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Via Hand Delivery and email bschwetz@osophs.dhhs.gov

Michael Carome, Associate Director for Regulatory Affairs
Office of Human Research Protections
Via Hand Delivery and email mcarome@osophs.dhhs.gov

cc: Kristina Borrer, Director of Compliance Oversight, OHRP
Jose Antonio Galaz, Counsellor, Embassy of Portugal
Vera Hassner, President, Alliance for Human Research Protection
The Honorable Diane Watson, D-CA
The Honorable Dan Burton, R-IN
The Honorable Mike Michaud, D-ME

RE: Children's Amalgam Trial in violation of 45 CFR 46.116, 45 CFR 46.408, and
45 CFR 46.409

Dear Dr. Schwetz and Dr. Carome:

Consumers for Dental Choice has reason to believe that federal regulations for the protection of human research subjects, including those for children, have been violated by a federally funded research study to test the safety of mercury amalgam dental fillings.

The study, known as The Children's Amalgam Trial (CAT), is being conducted in two trials on vulnerable children – urban and rural poor in Massachusetts and Maine and institutionalized children/wards of the state in Portugal – by researchers at the New England Research Institutes and the University of Washington respectively.¹ Despite the fact that amalgam fillings have been in use for some time, the CAT is the first ever phase III clinical trial to test the safety of this restorative material, with the secondary goal of determining the dose response relationship to mercury, a known toxin.

- The children enrolling as participants in the CAT were given inadequate and even misleading information about the potential risks of their participation in this experiment.

¹ The Casa Pia Study of Dental Amalgams in Children (Portugal) is being conducted by University of Washington (Seattle, Washington) researchers through a Cooperative Agreement with researchers at the University of Lisboa in Lisbon, Portugal. The Children's Amalgam Trial (New England) is being conducted by a consortium of scientists from the New England Research Institutes (NERI) in Cambridge, Massachusetts, Forsyth Dental Clinic and Harvard University in Boston, Massachusetts, and the University of Rochester in Rochester, New York.

- The risks to these child-subjects were not minimized in light of new scientific findings that emphasized the potential for harm from doses of mercury within the range of that received by the general population from amalgam fillings.
- The Portuguese trial arm continued unabated despite a pervasive pedophilia scandal at the school that has been referred to as one of the worst events in the history of Portugal. It is likely that the scientific integrity of the study has been compromised and as a result the children may be suffering undue harm.
- Several conflicts of interest for overseers of the CAT have been uncovered which may have influenced the decision to continue the Portuguese arm of the trial despite the potential for skewed results and harm to the children.

The CAT is funded by grants from the National Institute of Dental and Craniofacial Research (NIDCR) of the National Institutes of Health.²

Background

Dental amalgam is a commonly used dental restorative material containing approximately 50% elemental mercury by weight. Concerns about its toxicity have existed since the inception of its use, and have intensified as more sensitive scientific methods for detecting mercury exposure and plausible mechanisms for mercury toxicity have been developed. The CAT was initiated at the request of the Public Health Service in 1997, under a call for controlled clinical trials to address public concerns about mercury toxicity. Amalgam has never previously been tested for safety and was grandfathered into the FDA's classification system based on length of use. Consequently, the CAT is the first ever Phase III clinical trial to address the safety of exposure to low doses of mercury from amalgam fillings; its goal to define more clearly the "dose response relationship" of the toxicity of elemental mercury, amid growing concerns about the adverse health effects of this exposure. It is important to note that the CAT is designed primarily as a safety study and is therefore not concerned with other efficacy issues such as the durability of the materials.

According to the World Health Organization (WHO) and the US Agency for Toxic Substances and Disease Registry, mercury amalgam comprises a person's largest source of daily exposure to this toxic metal, greater than all other sources combined.³ The amount of exposure depends on a person's chewing habits and other factors, and varies greatly by individual.⁴ In extreme cases, people's mercury levels from amalgam have been found to overlap with levels found to be clinically significant in workers who were occupationally exposed.⁵

² University of Washington researchers were awarded grant no. U01 DE11894, and the New England Research Institutes was awarded grant no. U01 DE11886.

³ World Health Organization, Environmental Health Criteria 118, 1991. 3-17 µg of mercury are retained from dental amalgam while 5.2 µg are retained from other sources including air, food, and water. Dental amalgam is the main source of exposure to elemental mercury, while fish is the main source of exposure to methylmercury.

