



March 12, 2012

Dr. Joe V. Selby  
Executive Director  
Patient-Centered Outcomes Research Institute  
1701 Pennsylvania Avenue, NW, #300  
Washington, DC 20006

Re: National Priorities for Research and Research Agenda

Dear Dr. Selby:

Autism Speaks is the nation's largest autism science and advocacy organization, dedicated to funding research, increasing awareness, and advocating on behalf of affected individuals and their families. We write to comment on the draft National Priorities for Research and Research Agenda.

It may be helpful if we preface our comments by providing some background information. Autism is a general term used to describe a group of complex developmental brain disorders. These disorders have in common difficulty in reciprocal social interaction and communication, as well as repetition and insistence on sameness. Many people on the autism spectrum have language delays, and some have lifelong language disorders. Some people on the autism spectrum have an intellectual disability that affects every day self-care.

Once thought to be rare, autism is now believed to affect about 1 in 110 children in the United States.<sup>1</sup> The dramatic increase in reported prevalence – 57% in the past few years alone – has an uncertain cause.<sup>2</sup> Autism occurs in all racial, ethnic, and socioeconomic groups, and is 4 to 5 times more likely to occur in boys than in girls. The Centers for Disease Control and Prevention

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<sup>1</sup> Centers for Disease Control and Prevention, *Prevalence of Autism Spectrum Disorders-Autism and Developmental Disabilities Monitoring Network, United States, 2006*, Morbidity & Mortality Weekly Rep. 58 (SS-10) (Dec. 18, 2009).

<sup>2</sup> “No single factor explains the changes in identified ASD prevalence over the time period studied. Although some of the increases are due to better detection, a true increase in risk cannot be ruled out.” Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities, <http://www.cdc.gov/ncbddd/features/counting-autism.html> (accessed Jan. 18, 2012).

estimates that about 730,000 individuals age 21 and under have autism.<sup>3</sup> According to the Department of Health and Human Services, autism has become a top national health priority, a disorder whose cost to society is thought to range from \$35-\$90 billion annually.<sup>4</sup>

Clinical presentation, prevalence data, and economic costs, of course, do not tell the full story of autism. That story is often understood through the treatment choices affected individuals and their families must make every day. For that reason, Autism Speaks is vitally interested in the work of the Patient-Centered Outcomes Research Institute (PCORI).

PCORI's five comparative clinical effectiveness research priorities – assessment of prevention, diagnosis, and treatment options; improving healthcare systems; communications and dissemination research; addressing disparities; and accelerating patient-centered outcomes research and methodological research – are broad enough to encompass the following key issues for the autism community:

1. *Comparative effectiveness research must not only inform but enable patients to make the best possible decisions.* Comparative effectiveness research informs researchers, clinicians, policymakers, and patients. Each of these audiences may have different and competing priorities. Research findings that limit access to care may harm rather than advance public health. Comparative effectiveness research will not be valued by patients unless it both informs them of evidence-based care and facilitates a process through which that care is available. Patients often do not have the luxury of time – they cannot wait for additional studies. First and foremost, comparative effectiveness research should be done from the patient perspective, from the point of view of the individual who must decide whether to choose or decline an available course of treatment.
2. *Comparative effectiveness research must involve patient advocacy organizations.* The draft priorities are entirely silent on the role of patient advocacy organizations in advancing personalized decision-making. Patient advocacy organizations are vital intermediaries in the assessment of prevention, diagnosis, and treatment options. Organizations such as Autism Speaks are significant funders of research. We understand *both* the science and the patient's perspective and we are in constant discussion with the communities whom we represent. This discussion, it should be emphasized, is not a monologue; rather, it is a dialogue with the patients, caregivers, families, friends, scientists, and service providers who make decisions and influence decisions.

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<sup>3</sup> Centers for Disease Control and Prevention, Autism Spectrum Disorders (ASDs) Data and Statistics, <http://www.cdc.gov/ncbddd/autism/data.html> (accessed Jan. 18, 2012).

<sup>4</sup> Office of Autism Research Coordination, National Institutes of Health, *Report to Congress on Activities Related to Autism Spectrum Disorder and Other Developmental Disabilities Under the Combating Autism Act of 2006*, available at <http://iacc.hhs.gov/reports/reports-to-congress/FY2006-2009/caa-full-report-2006-2009.pdf>.

Consider the front page of the Autism Speaks website ([www.autismspeaks.org](http://www.autismspeaks.org)) as it appeared on March 8<sup>th</sup>. The “news” tab featured a story on the release by the Centers for Disease Control and Prevention of a summary of an Autism Speaks’ co-sponsored workshop on autism’s increasing prevalence. Under “science” is an invitation to join a live monthly web chat co-hosted by Autism Speaks’ chief science officer and its assistant vice-president and head of medical research. “Advocacy news” features stories about state and federal efforts to make insurance coverage of autism more comprehensive and more affordable.

