costs our economy between \$65 and \$130 billion per year. It also costs us about 18,000 premature deaths per year—or about 2 to 3 unnecessary deaths during the time it will take to hold this hearing.²

The data on this U.S.-OECD split is clear in the work of Johns Hopkins' Gerard Anderson. Other research by Princeton Economics Professor Uwe Reinhardt seems to show that the phenomena of high U.S. costs but fewer U.S. health care services is largely due to the reimbursement/salary structure (plus unusually high overhead and paperwork costs) in the U.S. health sector versus that of other OECD nations.

It is harder to control costs in the United States, because our health care system (or I should say non-system) is so much more fractured than the foreign systems. Other societies tend to have a universal-coverage, social-insurance system. Think of controlling health costs as a balloon. In foreign systems, it is possible to inflate or deflate the 'cost balloon' without huge distortions. In the United States, if one payer squeezes too hard on part of the cost balloon, it just causes bulges and distortions in other parts. Providers won't serve the tough buyer. Or they shift costs to others, just like we shift costs for caring for the uninsured onto those who have insurance and onto Medicare. Managed care found this out a couple of years ago, when it squeezed so hard it caused a backlash. In our diverse system, no payer can get too far out of line with others in trying to lower costs, or the providers won't play—and thus it is much harder to control costs.

Similar to the cost shifts within our system, in the area of prescription drug costs, it makes sense that foreign cost controls result in higher prices in our uncontrolled market. We are paying for the success of others in giving their consumers a better deal.

¹ Gerard Anderson, Uwe E. Reinhardt, Peter S. Hussey, and Varduhi Petrosyan, "It's the Prices, Stupid: Why the United States Is So Different From Other Countries," *Health Affairs*, Vol 22, No. 3, May/June 2003.

² Institute of Medicine, *Hidden Costs, Value Lost, Uninsurance in America*, June, 2003.

Families USA believes that the solution to all this would be to have everyone under one insurance umbrella and cost control system. But that is a discussion for another day.

What can be done in the short run to help get better prices?

In the Medicare Prescription drug bill that appears to be about to go to Conference, you can make some major savings.

Families USA believes that the best way to get a much better price from the giant multinational pharmaceutical companies is to use the clout of large buyers. Just like WalMart gets a better price from suppliers than smaller companies, so can Medicare, Medicaid, and the VA get a better price if they are allowed to be aggressive buyers.³ At every step in the Conference Committee process, Congress should choose to help Medicare, through its contractors, be an aggressive bulk buyer. For example, before 2006, if a discount card is offered to Medicare beneficiaries, it should be administered by just one or two winning contractors. Multiple vendors negotiating prices independently will not get deep discounts. With too many vendors, beneficiaries are likely to be no better off than they are now with a CVS card or an AARP card. By allowing a large buyer to use the clout of Medicare's purchasing power, Congress can truly help beneficiaries.

Congress allows the VA to negotiate and is proud of the low-cost pharmaceuticals available to our nation's veterans. Congress has allowed Medicaid to get the best price. Surely the nation's 41 million retirees and people with disabilities deserve a similar best price.

On the issue of best price, we note that throughout these Medicare bills, there are provisions that exempt the prices that are negotiated from being counted for purposes of the Medicaid best price. At the rate we are going, Medicaid may soon have one of the worst prices! We urge the Congress to consider what these exceptions will mean for Medicaid. If Congress really wanted to get a good price for the public, it would combine Medicare and Medicaid and the VA's purchasing power to truly get one BEST price.

Families USA hopes the House Medicare Prescription drug conferees will accept the Gregg-Schumer-McCain-Kennedy generic drug amendment that was approved 94-1 by the Senate last Thursday. This bill is estimated to save Americans about \$60 billion over the next decade, about \$20 billion of which will accrue to public programs.

Generics not only cost less, but they decline in price rapidly. Over the past few years, many hearings and government reports, including one last summer from the FTC, have documented the abuses the brand drug industry has employed to keep generics at bay. The need for reform is clear.