⁴ Toxicological Profile for Mercury, US ATSDR, 1999. CAS#7439-97-6.
<http://www.atsdr.cdc.gov/toxprofiles/tp46.html>

⁵ Mercury in dental-filling materials - an updated risk analysis in environmental medical terms. Maths Berlin for the The Dental Material Commission, Sweden. One of the conclusions of this extensive literature review was that, "For medical reasons, amalgam should be eliminated in dental care as soon as

When mercury is released from dental amalgam in the form of elemental mercury vapor, approximately 80% of this inhaled vapor is absorbed. It then diffuses via red blood cells to the central nervous system and other target organs, exerting its greatest chronic toxic effect in the brain and kidneys. CAT researchers acknowledge in their publications that, “At times mercury from dental amalgams has been suggested as the cause of disease manifestations that range from mild dermatologic conditions, to chronic debilitating neuromuscular diseases and even acute, life-threatening health outcomes.”⁶ Furthermore, it is recognized that mercury might cause “...immunotoxic effects [that] could lead to suppression or inhibition of immune competence, initiation and/or triggering of autoimmunity, or stimulation and triggering of hypersensitivity reactions.”⁷

New research published in 1998, prior to the end of the enrollment period for the CAT, found preclinical symptoms of mercury toxicity in adults exposed to low levels of mercury, within the range received by the general population from amalgam fillings.⁸ This publication, *Neurobehavioral effects from exposure to dental amalgam Hg^o: new distinctions between recent exposure and Hg body burden*, related changes in mood, motor function, and coordination to exposures in the range of 0-4 µg/L of urinary mercury. More importantly, it identified total body burden as a more accurate predictor of mercury toxicity than urinary mercury, as the latter only measures recent exposure, rather than the amount that the body has retained over time. Additional studies have supported the importance of total body burden as a predictor of toxicity, by showing that children with the lowest mercury excretion levels (as shown by urine, blood and hair levels) were more likely to be retaining the most mercury.⁹ Urinary mercury is the method being used by the CAT to assess mercury exposure and toxicity.

Numerous reports of adverse reactions to dental amalgam, have been filed with the Medwatch, the FDA Safety Information and Adverse Event Reporting Program. These include reports of severe, life-threatening reactions to Dispersalloy, the brand being used in the CAT.¹⁰ Furthermore, Dentsply, the makers of Dispersalloy, issued warnings for the U.S. population in 1997, the same year in which enrollment for the study began.

possible. This will confer gains in three respects. The prevalence of side-effects from patients' mercury exposure will decline; occupational exposure to mercury can cease in dental care; and one of our largest sources of mercury in the environment can be eliminated ... Dental materials left in patients' mouths should be treated as drugs for administrative purposes. Accordingly, toxicological and clinical testing should be required. Reporting of side-effects should also take place according to the same norms that apply to drugs ... It is imperative for doctors and dentists to be made aware of the fact that all dental restoration materials can give rise to side-effects, and that this eventuality should always be considered when the patient's pathological state is unclear. Side-effects may conceivably both cause, and be contributory factors in, various pathological states.”

⁶ TA DeRouen et al. *Issues in design and analysis of a randomized clinical trial to assess the safety of dental amalgam restorations in children*. *Controlled Clinical Trials* 23 (2002): 302.

⁷ SM McKinlay et al. *The Children's Amalgam Trial: design and methods*. *Controlled Clinical Trials* 24 (2003): 801.

⁸ D Echeverria et al. *Neurobehavioral effects from exposure to dental amalgam Hg^o: new distinctions between recent exposure and Hg body burden*. *The FASEB Journal* 12 (1998): 971-980. This paper was published in August 1998 while enrollment in the New England study ended in September 1999, and for the Portuguese study in October 1998.

⁹ Holmes, AS, et al., *Reduced levels of mercury in first baby haircuts of autistic children*, *Int. J. Toxicol.*, 2003 Jul-Aug; 22(4): 277-85.

¹⁰ <http://www.fda.gov/cdrh/maude.html>

Packing sheets for Dentsply's amalgam included the following contraindications (restrictions on use):

In proximal or occlusal contact to dissimilar metal restorations; In patients with severe renal deficiency; In patients with known allergies to amalgam; For retrograde endodontic filling; As a filling material for cast crown; In children 6 and under; In expectant mothers.¹¹

It is important to note that most of these "at risk" populations were excluded from participation in the CAT. For reasons unknown, the warnings were later withdrawn from the US market, but similar ones are still active in other countries, including Canada.