Our website as well as our social media and other platforms are an on-going effort to address the needs of the community. It would be a mistake not to utilize such tools in comparative effectiveness research.

3. *Comparative effectiveness research must reduce coverage-based disparities in healthcare.* Research is needed on access to care. Is the best care available to patients? What factors influence whether patients receive that care? Is the care affordable? What are the consequences of receiving or not receiving that care (e.g., health and cost outcomes)? It is noteworthy that the draft priorities mention cost only once, yet we know that the price of healthcare is a significant driver of availability.

Discrimination against persons with disabilities in the context of health insurance coverage, through practices that utilize disability status to determine financial risk, has long been normative practice in the health insurance industry.<sup>5</sup> Underinsurance, or having insurance that does not sufficiently meet one’s needs, is a particularly critical issue for children with autism. According to the 2005/06 National Survey of Children with Special Health Care Needs,<sup>6</sup>

- 48.6% of children with autism have inadequate insurance (as compared to 32.0% of children with special health care needs other than autism);
- 47.9% of children with autism have adequate private or public insurance to pay for needed services (63.1%);
- 31.1% of children with autism have an unmet need for a specific health care service (14.8%);
- 19.5% of children with autism have an unmet need for family support services (3.8%);

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<sup>5</sup> Sara Rosenbaum, Joel B. Teitelbaum & Katherine Hayes, Symposium on Health Care: Costs, Ethics & the Law: Article: Crossing the Rubicon: The Impact of the Affordable Care Act on the Content of Insurance Coverage for Persons with Disabilities, 25 ND J. L. Ethics & Pub Pol’y 527, 530 (2011).

<sup>6</sup> See [http://cshcndata.org/Conditions/Cond\\_Report.aspx?gid=0&rt=2&pgid=103&ind=14](http://cshcndata.org/Conditions/Cond_Report.aspx?gid=0&rt=2&pgid=103&ind=14) for the nationwide autism profile.

- 30.7% of children with autism who need a referral have difficulty getting it (20.1%);
- 31.0% of families who have a child with autism pay \$1,000 or more out of pocket in medical expenses per year for the child (19.5%);
- 38.6% of families who have a child with autism have financial problems (16.7%);
- 25.6% of families who have a child with autism spend 11 or more hours per week providing or coordinating the child's health care (8.7%); and
- 57.2% of families who have a child with autism cut back or stop working (21.7%).

This data highlights the difficulty families have in accessing proper treatment.<sup>7</sup> It also explains why twenty-nine states have enacted laws requiring coverage of autism spectrum disorders, with additional states considering similar measures in their 2012 legislative sessions.<sup>8</sup>

PCORI's work must address access to care issues. It is not enough that we know which treatments are effective – we must understand whether those treatments are reaching the people who need them.

If you have questions about our comments, please contact me at [sspielman@autismspeaks.org](mailto:sspielman@autismspeaks.org) or (202) 955-3312.

Sincerely,



Stuart Spielman  
Senior Policy Advisor and Counsel  
Autism Speaks

<sup>7</sup> For a fuller report on this data, see Michael D. Kogan et al., *A National Profile of the Health Care Experiences and Family Impact of Autism Spectrum Disorder Among Children in the United States, 2005-2006*, 122 *Pediatrics* e1149 (2008)

(<http://pediatrics.aappublications.org/cgi/content/full/122/6/e1149?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=kogan+strickland+and+autism&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT>).

See also Susan H. Busch & Colleen L. Barry, *Does Private Insurance Adequately Protect Families of Children with Mental Health Disorders?*, 124 *Pediatrics* S399 (2009)

([http://pediatrics.aappublications.org/cgi/content/full/124/Supplement\\_4/S399?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=mental+health+and+private+insurance&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT](http://pediatrics.aappublications.org/cgi/content/full/124/Supplement_4/S399?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=mental+health+and+private+insurance&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT)).

For additional information on autism and the loss of family income, see Guillermo Montes & Jill S. Halterman, *Association of Childhood Autism Spectrum Disorders and Loss of Family Income*, 121 *Pediatrics* e821 (2008)

(<http://pediatrics.aappublications.org/cgi/content/full/121/4/e821?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=montes+and+halterman&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT>).

<sup>8</sup> State laws and initiatives are fully described on the Autism Votes website,

[http://www.autismvotes.org/site/c.frKNI3PCImE/b.3909861/k.B9DF/State\\_Initiatives.htm](http://www.autismvotes.org/site/c.frKNI3PCImE/b.3909861/k.B9DF/State_Initiatives.htm)