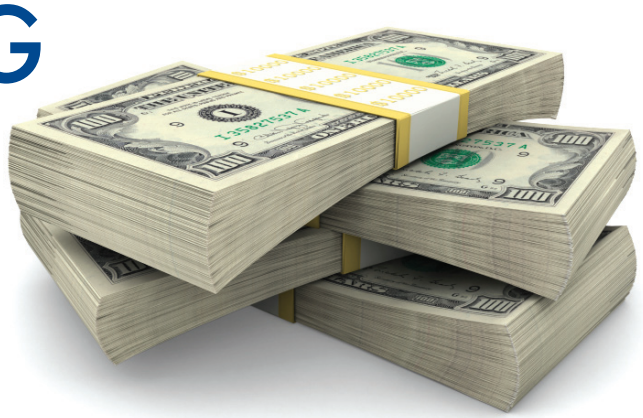
ARE FEDERAL RESEARCH DOLLARS BEING SPENT WISELY?



by Theresa Wrangham and Vicky Debold, PhD, RN

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Autism…it is everywhere. Almost everyone knows an affected person, and if they don't, they know about it because of media coverage and the fact that we now have a president who has made autism research a priority. Formerly, autism was a condition that rarely occurred; the statistic was 1 in 10,000 individuals. More recent statistics proclaim that 1 child in 150 is affected. The rise constitutes a national health emergency requiring commensurate research funds to bring much needed answers and support to affected individuals and their families. The heightened awareness resulting from autism's rise brings with it observations and questions relating to accountability regarding the infusion of millions into autism research.

Of the $10 billion in stimulus funds given to the National Institutes of Health (NIH), the $60 million earmarked for autism research is welcome news. Added to this is the $645 million over five years that the Combating Autism Act (CAA) set aside for the NIH-housed Interagency Autism Coordinating Committee (IACC). However, are research funds from the stimulus package and CAA being spent wisely? What is the likely impact of legislation being considered to assist families to gain insurance coverage for autism treatments?

Dr. Thomas Insel, who is the director of the National Institutes of Mental Health (NIMH) and also chairs the IACC, will direct use of the autism stimulus fund research monies. The ability of Dr. Insel to objectively lead these efforts is in question judging by numerous concerns voiced by leading autism organizations. These organizations cite possible violations of the Federal Advisory Committee Act that ultimately led to stripping previously approved vaccine safety research objectives from the IACC's Strategic Plan for Autism Research in January 2009. During this same meeting, Dr. Insel noted that federal agencies are named in ongoing vaccine-related litigation and, as a result, had a "conflict of interest." Therefore, he subsequently voted against including vaccine studies in the strategic plan. During February's IACC meeting, guest presenter Dr. Mark Noble of the University of Rochester proposed an independent panel as a way to resolve this conflict. As of this writing, the IACC has taken no action on Dr. Noble's recommendation.

Additionally, the current strategic plan allocates just over 10% of the budget to genetic research. While there may be a genetic component involved in regressive autism, genetic research is already well-funded privately, has not produced reliable and reproducible results, and does not substantially contribute to investigating the role of causal environmental factors. The need to look at environmental factors was again indicated by a recent U.C. Davis M.I.N.D. Institute study published in the journal *Epidemiology* (Hertz-Picciotto, 2009).

Also absent from the strategic plan are mechanisms to evaluate success, accountability, and a process to modify the

strategic plan over its five-year lifespan in response to new scientific knowledge. Creation of an Autism Advisory Board (AAB) to undertake these mechanisms is possible and outlined in the CAA; however, previous requests by autism organizations to the Secretary of Health and Human Services (HHS) to form such a body have been disregarded.

