July 25, 2006

Dear Shana, Steve and Jen,

First off, thank you for the improvements in CAA implemented in technical corrections and conforming amendments. We share your commitment to get the best bill possible through the Senate and onto the House. This is a follow-up to my email of last Wednesday morning and focuses on suggestions for report language and colloquy. These are based upon comments made during Shana's community briefing, discussions with HELP staff since then, a review of the bill text reported out by HELP last Thursday, extensive discussions within the community (mostly Safeminds, National Autism Association, and Generation Rescue), and discussions with Elizabeth Emken (Cure Autism Now) concerning her conversations with staff regarding the goals of potential report language to carry out Congressional intent and best meet the needs of the community.

1. National Autism Advisory Board: While we understand the rationale for not putting this program from the community consensus in statutory text, we very much appreciate staff's effort to enable NAAB through report language. Assuming the report reflects the new and enhanced role of the IACC, specifically the increased community membership and its power to make recommendations for enhanced public participation, the report should say something like: "As part of this increased public participation, the IACC should recommend to the Secretary the establishment of a NAAB with representation from the autism community, clinicians, and scientists. The committee notes with approval NIH's increased reliance on advisory committees and boards in carrying out its functions and the benefits achieved thus far from the close working relationship between parents, doctors, and scientists in gaining knowledge about the causes of and treatments for ASD. Especially in view of the new requirement for a strategic plan, a formal advisory board will play a vital role in ensuring that research dollars are well spent given the rapid rise in ASD incidence, the national priority of quelling this epidemic as science reveals its cause, and treating children with ASD while such treatments can make a difference in their quality of life. In lieu of an IACC recommendation, the Secretary should appoint an NAAB to advise the Secretary and Director, especially with respect to the strategic plan, on the best and most effective ways to implement this act." The report should expressly mention the strategic plan as this is a new and innovative mechanism of which the committee should be justly proud. The implementation, monitoring, revision, and oversight of this plan will surely help ensure the judicious and effective use of scarce research dollars during this period of heavy demands on the federal budget. The community is concerned that the NAAB should be mandatory for either the IACC or the Secretary because this mechanism is such an essential part of making this a meaningful bill and expenditure of scarce research dollars.

2. Diagnosis and "rule out:" While we think that the addition of "rule out"(used in 409C(c)(1)(B)(ii), 399BB(a)(1), 399BB(b)(4), 399BB(c)(1), and 399BB(c)(2)(B)) to diagnosis is somewhat redundant, we very much appreciate your intent to clarify in the report that "rule out" is limited to diagnosis and does not apply to intervention strategies and treatments. Although the report may state that "rule out" applies to the diagnostic process, the report should also expressly state that "rule out" "does not authorize a federal role to regulate or prohibit appropriate

interventions." Such "rule out" power could affect malpractice and insurance rates as well as the present delivery of care, e.g. by DAN! clinicians. This would allay community concerns that some in the federal government might be tempted to direct or dictate the practice of medicine, which as a matter of policy should be left up to treating doctors.

3. Consolidation of environmental research: With reference to the authority to "consolidate" activities authorized for the environmental centers (which appeared in the Manager's Amendment and is now in section 409C(e)), we very much appreciate your intent to provide additional clarity in report language that this should not be read as reducing the focus of activities on environmental health. We further understand that money is authorized to NIH as a whole but that it is the practice for the various Institutes, here NIEHS, to have control over funds actually appropriated for activities within their research jurisdiction. Mindful of the fact that the ACE's centers are authorized, e.g., to research toxicology, and the need for efficiency and avoidance duplication not scientifically justified (which can be done through the strategic plan), the community is concerned that the three environmental centers might get swallowed up in a wave of over-zealous consolidation. The same concern applies to non-center research money administered by NIEHS. Accordingly, the report should state not only that the "consolidation" authority should not be used to reduce the focus of activities on environmental health, but that the CEEHA distinct centers authorized under section 409C(c)(2) should not be abolished.

4. Meaning of "intervention:" We understand that language from the consensus bill bordering on a broad "right" to treatment could not be included in the final CAA. We appreciate your intent stated at the community briefing to clarify the meaning of "intervention." The report should state a definition as follows: "Interventions consist of biomedical, therapeutic, educational and other activities, and referral to providers of such interventions, that best practices determine should be prescribed given the diagnosis of the individual with an autism spectrum disorder and can cover activities to address developmental, psychosocial, behavioral, nutritional, neurological, immune, endocrine, gastrointestinal, metabolic, toxicological, genetic, learning and other problems relevant to the autism spectrum disorder diagnosis across the lifespan." This definition reflects the fact that the interventions (whether in the context of research or as part of surveillance activities) should be linked to the diagnosis and that the vast majority of ASD children that are part of the current "epidemic" present with sometimes very complex disorders of the brain, immune system, and gastrointestinal tract (e.g. autistic enterocolitis) related to the autism that effect the child far more broadly than the traditional "behavior" model of the disorder.

5. Meaning of "diagnosis:" We did not specifically discuss this at the community briefing, but the term does require some definition in light of the necessary definition of "intervention" above. The report should state: "Diagnosis consists of a determination of an autism spectrum disorder and category of autism spectrum disorder using standard diagnostic screening tools and, if an autism spectrum disorder diagnosis is identified, a complete medical history, physical examination and laboratory evaluation as they relate to the areas of developmental, psychosocial, behavioral, nutritional, neurological, immune, endocrine, gastrointestinal, metabolic, toxicological, genetic, learning and other relevant areas of health and development as deemed appropriate by the individual's health provider." As noted above, most autistic children present with a diverse and often quite complex array of biomedical disorders related to the autism.

