NATIONAL PHYSICIANS ALLIANCE

Senator Charles Grassley
Senator Ronald Wyden
Senate Finance Committee

March 4, 2016

Dear Senators Wyden and Grassley:

On behalf of the National Physicians Alliance, a nonpartisan, multispecialty organization that accepts no funding from pharmaceutical or medical device companies, we appreciate the opportunity to address the bipartisan leadership of the Senate Finance Committee on a critical issue with profound impact on the future of American health care: **the rapidly escalating cost of medications**.

Founded in 2005 with a commitment to health justice, the NPA has taken leading positions against physician conflict-of-interest. Through our "Unbranded Doctor" campaign, we have worked to end the acceptability of gifts and other marketing inducements from pharmaceutical companies to physicians. We support transparency and accountability around financial relationships between the pharmaceutical and medical device industry and physicians, including the Physician Payment Sunshine Act establishing the very important Open Payments database. NPA has also led efforts to reduce overtreatment. Our celebrated "Good Stewardship Project" inspired the American Board of Internal Medicine Foundation and Consumers Union to expand this work into the high impact "Choosing Wisely Campaign." To help ensure safe, effective, evidence-based treatment options for our patients, NPA has established an FDA Task Force that provides an independent physician voice to promote regulatory decisions grounded in science.

We address you from the perspective of practicing physicians in many specialties who are often dismayed at the unreasonable medication cost burdens placed on our patients. As one of our member's patients expressed it: "I can only afford enough insulin to stay alive, but not enough to protect myself from harm." The cost crisis is real; it is deep and it is wide. It encompasses all medicines, not only newer high-cost or breakthrough medicines. High prices have their greatest impact on individual patients with major illnesses, but they also affect those of us lucky enough to be healthy through their impact on the taxes that fund public insurance and the premiums for private coverage. We hope our experiences and perspectives offer a meaningful addition to your thinking on the following questions:

Question 2. Do the payers have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?

We respectfully suggest that the subject of your question be changed from "payers" to "decision-makers." In the clinical setting, decision-makers include the patient and the physician, the latter acting, in economic terms, as the former's agent. And our answer to the question is no, we do not have adequate information. The FDA permits a drug to be marketed if it passes a "non-inferiority standard,"

establishing that it is not *worse* than existing drugs, but leaving us unable to discern if a newly approved drug offers a safer or more effective alternative to treatments already on the market.

Drug companies are reluctant to pay for head-to-head comparisons of their products. Other advanced nations including Denmark, United Kingdom, France, Germany, the Netherlands, and Sweden incorporate comparative-effectiveness research to inform policies on drug pricing and coverage.[1] Moreover, these countries have also employed simple mechanisms to translate comparative effectiveness data so it is easily accessible to both practicing physicians and patients through web sites, targeted newsletters, as well as through medical education events hosted by local teams tasked to disseminate this information.

Fortunately, Congress has recognized the critical importance of comparative effectiveness testing through the establishment of institutions like Patient-Centered Outcomes Research Initiative (PCORI)—funding for which should be increased. As the electronic medical record (EMR) becomes increasingly universal across clinics and hospitals in the country, this can be a platform for ensuring that physicians are made aware of both comparative effectiveness and comparative cost of treatments at the point of care.

Enabling such research and disseminating the findings to decision-makers would prevent manufacturers from differentiating their products from competitor products based on characteristics other than health outcomes, such as emotion-grabbing television advertisements. This would offer clear guidance to physicians and patients and allow for more informed decisions about specific treatment options. Indeed the FDA should require this data prior to approval of new drugs.

Should comparative effectiveness data for a drug not exist, it is still important for physicians and patients to be aware of the *lack of evidence* demonstrating the superiority of the drug over another. This could have profound implications on cost by promoting more informed negotiations between payers and manufacturers on price.[2] Manufacturers would then have a financial incentive to conduct active-comparator trials in addition to placebo-controlled trials. Such a requirement may also dissuade companies from developing "me-too" products. This may also incentivize greater innovation; companies are currently investing more into marketing highly profitable "me-too" drugs to create brand awareness than into research for novel therapies.[3]

Decision-makers also lack adequate financial information on drug prices. While independent initiatives or tools including mobile applications such as GoodRx and newsletters such as *Consumers Reports* offer some insight on drug price comparisons, information on discounts for these drugs based on insurance coverage or other factors is often shrouded in mystery. Price comparisons should be simple and straightforward, visible like gas prices from the street, not made complex with hidden rebates available to some. Prescribing physicians would benefit from having visible access to retail prices coupled with effectiveness data to enable an informed decision-making process to select the best treatment at an affordable price.