The current administration appears to favor an "Autism Czar" to be in charge of all autism research. This is an important leadership position that should be occupied by someone who is broadly respected by the autism community and holds credentials that demonstrate extensive experience and understanding of NIH research grant processes. Such a leader will also need to have experience in environmental science and understand how the environment can differentially affect genetically vulnerable subgroups; this experience and understanding is needed in order to direct research funds in ways that will identify new and improved treatments and support affected individuals. Other improvements would include removing NIMH as the lead agency in directing autism research efforts – our children are physically ill, not mentally ill. Additionally, expansion of public representatives on the IACC to twelve – equal to that of federal agency members – is necessary to provide balanced dialogue and meaningful public engagement.

The vaccine safety debate did not start with autism: it is very broad and began nearly three decades ago by parents whose children were injured by DPT vaccine. In the early 80s, these parents formed an organization now known as the National Vaccine Information Center. They called for vaccine safety research and informed consent protections to be instituted in the mass vaccination system and were integral in the formation of the Vaccine Injury Compensation Program (VICP). The VICP was set up to compensate those injured by vaccines, including children who presented with autism and other neurological injuries following vaccination.

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Theorizing that the alarming rise in autism was related to mercury in vaccines, as documented in "Autism: a Novel Form of Mercury Poisoning" (Bernard, et al., 2000), a renewed call for more and better vaccine science has been championed by parent-led advocacy organizations of families with autistic children.

Though vaccines are one of several potential environmental triggers for autism – a debate that has polarized the autism community – many parents, both within and outside the autism community, along with physicians and scientists continue to be outspoken critics of research and regulatory gaps in the national vaccination system. The dearth of vaccine safety research and recent harsh criticism from the scientific community regarding the Centers for Disease Control and Prevention (CDC) decision to spend $300 billion a year on vaccine promotion and only $20 million on vaccine safety research has further fueled a decline in public trust in vaccine policies.

During the last two Institute of Medicine (IOM) meetings on various goals contained in the "Review of Priorities in the National Vaccine Plan," Dr. Louis Z. Cooper, professor emeritus of pediatrics at the College of Physicians and Surgeons of Columbia University and former president of the American Academy of Pediatrics (AAP), has repeatedly criticized some of the CDC's vaccine-related spending priorities. Specifically, he's noted that to date, vaccine safety research has been "done on the cheap." Consequently, scientists testifying before the IOM and comments from the public indicated that a great deal is unknown regarding the effect of vaccination on total health outcomes beyond the decline in rates for a handful of infectious diseases.

Other criticisms raised during the IOM meetings include the complete absence of independent and public oversight of the national vaccination program, over-generalizing vaccine efficacy and safety findings to the entire population when only healthy individuals were enrolled in pre-licensure clinical trials, limitations of Vaccine Adverse Event Reporting System (VAERS) reporting and data, the need to identify genetically susceptible subgroups at higher risk of experiencing vaccine adverse events, and the need for NIH to place a higher priority on funding post-licensure vaccine studies.

The National Vaccine Program Office (NVPO) is advised by the National Vaccine Advisory Committee (NVAC), and it convened a series of stakeholder meetings on vaccine safety as part of its work to review the CDC's Immunization Safety Office (ISO) Draft Research Agenda. During stakeholder meetings, the public also commented on a number of gaps in the current federal vaccine safety system. Data from these meetings show that the general public shares the same vaccine safety concerns as those raised by the autism community and requests similar measures in transparency and research.

A draft report of this effort has been released by NVAC's Vaccine Safety Working Group (http://www.hhs.gov/nvpo/nvac/PublicEngagement.html#current), which includes a recommendation that an external expert committee be used "to consider strengths and weaknesses, ethical issues and feasibility including timelines and cost of various study designs to examine outcomes in unvaccinated, vaccine delayed and vaccinated children and report back to the NVAC." This recommendation is similar to the vaccine research objective stripped from the IACC Strategic Plan in January.

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research impact families? On April 20, the IOM convened the first meeting of a new panel tasked to review scientific literature on adverse effects of vaccines for the varicella zoster vaccine, influenza vaccine, hepatitis B vaccine, and human papillomavirus vaccine. The IOM review will draw conclusions that could ultimately add adverse events to – or remove adverse events from – the Vaccine Injury Table, which is used to compensate people who are injured or die after vaccination. Transparency throughout the review process was the primary request made during the April 20 public comment period, followed by questions about how the IOM would be able to do its work given how little has been published on the mechanisms by which vaccines can cause specific injuries.