According to the researchers, children were chosen over adults to be the subjects of research because "they are thought to be **more susceptible to the neurobehavioral effects of mercury intoxication** [poisoning] **and would be more likely to show an effect if there is one** [*emphasis added*]." ¹² In one of their publications, the researchers note: "If there were alternative restorative materials that were entirely equivalent to amalgam in terms of strength, longevity, cost, and ease of use, then the known risk for high-level exposure to mercury suggests that it might be prudent to eliminate low-level exposure from amalgam, even in the absence of documented health effects."¹³ **That the children are being unnecessarily exposed to a known toxin that is predicted to be a higher risk to them than to another study population, when other alternatives are readily available, is extremely troubling.** It is imperative that a thorough investigation be conducted into all aspects of planning, implementation, and monitoring of these studies to assure that the children are not the subjects of undue harm.

Consent Forms

The consent forms for both study arms were obtained from Mary Ann Redford, then director of the Clinical Trials Program at NIDCR, by Freya Koss, a concerned citizen who suffered a severe adverse reaction to the same medical device with which these children were being treated.¹⁴ Preliminary analysis of these forms reveals that, like much of the American public who receive these devices every day, the children and their parents/guardians for both studies were not given adequate information about mercury dental amalgam to make an informed decision about participating in the experiments.¹⁵

¹¹ Dispersion Directions for Use. Dentsply International INC. (R-9/97).

¹² Statement of researchers from the University of Washington, quoting NIDCR's RFA. Martin, MD; DeRouen, TA; Leroux, BG. *Is Mercury Amalgam Safe for Dental Fillings?* Washington Public Health, Vol. 15, Fall 1997. <http://healthlinks.washington.edu/nwcp/wph97/mercury.html>. Accessed 9/10/04.

¹³ Id 6: p303.

¹⁴ Freya B. Koss learned she likely had mercury poisoning from dental work on an amalgam filling in 1998 and stumbled across the CAT while searching for a lab to test her mercury levels. She joined the staff of Consumers for Dental Choice as our Director of Development in 2002. [519 Sussex Road, Wynnewood, PA 19096, phone: 610.649-2606]

¹⁵ Several states (Maine, California, Arizona, and New Hampshire) have addressed the issue of informed consent by passing legislation requiring disclosure be given to patients prior to placement of amalgam fillings. Federal Legislation has been introduced for the past several years by Diane Watson (D-CA) and Dan Burton (R-IN), and would also require warnings about the dangers of mercury toxicity from dental amalgam be given to patients prior to dental work.

The American consent forms, from the *Children's Amalgam Trial Manual of Procedures*, are dated February 3, 2000, and the Portuguese consent forms, from the *Children's Manual of Operations* for the Casa Pia Study of Dental Amalgam, are dated January 28, 2000. Both sets of forms are presumed to be those originally used to consent the children, but if additional forms exist, they would merit additional analysis. The forms are in English, and it is unknown whether the ones provided to the Portuguese children or to immigrants enrolled in the New England study were in their native language, in compliance with federal guidelines. Also, it is unclear how the Portuguese children were re-consented given that the director of Casa Pia, who served as an advocate for the 100 wards enrolled in the study, stepped down in 2002 in wake of the pedophilia scandal.

Both sets of forms contain coercive and even dishonest language regarding the current state of knowledge about the amount of exposure to, and the toxicity of elemental mercury from dental amalgam – including the potential health risks involved in such exposure. Likewise, benefits of participating in the studies may have been overstated. The concerns listed below are consistent with the pattern of violations in the University of Washington's human subjects review process, as outlined in the OHRP's April 1st letter to the president.¹⁶ The CAT is in violation of federal laws 45 CFR 46.116 and 45 CFR 46.408 for the protection of human research subjects.