Question 3. What role does the concept of "value" play into this debate, and how should an innovative therapy's value be represented in its price?

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[1] Sorenson, C. (2010). Use of comparative effectiveness research in drug coverage and pricing decisions: a six-country comparison. *Issue Brief (Commonwealth Fund), 91*, 1-14.

[2] Stafford, R. S., Wagner, T. H., & Lavori, P. W. (2009). New, but not improved? Incorporating comparative-effectiveness information into FDA labeling. *New England Journal of Medicine*, *361*(13), 1230-1233.

[3] Anderson, R. (2014, November 6). Pharmaceutical industry gets high on fat profits. *British Broadcasting Company News*. Retrieved fromhttp://www.bbc.com/news/business-28212223

There are many methodological difficulties in creating an accurate measurement of absolute value that aggregates subjective value to individuals (such as improved quality of life) as well as objective measures (such as lengthened survival). What matters most is not some measure of absolute value, but marginal value, and marginal value is a function of price. The greater the price of the medicine, the higher the opportunity cost—the lost ability to purchase other services that may be equally or more helpful to the patient's health or to the nation's health.

The concept of *fairness*, as in fair price, is more useful than the concept of *value*. A century ago, there was bipartisan support for the legal concept of certain industries having an inherent public interest, industries that produced essential products. Life-saving and life-extending medications certainly fit that definition. Both the World Health Organization (WHO) and many other countries have developed lists of "essential medicines." These essential medicines lists have served as a tool to improve availability and accessibility of these drugs. Research across countries has demonstrated that when medicines are included in these lists, they are often more affordable than those not on the list. Unfortunately, in the U.S., no such analogous list exists that might serve as a catalyst to lower the prices of medicines. In fact, studies have found that less than 5% of the drugs listed on the WHO Model Essential Medicines List were also listed in the Medicaid Preferred Drug List.[4] Researchers also conclude that this concept of essential medicines could lower drug costs and provide better care for low-income patients in the country.

In the early decades of the twentieth century, quasi-public American agencies set prices for essentials for both households and businesses, prices that reflected the cost of production and a reasonable return on investment, comparable to other industries. We are not suggesting creating a precise replica of utility pricing and we recognize that competition can promote innovation. But the concept of a fair price is still relevant for essential commodities like medications. Fair price is simply the outcome of negotiations between equally strong and informed parties, not the asymmetric negotiations that characterize too many markets today.

Question 4. What measures might improve transparency…?

As a means to an end and not an end in itself, transparency alone cannot ensure affordable access to medicines. It can only reveal to decision-makers and payers the need to negotiate better drug prices. It enables assessment of whether a price is fair, whether it makes a product affordable and allows for a reasonable return on investment. Transparency should not be limited to new or costly drugs; it is needed for all medications.

A number of transparency proposals have been put forth at the state and federal levels. These proposals tend to call for manufacturers to disclose costs of production including R&D, manufacturing costs, regulatory costs, as well as the contributions to drug development by public institutions through government grants. Proposals also tend to require additional cost information about administration, marketing and advertising. Requiring the standard reporting of marketing may help reduce direct-to-consumer advertising, a $4 billion burden in 2007 and likely much higher now.[5] Moreover, many transparency bills mandate transparency of prices to payers, including public and private insurers, pharmacies, and others. Finally, some make the manufacturer disclose the specific drug profits based on these prices. All of this information would be reported to a relevant government agency on an annual

[4] Millar TP, Wong S, Odierna DH, Bero LA. Applying the Essential Medicines Concept to US Preferred Drug Lists. *American Journal of Public Health*. 2011;101(8):1444-1448. doi:10.2105/AJPH.2010.300054.

