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Chair, Government Affairs Committee

American College of Rheumatology

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Chairman Pitts, Ranking Member Pallone, Chairman Upton, Ranking Member Waxman and distinguished members of the Health Subcommittee, thank you for allowing me to speak before you today. My name is Dr. William F. Harvey and I am a practicing rheumatologist at Tufts Medical Center in Boston, MA. In addition to my daily duties caring for patients with rheumatic and musculoskeletal disease, I am privileged to chair the Committee on Government Affairs of the American College of Rheumatology (ACR). The ACR represents approximately 9,300 rheumatologists and rheumatology health professionals. As a member of the Coalition for Accessible Treatments (CAT), the ACR advocates for, among other things, affordable access to treatments for chronic conditions including Rheumatoid Arthritis (RA), Multiple Sclerosis (MS), Lupus, hemophilia, certain cancers and many more. I wear on my lapel a bent fork, created by the ACR to remind everyone that when you have arthritis, even simple tasks, like using a fork can be difficult. Recent advances in the treatment of RA and other diseases have created a 'new normal' for patients suffering from rheumatic diseases. With early diagnosis and treatment the disability and disfigurement also symbolized by the bent tines may be prevented. But a great tragedy emerging in our country involves the increasing barriers to accessing these treatments. Some of these barriers include cuts to provider networks, step and fail first therapies, co-pay assistance, and specialty tiers. I appreciate the opportunity to discuss some of these barriers in more detail with you today.

The first barrier I wish to bring before the committee relates to the practice of co-pays. I have no doubt that Members of this Committee are familiar with co-pays. Co-payments, among other purposes, are designed to create a dis-incentive for access by requiring patients to pay a larger amount for more expensive treatments. This type of structure in a setting where myriad choices are available, choosing to forego expensive treatments when cheaper alternatives abound has little consequence. However, for patients suffering from chronic diseases with limited effective therapies, the 'skin in the game' mentality backfires to the detriment of patients, particularly if the co-payment is not affordable. Again, Members of this Committee are likely familiar with the notion that they may pay a co-pay of 20, 40 or 60 dollars for a prescription, depending on whether the medication is generic, brand name preferred, or brand name non-preferred. The dollar amount of the co-pays for each of these 'tiers' has increased steadily over the last decade. Today, costs of many medications far exceed the amounts actuarially set within tiers by insurers. In response, insurers and plans in the exchanges are moving to create a fourth tier of expensive specialty drugs. Biologic therapies for RA and many other diseases, because of their nature and cost, are always included in this specialty tier. Because even among these treatments costs vary considerably, insurers and plans in the exchanges have often assigned a co-insurance on a percentage basis, ranging from 20-50% of the cost of the drug. This results in patients, who did not choose their disease or its expensive, innovative treatments, facing thousands of dollars per annum in out-of-pocket costs. Prior to the ACA, about twenty-three percent of plans included a fourth tier. Based on data from Avalere, 91% of exchange plans use a fourth tier and 63% of exchange plans use a co-insurance for that tier; 65% of silver plans and 75% of bronze plans use co-insurance. [Reference: Avalere PlanScape, Updated November 2013. <http://avalerehealth.com/expertise/managed-care/insights/analysis-exchange-formulary-structure-more-similar-to-part-d-than-employer>]. Not only do the Silver plans have higher premiums than the Bronze plans, the co-insurance could result in additional and substantial out-of-pocket costs. While this has been a very big problem for patient access both in the Medicare space

