



## **The CAA Problem: Background and Introduction**

In enacting the Combating Autism Act of 2006, the Reauthorization of 2011, and the CARES Act of 2014, Congresses and Presidents of both parties demonstrated a national commitment to create an appropriately designed and scaled federal response to autism. They understood the growing prevalence of autism and both its fiscal and human costs to the nation. Importantly, these pieces of legislation contain sunset provisions, to reflect the urgency of the needed response and the need for that response to rapidly evolve as new knowledge emerged. Any reasonable American, viewing the CDC estimates of prevalence, would call autism an epidemic, and the effectiveness of the legislated response to that epidemic, critically important.

When the CAA was adopted, autism prevalence was estimated at 1 in 110. Today, it is estimated at 1 in 45. While the APRC takes pride in the activism of parents and other loved ones of people facing autism in having generated greater awareness, it is absurd on its face to argue that there were just as many, or even anywhere near so many, severely affected children and adults with autism in earlier years as today. One would have to believe that large numbers of nonverbal, often self-injurious children, unable to pass basic developmental milestones towards independence, including being able to toilet oneself, many suffering intense pain from GI disorders or seizures, were somehow just never noticed before in American society.

In fact, the number of our children severely affected has skyrocketed, even during the years of the increased efforts on autism authorized by the CAA and its successors, and if there is consensus on anything in the field, it is that there are still far more questions than answers as to why this is happening. There are still no meaningful advances in generally accepted and widely available techniques for the prevention of autism or the treatment and/or recovery for those so adversely impacted.

**Today, we spend less per affected person looking for these scientific answers than at the passage of the CAA, because the rising tide of Autism has swamped the intensification of research spending. But the APRC believes, supported by the GAO studies of the matter, that much, perhaps most, of the significant taxpayer investment in research since the passage of the CAA has been wasted.**

**We do not petition Congress for more money, but for meaningful policy reforms to bring accountability and effectiveness to federal efforts on Autism.**

## **Our Proposed Answers: Fixing the Autism CARES Act**

- I. The NIH Autism Program
  - Create a new lead entity within the NIH for the direction of all NIH research on autism.
  - The new entity, “The Office of Autism Spectrum Disorders Research,” should be modeled on the statute creating the “Office of AIDS Research.” This office should be funded through a separate line-item in the appropriations bill funding the NIH and that line-item should include all funds to be spent on autism by the NIH for each fiscal year, with the

Office responsible to distribute funds to any appropriate other entity within the NIH, for research purposes, subject to a "Strategic Plan for Autism Research." **The statute should require the NIH to fund research in accordance with the budget requirement proportions laid out regarding the various objectives of the plan.**

- The Office of Autism Spectrum Disorders Research (OASDR) should be directed by a Presidential appointee, with Senate confirmation, modelled on the National Cancer Institute.
- The OASDR shall create and annually update a "strategic plan for autism research" and shall allocate funds appropriated to the Office in accordance with the strategic plan. The OASDR shall create metrics for the evaluation of progress on the plan's objectives and shall annually review the return on investment of the program. The OASDR shall also be responsible for assessment of duplication of research and for taking steps to correct such duplication.
- An Advisory Panel of qualified parents or other relatives of persons with autism shall be established, modeled on the integration panel for this purpose existing within the Congressionally Directed Medical Research Program (CDMRP). As with the CDMRP panel, the integration panel to the OASDR shall have voting rights with respect to the drafting of the annual strategic plan for autism research, and with respect to grant requests presented to the OASDR for the award of autism research funds.
- The statute shall contain language setting forth the mission of the OASDR to include: environmental risk factors for autism, translational medicine and clinical research related to the prevention and treatment of autism, the etiology and pathogenesis of autism, epigenetics, neurotoxicity, and regression analysis.
- The director of the OASDR at NIH shall coordinate with the FDA/CBER as necessary.

## II. Reforming HRSA Autism Activities

- The statute should redirect HRSA resources on autism towards research designed to create a medical model for autism management, a special patient population standard of care.
- The statute should set forth the mission of HRSA autism activities, to include: Research-focused on people with ASD who have developmental regressions and co-occurring conditions and are suffering pain and multi-symptom medical concerns. The objective should be required to develop and appropriately train all relevant medical personnel with regard to a treatment lifecycle for the co-occurring and underlying medical conditions for those with autism, including, but not limited to, GI disease, immunological disease, neurological disorders and metabolic disorder.
- A multidisciplinary medical management model should be developed to expand appropriately upon the existing psychiatric model for the diagnosis and management of persons with ASD.
- From this research, Congress should request HRSA to present ASD recommended medical treatment plans and screening tools, including standard emergency care practices regarding the co-occurring morbidities for those with ASD.
- HRSA should also be made responsible to conduct research, based on de-identified records, regarding surveillance of medical/clinical care of persons with autism, specifically

to include developing data on how many persons with autism use emergency rooms or have hospital stays each year, the nature of their diagnoses and treatments, and outcomes.

- The Advisory Panel created under the NIH section of the statute should be empowered to play the same role with respect to guidance of the research on these questions to be conducted under the statute by HRSA.

As the Autism CARES Act is due to sunset this year, APRC urges Congress to reauthorize federal autism policy and programs with these reforms, aimed at fulfilling the original purposes sought more than a decade ago – federally funded research focused on identifying, to the greatest extent scientifically feasible and in the shortest time possible, means for the prevention of autism and for the treatment and recovery of those most severely impacted by autism.

Like the “Cancer Moonshot” which has received bipartisan support to accelerate clinically relevant science on cancer and increase the return on investment of taxpayer dollars, the reforms proposed by APRC are necessary and proper, both fiscally and morally.