Of great concern are past IOM conclusions related to biological plausibility which were based on inadequate science but that have been used, nonetheless, as a reason to not conduct vaccine safety research. Correction rests with the IOM. Adoption of a safety-first agenda insisting that the government conduct research where inadequate evidence exists to draw conclusions is both necessary and appropriate. The government must "err" in favor of families until the government's failure to provide relevant evidence is remedied. The IOM can and should align their practices to President Obama's transparency expectations instead of using the exception granted them under the Federal Advisory Committee Act that allows for closing their doors during deliberations. Adopting these measures would improve the VICP's ability to operate as originally required by the 1986 law, which was supposed to operate in a family-friendly and generous manner. It would also be a signal to the public that legitimate vaccine safety concerns will be addressed, thus initiating a process that could begin to restore public trust in the national vaccination program and in the IOM as a source of credible science-based analysis.

With regard to how research impacts legislation, the Autism Treatment Acceleration Act of 2009 (ATAA) is a current attempt by Senator Dick Durbin (D-IL) to require insurance coverage for autism treatment, create autism treatment centers, and create a voluntary registry to track trends and assist in understanding causes and rates of autism. The intent of this bill is laudable. However, the autism community has learned to be cautious of even the best of intentions. The resistance by IACC, specifically, and NIH, generally, to shift research objectives and monies away from investigation of autism's biological underpinnings, to account for private research investments, and to more thoroughly investigate the role of the environment impedes legislative efforts to be more inclusive of successful treatments used by many families.

Legislative efforts deferring oversight to already conflicted government agencies, such as the CDC, fuels public distrust of legislative efforts. These efforts must, therefore, recognize the current political atmosphere and aim to diffuse it by including a broad array of support and services within the ATAA. Clarifications on ATAA are needed on the use of an autism registry: Will it be prohibited for use by independent researchers as the Vaccine Safety Datalink database has been? Will consumer representation be trumped by federal agency representation on various new and existing committees created/included in this effort? Will off-label and alternative treatment of medical conditions co-occurring in autism continue to be excluded from insurance coverage when prescribed by a primary care physician? Will parents have access to insurance coverage if they choose not to use an autism care center and remain with private practice physicians? Autism organizations continue to work with Senator's Durbin's office for clarifications and are appreciative of Senator Durbin's efforts to assist our families.

In the end, research plays a pivotal role in the lives of every individual. Wise investment of research dollars into the investigation of environmental toxins is necessary, whether we are discussing autism, cancer, or multiple sclerosis, and whether the toxin is from a vaccine or the smoke stack of a coal-fired power plant. Autism is not an exception for which these roadblocks exist. But it could be used as an example to improve public trust, turn the boat around, and get back on course.

Our culture of science should be akin to Galileo and da Vinci who risked their reputations to find the truth without regard to dogmatic fear. Government must be mindful that, in its efforts to provide services and supports to our community that it is working for "We the People" and not for "Corporate America." Public stakeholders must be meaningfully included and engaged in every process and not simply given an opportunity to offer public comment. Government agencies must fall in step with President Obama's transparency ethos to gain back the respect and trust lost in recent years.

What is specifically needed in terms of autism supports and services is leadership and additional consumer representation in pursuing bold and meaningful investments in research. Best addressing the needs of our community would include delving into the case histories of those who have recovered from autism; using clinical data from the doctors treating them to determine the most effective, safe, and economically efficient interventions for individuals; considering mechanisms to make treatment affordable to all; and upholding the informed consent ethic. Treating legitimate physiological conditions that underlie the diagnosis labeled "autism" in an effective and efficient manner would benefit both the economies of federal and state governments and relieve the financial struggles of so many American families. In evaluating the current use of research monies and associated leadership for autism research, there is notable room for improvement if we are to guarantee the brighter future that affected individuals deserve.