Overview of Deficiencies in the American Consent Forms:

- Contain coercive language regarding participation in the study based on the availability of alternatives and the risks associated with them;
 - Example: “Dental amalgam ... is currently the most frequently used material to fill cavities in the back teeth, and **if I choose to not participate in this study, it is very likely that my child's teeth will be filled with amalgam by another dentist** [*emphasis added*].”
 - Comment: While dental amalgam is a standard restorative treatment, it is likely that the children could go elsewhere and receive alternative filling materials, especially given the availability of low cost dental care available in the Boston area. Also, Maine Medicare has paid for alternatives to amalgam for several years. This is also juxtaposed with the statement “...**the dental composite releases a chemical in the mouth that in much larger amounts may cause cancer** [*emphasis added*].” This is not a fair and balanced assessment of the potential risks that can be expected from being exposed to either of these materials. Furthermore, the risks of mercury exposure are described in the “Background” section, rather than the “Risks/Mitigation” section of the forms.
- No disclosure of the realistic amount of mercury exposure or absorption to be expected from amalgam fillings;
 - Example: “Because mercury in large amounts can cause health problems, scientists have wondered whether the **very small amounts** of mercury from dental amalgam **and even from food, water and air can also cause some of these problems** [*emphasis added*].”
 - Comment: As noted above, the WHO recognizes dental amalgam as the major source of daily exposure to mercury for those who have them. The

¹⁶ http://www.washington.edu/research/hsd/forms/ohrp_letter.pdf

deceptiveness of the researchers' statement is reinforced by the subsequent statement: "It is important to note that the mercury collected in body tissues **originates from many sources other than dental amalgam, including the foods that we eat** [*emphasis added*]."

- No disclosure of previous human or animal studies that reflect adverse health events;
 - Example: "There is **no evidence** that any of these health effects happen with the small amounts of mercury from dental fillings [*emphasis added*]."
 - Comment: This is in stark contrast to the results of numerous scientific studies on amalgam, some of which the researchers acknowledge in their publications. Also, at least five of the symptoms of mercury poisoning mentioned in the study's RFA were selectively excluded from the consent forms (personality change, depression, weight loss, psychological distress, gingivitis).

Overview of Deficiencies in the Portuguese Consent Forms:

- The purpose of the study with respect to mercury exposure was concealed from the participants;
 - Example: "There are two main types of tooth filling materials commonly in use today. One is **silver amalgam** and the other is a plastic composite material [*emphasis added*]."
 - Comment: It was not disclosed to the children that amalgam even contains mercury, as it is promoted to them under the deceptive term "silver". Study participants likewise, were not even warned of the possibility that they would be exposed to mercury from their fillings.
- Participants were not warned of any risks associated with exposure to mercury;
 - Example: "**The only risks or discomfort** from these procedures **are the ones usually associated with routine dental care or with routine medical examinations and tests** [*emphasis added*]."
 - Comment: The procedures used are not necessarily minimal risk, even though they are accepted as "routine". It was once routine to administer thalidomide to pregnant women although it was later found to cause considerable harm to the fetus by inducing birth defects and other abnormalities. There is a huge body of literature supporting the potential for harm from amalgam fillings, and these risks should have been communicated in the consent forms.
- The language used in the consent forms is confusing and misleading;
 - Example: "Even though these filling materials are the standard ones used **in hundreds of millions of fillings each year throughout the world**, questions remain about the safety of the materials [*emphasis added*]."
 - Comment: They fail to note warnings afforded by other countries while at the same time overstating the usage to mute concerns over safety.

Vulnerable Populations

The CAT involves 507 children in Portugal ranging from ages 8-12 at enrollment, and 534 children in Massachusetts and Maine ranging from ages 6-10 at enrollment. These children allegedly were in need of dental care, and fit the definition of vulnerable populations for multiple reasons. A large proportion of the New England children are minorities (37%) and over half of them come from families with annual incomes below \$30,000. These children are being paid to submit to tests, and the amount of money the children receive was doubled from its original offering.¹⁷ Researchers had a hard time recruiting the study population in Boston due to the availability of low cost alternative dental care.¹⁸

The Portuguese arm of the study is being conducted on children attending the Casa Pia schools in Lisbon, Portugal. In the words of the University of Washington researchers, this school system “provides educational and cultural opportunities to...children who are orphaned, from troubled homes or [who are] otherwise disadvantaged. Many of these children are economically disadvantaged and have had no access to dental care. The school population is relatively homogeneous culturally and stable geographically.”¹⁹ Approximately 20% of the children in the school system are wards of the state. Accordingly, 20% of the study population, or over 100 wards were enrolled in the CAT. The researchers describe these children as the “ideal” study population, having used them previously as the subjects of other collaborative research projects.