³ We commend to the Subcommittee the article in the Washington Post Outlook section of June 22, 2003, by Marc Siegel, "This Doesn't Have to Be the Price We Pay," in which he points out that an aggressive Medicare purchaser would be able to get a much better price than lots of smaller buyers.

The FDA has just finalized a regulation to address some of the brand company abuses. However, the FDA regulations do not go far enough, and in some cases continue the delay in generic entry. Specifically, the FDA regulations fail to give enough market certainty to generic manufacturers by not requiring brand manufacturers to initiate patent infringement lawsuits within any specified period. This uncertainty may cause some generic manufacturers to delay market entry. The regulations also still allow generic companies to “sit on” the 180-day exclusivity period, leaving the door open for brand/generic manufacturer deals that keep all generics off the market. Patents were never intended to give innovators never-ending exclusivity that would stifle innovation—but that is what has happened, and that is why Congress should include the Senate Gregg-Schumer amendment in the final Medicare bill.

--Medicare should be able to decide whether or not to pay for a drug that is just a me-too drug. We support H.R. 2356, by Rep. Allen and by you, Chairman Burton, which would require NIH to conduct research on the comparative effectiveness and cost-effectiveness of prescription drugs that account for high levels of use by individuals in federally funded health programs. We hope that your approach to intelligent purchasing by Medicare could be added to the Medicare Prescription drug bill.

--There is a chance to end the Average Wholesale Price abuse, in which companies have actually used the AWP spread to encourage doctors to use less effective but more profitable drugs—surely a form of malpractice. Families USA urges you to urge the Conferees to take the AWP reform approach that CBO says will achieve the most savings. The Senate bill reduces the AWP to 95% and then 85%. We believe that drug prices are often much lower than 85% of AWP, and that the House’s effort to develop a competitive bidding type of distribution system will probably save more money and stretch the Medicare dollar. Some of the worst AWP abuses have occurred in the end stage renal disease (ESRD) program, where dialysis centers make most of their profit outside of the dialysis composite rate. The abuse is so large that one wonders if patients’ are not being given much more medicine than they need. The Senate appears to lock in the current inflated ESRD AWP, but exempts EPO from any future lock-in. Hundreds of millions could be saved in this sector, and EPO—which is garnering its manufacturer about \$1 billion a year in profit from Medicare—should not be exempt.⁴

--We also hope the House will support the Senate amendment for what is basically free trade in pharmaceuticals with Canada and, hopefully, other nations with good quality control standards. Yesterday Rep. Gutknecht and Emanuel introduced a similar bill, and we hope the House will consider it. A great deal is made over the fact that the re-imported drugs may come back adulterated or sabotaged. As a consumer advocacy group, we hope the FDA will spend as much time worrying about someone adulterating tank loads of Molson’s or quarts of Canadian maple syrup as they do worrying about trade in pharmaceuticals.

⁴ See the HHS Inspector General’s 2003 Red Book (Cost-Saver Handbook), for further description of these items and the billions of dollars in savings that are possible.

What can be done in the long run to get better prices without, as the Committee's letter said, "price controls"?

We understand the reluctance to talk about "price controls," because the pharmaceutical industry has mastered the art of saying that anything that impacts their record (highest-of-any-industrial-sector) profits will cause them to stop all research. If you question them, you will be guilty of not saving your constituents from terrible diseases. That charge is very hard for a Member of Congress to deal with.

Families USA urges you to reverse this rhetoric. The United States Pharmaceutical industry does not do enough research. With these incredible, year-after-year record profits, they should be doing more research. They should be ashamed at how little research they are doing. They are passing up the chance to cure cancer, and Alzheimer's, and AIDS every time their sales and advertising and profit targets exceeds their R&D budget. They are failing American society every time they spend money on a me-too drug instead of a breakthrough drug. Members of Congress should push back at the industry and its front groups and demand more life-saving, life-enhancing research.

Following are some ideas on how to get more research out of this profitable industry without price controls:

--Stop the advertising. It is frequently inaccurate or doesn't give adequate weight to the adverse reactions. It clearly drives demand and even over-utilization. An important, blockbuster, life-saving drug doesn't need to be advertised. What we are seeing is billions of potential research dollars wasted on the advertising of me-too pills. We should copy the European Union and not allow it.

