



March 4, 2016

The Honorable Charles Grassley
Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Wyden and Senator Grassley:

The American College of Rheumatology, representing over 9,500 rheumatologists and health professionals, shares your concern about the effects that drug pricing decisions and practices may have on patients' access to treatments. We appreciate this opportunity to provide feedback in response to your important inquiries and we hope to be a resource to you as your work moves forward.

Rheumatologists treat patients with serious chronic conditions that can be difficult to diagnose and treat, including rheumatoid arthritis, systemic lupus erythematosus, and other debilitating and potentially-disabling rheumatic diseases. Inflammatory rheumatic diseases are the number one cause of disability in the United States and cause more disability in America than heart disease, cancer or diabetes. In addition, care and management of these diseases, and consequent disability, produce higher costs than cancer care.

Rheumatologists primarily provide face-to-face, non-procedural care in which they evaluate, manage, and treat patients' complex chronic and acute conditions. Early access to a rheumatologist who can prescribe timely interventions has been shown to improve patient outcomes and prevent disability and costly procedures. Many diseases are managed by primary care internists and family practitioners. However some diseases require expertise beyond that of primary care providers and are best managed by specialists trained to diagnose and treat them. **Lack of early access to rheumatologists can lead to significant increased cost because of greater health care spending including: 1) extended hospital stays; 2) inappropriate care and testing; and 3) the indirect costs of unemployment and disability.**

In response to the questions posed in your letter, we submit the following for your consideration:

- **What are the possible effects of a breakthrough, single source, innovator drug on the marketplace?**

It is currently unlikely that a breakthrough, single source, innovator drug could cure the inflammatory rheumatic diseases that rheumatologists manage, since as to date no infectious agent has been identified as a cause of these illnesses. However, it is possible that a breakthrough, single source, innovator drug, especially for some of our orphan diseases, could be developed. While the market impact of a single source innovator drug would be difficult to ascertain, the impact of a single source legacy product is clear. Rheumatologists have seen increases in generic drug pricing that are as impactful to patient access as those seen with breakthrough drugs.

The value of established drugs is well understood. Rheumatologists know the potential benefit and adverse outcomes related to use of established treatments, and we can make a value judgment regarding the affordability of the drug. However, far too often manufacturers of even generic medications set prices that exceed that affordability. Unfortunately, in the rheumatology space where there are few FDA approved therapies for many conditions, there are no other more affordable options to achieve the same clinical benefit. **The ACR therefore strongly advises that the Committee include the sharp rise in price of generic or existing brand name drugs in its investigation.**

- **What role does the concept of "value" play in the pricing debate and how should an innovative therapy's value be represented through its price?**

The role of value is of utmost importance as a key component for understanding the cost of drugs. The difficulty lies in appropriately integrating all the components of value relevant to chronic diseases. In the case reviewed by the Committee, one can more readily consider the 'value' of a cure. **In the management of chronic diseases, value must be tied not only to the cost of therapy, and the cost to the payer, but must also take into account the costs that are likely to result if therapies are not accessible due to cost.** These costs include disability, with all of its economic impacts including both absenteeism from work and impairment at work, and on quality of life. It may also include the greater likelihood of the need for surgeries and other expensive services, to name a few.

These direct costs, and especially the indirect costs, are not always borne by the same party. For example, a private payer does not see the indirect costs related to lost wages; however a public payer, through tax revenues and economic impacts, would see those costs. There is also a value threshold, particularly when the practice of cost-sharing becomes more pervasive. With the rising cost of drugs and greater use of co-insurance, or specialty tiering, requiring excessive patient cost-sharing, we are seeing more out of pocket expenses exceed that value threshold. **In these cases it makes no difference whether there is value to the system in covering the therapy. The patient simply cannot afford her share and is forced to do without necessary treatment.**

- **What measures could be put in place to improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?**

Price transparency has particular value for providing a window into the decisions made around drug pricing, such as those in the hepatitis example explored by the Committee. However, it is more challenging, though not impossible, to make that window wide enough and deep enough to truly understand the impact of research and development (R&D) and marketing on pricing decisions.

With regard to marketing, direct to consumer advertising often makes up a very significant part of a pharmaceutical company's budget. **Reporting those dollars or curtailing the practice would be one way to impact a segment of cost to manufacturers that is frequently cited as a reason for pricing.** While R&D costs may be difficult to separate and assign to a specific drug, the marketing costs may be more straightforward and could be made a minimum transparency requirement.

One additional methodology could involve issues surrounding exclusivity, which often truly drive manufacturers' ability to impact the market. With regard to biologic drugs, the 12 years of exclusivity granted followed by the potential for years of patent litigation has prevented biosimilar drugs from hitting the market as quickly in as may otherwise have been possible. Limitations in duration of exclusivity or changes to patent litigation practices could be an additional mechanism to be explored.

A layer of additional sophistication could be considered, in which there would be an option for manufacturers to choose between a high sales price and a shorter exclusivity period versus a lower sales price and a longer exclusivity period. This would require a transparent value judgment about the proper ratio, but conceptually would allow the system to recognize the value of an innovator product, as well as speed the arrival of competitors to the marketplace.

- **What tools currently exist, or should exist, to address the impact of high cost drugs and the corresponding access restrictions, especially on low-income populations and state Medicaid programs?**

Some of these high-cost therapies are simply not covered by low income and Medicaid programs. If they are covered, these income populations often have subsidies that limit their out-of-pocket expense for these therapies. This scenario places the entire value of the service on the payer, in contrast to the situation described above. We are in need of a tool to estimate the indirect cost impact of these therapies in those circumstances, such that coverage determinations are not made solely on the basis upon a drug's price, but also on the value those drugs bring.

The American College of Rheumatology appreciates your leadership and your commitment to improving patients' access to effective therapies. We are available to assist you as you continue to refine policy options to reach your important goals. If you have questions or if we can provide further information, please contact Adam Cooper, senior director of government affairs, at (404) 633-3777 or acooper@rheumatology.org

Sincerely,



Joan M. Von Feldt, MD, MEd
President, American College of Rheumatology