and in the private insurance market, it's now much greater a problem in the exchanges and must be addressed. This leads to two distinct phenomena. First, perhaps obviously, is that many patients decline the treatment based on cost. In many cases when patients fail to access these treatments, they become disabled and can no longer remain in the workforce, thus costing the federal government money on disability. Arthritis remains one of the top reasons for disability in the United States, at high cost to the federal government. Additionally, appropriate use of these treatments may prevent hospitalizations, and prevent the need for expensive procedures like joint replacements. Recent data suggests also that treating rheumatoid arthritis patients with certain of these medications reduces the risk of heart disease and its attendant costs [Bili et.al Arthritis Care & Research, Vol 66 (3), p355-363, March 2014]. Here is a stark example sent to me by a colleague in Wisconsin. "I have a young mother with rheumatoid arthritis who cannot afford biologic treatments because of high co-pays and deductibles. As a result, she has had many erosive changes in hands and feet. My concern is that this will affect her employment eventually. It has already limited the activities she can do with her children. She is using a lot of Prednisone to control her symptoms, which I think will also cause long term side effects. I have many other stories where patients go without their medications, but this patient is in her 30's and I have watched RA erode her joints without being able to help her." The second phenomenon relates to truth in advertising. When faced with the prospect of changing their insurance, a patient may look at posted formularies and see that a biologic treatment for rheumatoid arthritis, multiple sclerosis or other chronic disease is "covered", only to learn later that it is covered only in the context of a 20% or more co-insurance payment. For far too many Americans, this level of financial obligation cannot be afforded and is in effect not coverage. I am not here to argue any point about right to specific care, only the notion that a medication should not be listed as covered if its out-of-pocket costs result in such unaffordability as to reasonably regard it as un-covered. Fortunately, 127 members of Congress have charted a path forward. HR 460 (The Patients' Access to Treatments Act), sponsored by Congressman McKinley and

Congresswoman Capps, limits the practice of Tier IV pricing by preventing a percentage-based approach in favor of pegging Tier IV co-payments to the lower tiers. The bill has garnered 127 House co-sponsors and we are actively seeking introduction of a Senate companion bill. The ACR and the coalition would like to thank Representatives McKinley and Capps for their heroic leadership in this regard. We strongly urge this subcommittee to review and mark up this legislation, then pass it on to the Full Committee and the House floor for a vote during this 113th Congress. It has been noted that a potential consequence of such action is an increase in premiums across all beneficiaries of a plan. In order to address this concern, our coalition commissioned the renowned health-care firm Avalere to conduct an evidence-based assessment of the likely impact of HR460 on premiums. Results indicated that if passed, HR 460 would in fact raise premiums in plans with specialty tiers by approximately \$3 per year or twenty-five cents per month. It's time for this country, and this Congress, to say to the American people that halting the practice of excessive co-payment and co-insurance is a reasonable step to ensure that patients who have not chosen their disease, nor its innovative treatments, shall not be denied that treatment in order to balance an actuarial chart for \$3 dollars per year. There is too much at stake for patients who might stay in the workforce longer, avoid costlier treatments, and remain productive members of our society to let this practice continue.

Another issue I wish to bring before the committee relates to changes in provider networks that are a growing problem. The trend appears to have started with Medicare Advantage plans and there is great trepidation amongst my colleagues that it will expand to plans within the ACA exchanges. Over the last year, insurers have attempted to control costs by dramatically cutting provider networks. This has been a problem across the country, but has been felt acutely in the northeast. This Subcommittee's website cites a recent article in the Boston Globe highlighting these concerns and describing their impact on patients. In particular, the common practice is to change these networks after the conclusion of the open enrollment period. The result is that savvy consumers seeking to select a network with

access to certain specialists or to maintain their current network can select plans which will later not cover the providers they seek. Indeed litigation is pending in several states to limit this practice. Patients should not be limited arbitrarily by insurers to see certain providers without fair notice. The basic free market principles of full and necessary disclosure therefore dictate that insurers should be required to disclose to patients any planned network changes during the open enrollment period. Should plans within the ACA adopt similar practices, the results could be catastrophic. A colleague in Connecticut recently described the story of a patient she saw for many years. When the open enrollment period ended, my colleague was dropped, without warning, from the Medicare Advantage insurer's network. Without recourse until then next open enrollment period, her patient not only had to re-establish care with another provider, but had to drive an additional two hours to reach that provider. Congress should step in to prevent this practice in all insurance plans, including those in ACA exchanges.

Similar to ongoing changes to provider networks, another rampant practice that has been in existence for some time, but has now increased within exchange plans is changes in formulary coverage of medications. While common and relatively inexpensive medications used to treat some chronic diseases such as diabetes and heart disease have many viable alternatives, recent advances in the care of many diseases have few options. Please allow me to describe for you a class of medications known as 'biologics'. In comparison to most medications, like aspirin, with a simple chemical formula discovered and manufactured with relative ease, biologics are treatments derived from or consisting of components of living organisms. Examples include antibodies or proteins designed to react with our immune systems. They require significantly more intensive research and development, as well as production costs. With this innovation comes many of the revolutionary treatments changing the paradigm of care I described in relation to my bent fork. But a consequence of these advancements is their escalating cost. That cost, while arguably justified by the manufacturer, invariably gets passed on to patients and