[5] Donohue, J. M., Cevasco, M., & Rosenthal, M. B. (2007). A decade of direct-to-consumer advertising of prescription drugs. N Engl J Med, 357(7), 673-681. doi: 10.1056/NEJMsa070502

basis and made publicly available so that it can be used in price negotiations for those drugs found to be major contributors to health budgets.

With such transparency, policies such as those outlined in Question 5 could be employed to set ceilings for prices based on maximizing access rather than on charging what the market will bear.

Question 5. What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

We believe that new tools are needed based on the concept of fair price described above. A few directions towards which Congress should look are sketched out below.

Foreign Country Pricing: At least half of the leading drug manufacturers are headquartered in other countries. When U.S pharmaceutical companies threaten to relocate their headquarters to another country to reduce their tax burden, they are still able to take advantage of the higher allowable U.S. drug prices. Using insulin as an example, the cost of one common type of insulin is $20 in Europe (where it is manufactured) and $244 here. A study by Professor Andrew Hill of the University of Liverpool found that of the top twenty best selling drugs in the world, Americans were paying 3.1 times the prices of the medications in the U.K.[6] Directions towards solutions to fix this discrepancy might include:

- Pegging the price of drugs manufactured by a foreign-based company to within 10% of the list price charged to the citizens of the country in which the company is headquartered.

- Subjecting pharmaceutical companies moving from the U.S. to a foreign country to this 10% rule.

Intellectual Property Laws: Currently, U.S. regulations allow for extended patent periods based on minor changes to medications with little or no impact on therapeutic benefit, thereby preventing more affordable, generic alternatives from entering the market. These extensions beyond patent periods are awarded based on therapeutic class rather than as a reward for added therapeutic benefit or safety. For instance, the Biologics Price Competition and Innovation Act that was included as part of the Affordable Care Act awarded 12 additional years of data exclusivity to all biologic drugs. Analyses have shown that this has led to significant price hikes to this class of medicines and to pharmaceutical spending overall.[7] As a result, the White House has called for a reduction to this exclusivity period in their annual budget proposal over the past few years, noting the large cost-savings that would result.

Moreover, intellectual property (IP) rights including market and data exclusivity periods are awarded to all drugs without consideration of contributions to R&D from public institutions such as the NIH. Some specific directions towards aligning IP to affordable drug prices include:

- Adjusting legislation to prevent granting of IP rights and, therefore, extended monopoly for minor modifications of existing drugs without evidence that they represent a significant therapeutic advance

[6] Hirschler, Ben. (2015, October 12). Exclusive - Transatlantic divide: how U.S. pays three times more for drugs. *Reuters*. Retrieved from http://www.reuters.com/article/us-pharmaceuticals-usa-comparison-idUSKCN0S61KU20151012.
[7] U.S. Government Accountability Office (2012), "Medicare: High-Expenditure Part B Drugs," GAO-13-46R 7. Available at http://www.gao.gov/assets/650/649459.pdf.

- Adjusting legislation to prevent granting of IP rights to new drugs without evidence of increased therapeutic benefit or safety compared to already existing drugs on the market

- Promoting corporate accountability through relinquishing patent or exclusivity rights if companies commit violations of laws such as the False Claims Act or Foreign Corrupt Practices Act

- Providing funding for appropriate government agencies to exercise "march in" rights for drugs developed with public funding whose unreasonable prices create a deterrent to public access to critical treatments

Aggressive Anti-Trust Legislation: Competition not only drives innovation but can also lower prices of products. The complex nature of drug discovery and manufacturing make monopoly status quite common. For pricing to become fair, this situation has to be addressed. Some potentially fruitful approaches include:

- A rise in prices on established or generic medications significantly above the inflation rate will trigger FDA investigation and potential action to obtain comparable medications from other sources including foreign manufacturers. With consolidation in the generic drug industry, physicians have had to grapple with unpredicted (and we suspect unwarranted) increases in the uses of common medicines such as doxycycline, SSRIs and asthma inhalers, to name a few.

- New medications deemed to be life saving or shown to have significantly better outcomes, such as Sovaldi and Harvoni, would require CMS input in price negotiations.

We thank you for the opportunity to share our thinking on the critical issue of high drug pricing and for your leadership in raising these important questions.

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