In 2002, Casa Pia was rocked by a sex abuse scandal so severe in its reach that it has been described as one of the worst events in the country’s history. One of the facilitators of the abuse confessed to his involvement in 30 years of abuse involving school administrators, including the school’s deputy director and doctor, and top officials in the government. It is unclear whether any children enrolled in the CAT were subjects of abuse, but the atmosphere of the school had to have been one of severe psychological duress, as it was likened to that of a “terror movie” by the school’s new director, Catalina Pestana.^{20 21}

The director of the Casa Pia School system who originally consented for the 100 children in the study who are wards of the state, stepped down from his post in 2002, in the wake of the pedophilia scandal.

45 CFR 46.409 states:

- (a) Children who are wards of the State or any other agency, institution, or entity can be including in research approved under 46.406 or 46.407 only if such research is:
 - 1. related to their status as wards; or

¹⁷ Increased from \$25 to \$50 per visit according to testimony by researchers before the King County Board of Health in 2002.

¹⁸ The Children’s Amalgam Trial Study Group. *The Children’s Amalgam Trial: design and methods*. *Controlled Clinical Trials*: 24 (2003): 795-814.

¹⁹Id 12.

²⁰ Authorities recognized that 128 students still enrolled in the school had been abused.

²¹ *Prominent figures detained as child-sex scandal rocks Portugal*. The Star, South Africa. June 4, 2003. Elizabeth Nash. <http://www.thestar.co.za/index.php?fSectionId=132&fArticleId=163389>

2. conducted in schools, camps, hospitals, institutions, or similar setting in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in and agrees to act in, the best interests of the child **for the duration of the child's participation in the research and who is not associated in any way** (except in the role as advocate or member of the IRB) **with the research, the investigator(s), or the guardian organization** [*emphasis added*].

Subpart (b) of 46.409 requires that a personal advocate be appointed for each child for the duration of the research, who is not, "associated in any ways with the research, the investigator(s), or the guardian organization." The original appointment of the director to consent for the child wards of the state is a violation of subpart (b) of 46.409, because of his conflict as leader of the guardian organization, whose administration stood to benefit from the money saved on free dental care for the children. The question as to whether the director could consent for so many children was originally raised by the DSMB, and the answer was deferred to the University of Lisboa's IRB, on suggestion from NIH's Office of Research Integrity. Given the substantial amounts of money to be gained through a potential contract, it is questionable whether this ethical deferral was appropriate, but the Lisboa IRB made its approval on the grounds that, "The director of Casa Pia is highly respected in the community and takes his responsibilities as legal guardian of the resident children very seriously."²²

It is impossible that the researchers at the University of Lisboa, or their counterparts at the University of Washington were unaware of this high profile scandal involving very top officials at Casa Pia. They had a responsibility to report the news to the IRBs/DSMB regardless of its bearing on the study, given the profound ethical and scientific implications of the revelation of abuse. To our knowledge this did not occur, as the study continued for its full five-year period and was even extended for two years. It is hard to imagine how this extremely vulnerable group of children was re-consented for this period given the profound ethical issues involved.

Evidence of Harm

Preliminary results from the Boston arm have not been released, but it is known that the Portuguese children have shown elevated levels of mercury in their urine. At three-year follow-up, those with amalgams had over three times as much mercury in their urine as the control group, at 4.22 µg/L and 1.82 µg/L of mercury respectively. In his testimony of November 14, 2002, before the House Government Reform Committee of the U.S. Congress, Lawrence A. Tabak, Director of NIDCR, noted that at times, some of the children's mercury levels have been "higher than acceptable". In fact, their reported urinary mercury levels are higher than those shown to cause neurological harm to dentists

²² Id 6: p315.

by Echeverria et al. in 1998.²³ Furthermore, because the children's total body burden of mercury is not being assessed (and because of potential complicating factors such as the psychological distress suffered on account of the sex abuse scandal) the children may be suffering from subtle preclinical symptoms of mercury poisoning that are going undetected.

The publication of the Echeverria study should have prompted both a warning to participants in the CAT that low levels of mercury had been found to cause harm in adult populations, and also a reevaluation of the accuracy of techniques employed in the CAT to assess mercury toxicity. As noted earlier, this study established total body burden as a more accurate predictor of mercury toxicity than urinary mercury levels. From the documents we have in our possession, there is no evidence that an effort was made to communicate the updated scientific findings to enrollees, so that they could make an informed decision about continuing their participation in the trials. It is unclear whether the DSMB or IRB was apprised of the results of this study by the researchers, as was their ethical duty, although it is obvious that at least some of the researchers were aware of the study's results.²⁴

As no long-term care will be provided for those injured by their participation in this trial, and noting the cumulative nature of mercury as outlined above, such future risks as those posed to pregnant women should also have been taken into account. This is why it is imperative that a thorough investigation be implemented, as these populations are extremely vulnerable and clearly have little or no ability to advocate for themselves.