insurers covering their care. The biologic medications used in the treatment of rheumatoid arthritis may cost as much as \$15,000-\$30,000 annually and that's just for one medication. Many patients with chronic conditions such as RA are forced to take several medications each month. Additionally, the figure grows with every new pharmaceutical innovation. A great deal of press has been garnered by recent advances in the treatment of hepatitis C which could be three times this cost. A ubiquitous tool employed by all payers, except Medicare, is to negotiate prices for drugs with the manufacturer in exchange for preferred status on that insurer's formulary. The insurer then creates financial disincentives, ranging from non-coverage to excessive co-insurance to restrict use of the more expensive, non-formulary alternatives. Step therapy and 'must fail first' policies are the norm amongst payers across the spectrum both within and outside of ACA exchanges. Even when an individual fails the formulary treatment, barriers to accessing non-formulary alternatives are difficult to overcome. As insurers within various tiers of the exchange plans seek to control costs, limiting the formulary remains an effective and often used tool. These changes may occur irrespective of open enrollment periods and we have grave concerns again that a savvy patient will not have the ability to make an informed decision during the open enrollment process. Congress should step in to limit changes to plan formularies outside of open enrollment periods and place reasonable limits around step or fail first policies amongst insurers.

One way to manage the growing burden of co-pay and co-insurance is allowing manufacturers to provide co-pay assistance. The practice typically is undertaken by charitable foundations established by manufacturers to provide co-pay assistance to patients. Based on current law and precedent, Medicare and other federally subsidized insurance recipients are not permitted to use these services. While I am not here to debate that particular point, the fact remains that patients covered in the private marketplace can utilize these options. Legitimate questions have been raised about the applicability of these programs to patients obtaining coverage through exchanges, even if the plan is not directly

subsidized by government. While a recent clarification from CMS has indicated that patients with private plans within exchanges may benefit from this practice, there is still concern about legal challenges to this determination. One unfortunate phenomenon of relying on co-payment assistance from a manufacturer is that the entities providing the support have limited funds. It is not at all uncommon for a patient to receive assistance throughout the year only to have the entity run out of funds by year end. For these patients, cessation of therapy, particularly if it has proven effective, could have dire consequences. Another patient story comes from a man with severe psoriasis for the last 20 years living in Dallas, TX. It took him three months to find a plan that worked for him in the marketplace. Mr. E was frustrated he never got to see the details of the plans available to him and made choosing a plan very difficult. In particular he wanted to find something similar in terms of access to prescriptions. Once he chose a plan, he had to go through the approval process again in order to continue taking his previous biologic and treatment was delayed. For individuals living with psoriatic disease, cycling on and off biologics can impact the efficacy of the medication and quality of life. Mr. E also depends on co-pay assistance from the manufacturer. If he cannot use the manufacturer assistant program for his biologic in the marketplace, he worries he may no longer be able to afford the medication. Congress should step in to clarify that beneficiaries of any fully private plan, even those within exchanges, may leverage co-pay assistance provided by any source and enforce truth in advertising among exchange plans.

In conclusion, I wish to thank the Chairman and Ranking Member for the opportunity to speak with you today. I have great faith in the institution of government and that its members will do everything in their power to protect the people of our nation who suffer from chronic disease and are burdened with the growing expense of treatment and with access to the experts who can diagnose and treat their condition. I cannot leave without acknowledging that the ACA has had successes and has been a benefit to many Americans, but the healthcare system is far from fixed and much work is still necessary. As we gain further experience with the plans and coverage contained within the auspices of

ACA healthcare exchanges, we need to be cognizant of unintended consequences in need of redress. The committee should take swift action to: 1) maintain truth in advertising by requiring insurers in exchanges and in the broader marketplace to disclose planned changes to provider networks and drug formularies during open enrollment so that patients can make informed decisions about their healthcare coverage; 2) reaffirm the intent of Congress that individuals on private plans offered through healthcare exchanges be permitted to benefit from co-pay and co-insurance assistance offered through pharmaceutical manufacturers; and 3) prevent excessive cost sharing by blameless patients with chronic diseases by supporting HR 460, the Patients' Access to Treatments Act, which would apply to any private insurer within the ACA exchanges.

Thank you again for accepting this testimony and I am happy to address any questions the Committee may have.