6. Definition of “evidence-based:” In light of a thorough definition of terms, the report should include a definition of ‘evidence-based’ as it is used throughout the bill. A suggested definition is: “Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence - based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer.” This is taken from the standard reference work: Sackett DL, Richardson WS, Rosenberg W, Haynes RB. (1997). Evidence-based Medicine. New York, NY: Churchhill Livingstone.

7. Qualification for CEASDE: Section 399AA(b) authorizes the epidemiology centers. The application for grants and contracts requires such “information as the Secretary may require.” 399AA(b)(2). In order for the centers to “develop or extend an area of special research expertise” noted in 399AA(2)(B), the proposed centers should demonstrate a competency in epidemiology related to the desired expertise, i.e. environmental exposures. The expertise needed to adequately study environmental epidemiology is different than that required to study the epidemiology of infectious diseases or even of adverse reactions to vaccines. Understanding environmental impacts requires, for example, an understanding of the role of complex agents, the linkage between genetic susceptibility and environmental triggers, and the potential for impacts from very low dose exposures.

8. The vaccine research colloquy: Sorry to keep beating up on this, but this colloquy is the single most important feature of the bill as we go forward. Getting the vaccine research on the “cause” side and research into biomedical treatments on the “cure” side are perceived by many in the community as the real net gain from money authorized by this bill, as much of the CDC and other functions would most likely be handled in the annual appropriations process. We very much appreciate the commitment of staff to return to this drafting once the report language is settled. My previous email suggested a broadening of the language to include all vaccine-related issues (rather than just the preservative thimerosal) because there is a considerable body of scientific evidence pointing to, e.g., MMR (which did not itself contain thimerosal) as a cause or contributing factor. Also, although anecdotal, the investigative reporting of the AP’s Dan Olmstead revealing the absence of autism (and other auto-immune disorders) from unvaccinated populations such as the Amish and a large HMO in Chicago suggest the need for a well-designed research study comparing a large population of vaccinated versus unvaccinated children (perhaps using the VSD or state waivers as a source to identify unvaccinated controls). The original language suggested in my July 19 email was: “ "Senator Enzi has agreed to a colloquy on the

Senate floor stating that, for purposes of biomedical research, no research avenue should be eliminated, including biomedical research examining potential links between autism and vaccines, other biological products, and their components (such as the preservative thimerosal)." A concern has recently arisen that the use of "biomedical research" may itself be a limiting term rather than simply the focus of the "deliberate ignorance versus sound science" debate. While the epidemiological studies to date conducted and funded by CDC have been at best poorly designed, with protocols modified after results were obtained in what appeared to be an effort to hide statistical significance, and the lead author of the only American study, Thomas Verstraeten, has publicly disavowed reliance on his study to rule out vaccines as a cause of autism, there may be further opportunities to do useful epidemiological research. Any such research that is done under this bill should, as is the case for biomedical research, not rule out vaccines as a cause or contributing factor. According we would suggest adding "epidemiological or" in front of "biomedical research."

To the extent needed to address the legitimate concerns of the budget hawks, it is well worth noting that investing in research on environmental factors that bear on neurodevelopmental delays including ASD, especially vaccines, is money well spent. I know you're aware of the numbers, but it can cost up to $100k per year to care for an autistic child, and lifetime costs can exceed $3 million, not counting opportunity costs and costs to federal/state programs such as Medicaid and IDEA. Full-time aides and special schooling can cost $50k per child per year to IDEA.

We understand your strategy that taking the "vaccine" language out of the community consensus was necessary to achieve UC and that you can achieve the same effective result by expressing Congressional intent in a colloquy. You've asked for trust on this issue and we do. However, this is such an important issue to many in the community, both as a matter of process and on the merits, that the absence of a colloquy for whatever reason would provoke many groups and parents to desert the CAA in the House, and even to actively oppose it. We are working very hard to maintain a community consensus to get CAA successfully through the House, but we respectfully ask that you trust us on the importance of an effective colloquy.

9. The reference in 399BB(a)(1) to an "interdisciplinary approach (as defined in programs developed under section 501(a)(2) of the Social Security Act)" does not appear to be defined in that section, codified at 42 USC 701(a)(2), which is authorizing language for programs for child and maternal health focusing of "special needs." Maybe "interdisciplinary approach" is defined someplace in the grants and contracts implementing these programs, but maybe the reference was intended to point someplace else or that section got redesignated. Obviously an "interdisciplinary approach' is a useful concept, so perhaps the report could give some added details on the programs under the Social Security Act being referred to.

Finally, we very much appreciate the opportunity to remain engaged in the "drafting process" especially in view of the short time and your heavy workload. As we work together toward the goal of Senate passage by August 4, please let us continue to help you especially in fending off any real or threatened "holds." As parents and advocates, we can defend the need for this or that provision in the overall context of Congressional intent perhaps even more passionately and

forcefully than you. :-). Please let us know if we can provide any other information useful in finishing the report, such as general information about the autism epidemic, struggles faced by the families, cost estimates, or anything else of a more general nature.

Kindest regards,
Jim Moody
National Autism Association
SafeMinds