Conflicts of Interest

Several conflicts of interest for project overseers have been uncovered, although it is unclear what their bearings, if any, they have had on the course of research.

- Dr. Michael Martin is the Co-principal investigator and Project Director on the Casa Pia Study of Dental Amalgam. Martin testified to amalgam's safety at a public hearing in 2002 before the King County Board of Health. He represented himself as an advocate for amalgam on the "pro" side of the argument, years before the completion of the study. This decision was roundly criticized by the toxicologist for the study, James Woods. Additionally, Martin was recently appointed to the American Dental Association's Council on Scientific Affairs.²⁵ This committee oversees ADA programs including the ADA's "Seal of Acceptance" program, through which the ADA promotes the "safety and effectiveness" of a variety of products, including dental amalgam. His participation in the study may constitute a financial and proprietary conflict of interest.

²³ Id 8.

²⁴ James S. Woods, and author on the Casa Pia Study on Dental Amalgam, is an author on this publication. In their publication on preliminary data from the CAT (Id 6), UW researchers acknowledge that they are aware of the new study about low dose exposure to mercury – but no explanation is given as to why the findings were not integrated into procedures in the CAT. The Boston researchers make no acknowledgement of this study in their publications.

²⁵ According to the winter/spring 2004 issue Dental Alumni News from the University of Washington.

- According to his website, John W. Reinhardt, chair of the CAT's DSMB, is the current recipient of "[s]everal small grants related to the study of dental amalgam and mercury safety in dentistry," from the CAT's sponsor: NIDCR.²⁶ He is also on the Board of the Friends of the National Institute of Dental and Craniofacial Research (FNIDCR), an organization that procures money for NIDCR and has ties to amalgam manufacturers including Dentsply.²⁷ A search of the PubMed database revealed that Reinhardt has not published an amalgam related article since 1984, and references to these grants were not found in the NIH's CRISP database. If these grants do exist it is possible that they constitute a financial and proprietary conflict of interest. Given the DSMB's central role in ensuring patient safety and the scientific integrity of the trial, as well as the value of the results – and also given the DSMB chair's essential role in making sure that any concerns expressed by the panel translate into action – the DSMB, and particularly its chair, should be devoid of any conflicts of interest.
- Thomas Clarkson, PhD – Co-Principal Investigator on the Children's Amalgam Trial (New England). Dr. Clarkson served as an expert witness for Kerr Corporation in the defense of a recent lawsuit by a consumer alleging harm from their mercury fillings – *Barnes v. The Kerr Corporation*, (Case No. 4:99-CV-79, U.S. District Ct., E.D.Tenn.) on December 5, 2002. Kerr currently holds 46% of the U.S. market share for dental amalgam. His involvement in the study may constitute a financial and proprietary conflict of interest.

We have uncovered multiple breaches of ethical standards in the way that the CAT has been conducted. As levels of mercury once thought to be safe, have consistently fallen, and given the solid pattern of violations by those conducting the CAT, it is imperative that the OHRP fully review all aspects of this trial to ensure the safety of the children involved.

Consumers for Dental Choice calls for a moratorium on the Children's Amalgam Trial pending the outcome of an investigation into the consent and monitoring practices of both arms of the trial; compliance with 45 CFR 46.116, 45 CFR 46.408, and 45 CFR 46.409; disclosure of any conflicts of interest by the researchers and/or IRB/DSMB members and expulsion of those with severe conflicts; reassessment of the children's health by more sensitive methods of detection to assess preclinical symptoms of disease; long term health monitoring and redress for any consequential health problems suffered by the child-subjects; inquiry as to why the clinical trial in Portugal did not stop immediately following the pedophile scandal; additional assurances that the generalizability of the results will not be overstated; if the consent process is deemed inadequate that choice be given to those children enrolled in the trials to have their fillings replaced with alternative materials that do not contain mercury should they desire it.

Sincerely,

Amanda Ganong

²⁶ <http://app1.unmc.edu/dentistry/Submit1.cfm?DocNameCombo=56>

²⁷ The FNIDCR is a nonprofit organization founded in 1998 to support the NIDCR. Reinhardt has been a Board Member since at least 2003. <http://www.fnidcr.org/board.html>

Director of Programs

Attachments