



Mission: To find a cure for psoriasis and psoriatic arthritis and to eliminate their devastating effects through research, advocacy and education.

March 15, 2012

Dr. Joe Selby
Executive Director
Patient-Centered Outcomes Research Institute (PCORI)
1701 Pennsylvania Ave. NW, Suite 300
Washington, DC 20006

RE: National Priorities for Research and Research Agenda

Dear Dr. Selby:

On behalf of the National Psoriasis Foundation (NPF), I am writing to thank you for the opportunity to provide input on PCORI's National Priorities for Research and Research Agenda. The National Psoriasis Foundation is the largest psoriasis patient advocacy organization and charitable funder of psoriatic disease research worldwide, and assists approximately 1.5 million people annually through educational programs and services.

Psoriasis is a chronic, painful, inflammatory disease, and the most prevalent autoimmune disease in the United States. An estimated 7.5 million Americans are affected by psoriasis, and up to 30 percent may also have psoriatic arthritis, which is often disabling and causes progressive joint damage. There is also an increased risk for psoriasis patients developing other serious conditions such as heart disease, stroke, hypertension and diabetes. Access to treatment is important to prevent much of the disability and psychosocial impacts of the disease.

The top stated priority in the PCORI National Priorities for Research and Research Agenda is the "Assessment of Prevention, Diagnosis, and Treatment Options." This priority warrants further elaboration. It is unclear from the National Priorities for Research and Research Agenda exactly which prevention, diagnosis, and treatment options will be evaluated. As you know from our meeting hosted by the National Health Council, the National Psoriasis Foundation has grave concern about the extent to which comparative effectiveness research (CER) may be used by insurers to inappropriately determine benefit coverage. The fact that the federal government is investing in comparative effectiveness research is a significant and positive step forward in establishing a scientific body of evidence as a platform from which physicians can make treatment decisions. Particularly in the realm of chronic diseases, and within that, autoimmune diseases, having that scientific basis will be an important contribution to a sound and systematic treatment framework for physicians. Unfortunately, in

the practical, day-to-day world of managed care, insurers rely on arbitrary reasons and requirements for *not* approving treatments. These insurance practices are more the norm than the exception and they interfere with a physician's ability to choose the right treatment for the right patient.

In the world of psoriasis care, insurers depend on treatment utilization tools as a way to restrict access to medications. These restrictions include: step-therapy (a requirement for a patient to fail one or several treatments before being able to access the prescribed medication), stiff pre-authorization or re-authorization requirements, and disease presentation requirements – i.e., percentage of body surface area (BSA) coverage of psoriasis (BSA is one measurement tool for psoriasis severity but certainly not conclusive). These barriers have the purpose of controlling costs by limiting access to expensive therapies. For a patient with psoriasis, who is in pain and prevented from performing normal everyday functions, and in the case of psoriatic arthritis, risking irreversible joint damage by not being on treatment, these access to care barriers are devastating. As progress is made on measuring outcomes and cost-effectiveness of treatments, sophisticated methods of data collection and analysis are needed to ensure that the needs of the individual patient are not sacrificed. A CER model must protect and take into account the unique, individual circumstances that each patient brings into the health care provider's office.

If PCORI's ultimate aim is to ensure that patients and their health care providers are able to make more informed decisions, patients must be effectively integrated in PCORI's work. To this end, more needs to be done to maximize patient engagement in PCORI's processes. We believe a key step is establishing a defined role for patients. Formalizing opportunities for patient engagement would improve transparency and communication with stakeholders. Publishing and promoting a timeline of events, specifying opportunities for engagement, and keeping discussions on a practical consumer level will ensure that public input builds and is meaningful.

The primary focus of research supported by PCORI should be the improvement of outcomes in patient care. Our goal is to work together with you to provide the information that you may need in order to develop a patient-centered research agenda. If you have any questions about these comments, please contact Ms. Niva Haynes, NPF's Health Policy Manager at nhaynes@psoriasis.org or at (202) 465-4262. Thank you in advance for your consideration. We look forward to working with you.

Sincerely,

A handwritten signature in black ink that reads "Sheila Rittenberg". The signature is written in a cursive style with a large, looped "S" and a long, sweeping underline.

Sheila Rittenberg
Senior Director, Advocacy and External Affairs