--There should be a surtax on pharmaceutical industry profits when their overhead, advertising, sales, and profits exceed their R&D budgets. The money from such a tax should be dedicated to NIH pharmaceutical research and development or to helping the public pay for needed pharmaceuticals. Of course, no company would need to pay the tax: all they have to do is reduce overhead and increase research.

--Use Medicare/Medicaid's buying power to force more research. Under this proposal, Congress could estimate what Medicare and/or Medicaid will spend on pharmaceuticals in the coming year. For example, in 2006, let us say it will be \$40 billion. Then Congress could set a rate of inflation, say CPI or WPI, and let us say that is 5 percent.⁵ Then in 2007, Medicare/Medicaid should spend 105 percent of \$40 billion or \$42 billion. But if in 2007 spending is higher than \$42 billion, then in the next year (2008) the rate of growth would be reduced to 'recover' the amount of overspending in 2007. But the key to driving the companies to spend more on research would be to take the reduction out of OLD product, and not out of recent NEW, breakthrough drug prices. The FDA—or the NIH in Chairman Burton's bill HR 2356---could determine what was an important breakthrough drug. The pharmaceutical companies would know that if they want to sell into the huge Medicare/Medicaid market, they will face gradually lower prices on their

⁵ In this example, we assume no growth in population served.

older products, but if they can bring a new breakthrough drug to market, they can charge anything they want. The company that makes the most new, important drugs will have the most profits.

--Do a better job of recovering the public's investment in pharmaceutical research and rededicate that money to research or to programs that help citizens buy the new medicines. A soon-to-be-published book by Merrill Goozner, entitled The \$800 Million Pill, documents how almost every major drug breakthrough of our lifetime has come from the research base funded by the government and its taxpayers, yet the companies get almost all the profits and the taxpayer gets little on their investment.⁶ Congress could establish a board, like the World War II-Korean War-Cold War Renegotiation Board, that would look at how much the taxpayer contributed to the development of particular drugs and recover the investment over time. The old Renegotiation Board collected hundreds of millions from defense contractors over three and a half decades. It basically audited the books of weapons contractors who had undertaken difficult and novel defense projects and determined whether they had made a fair profit or a windfall profit. If the profits were excessive, the public recouped some of its defense dollars. A similar board is worth considering in the pharmaceutical sector, since so much of the investment comes from the publicly-financed research base.

--When a breakthrough drug enters the market that may be largely paid for by Medicare (e.g., an Alzheimer's drug), it is worth considering a system of negotiations on price. Something similar to this almost happened with the introduction of EPO, a drug mostly paid for by Medicare to lower anemia in kidney disease patients (a program largely financed by Medicare and Medicaid). An effort was made to get a low price on EPO in exchange for a commitment for years of purchases, regardless of other new drugs coming on the market. The deal never happened, but the jawboning appears to have obtained for Medicare a lower price. The drug's manufacturer makes huge profits from Medicare, but in the past has complained that its U.S. price is lower than its price in other nations. If accurate, that is one of the few cases where U.S. citizens may be paying less for a drug than the citizens of other nations. Whether a lower-price/long-term-commitment-to-purchase arrangement could work for both government and manufacturers is worth exploring.

Thank you again for inviting us to testify. Good luck on what will be a most difficult and important task.

⁶ For just one example, see the Wall Street Journal on June 9, 2003, and the article (based on a GAO report) entitled, "U.S. Recovers only \$35 Million of \$183 Million Spent on Taxol. NIH Says It Lacked Power to Pressure Bristol-Myers for Better Licensing Terms." Taxol, of course, is the best-selling cancer drug in history, with sales of \$9 billion.

Families USA received \$100,000 from HHS HSRA for work on presumptive eligibility in the State-Children's Health Insurance Program.

William Vaughan worked for various Members of the U.S. House of Representatives Ways and Means Committee between 1965 and 2001. He served on the Health Subcommittee for 16 years, the last five years as Minority Staff Director. In 2003, he was hired as Director, Government Relations, Families USA.