A DEVELOPMENTAL TOXICOLOGISTS VIEW

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TALKING POINTS

MERCURY AS A NEUROTOXICANT—
INORGANIC/ ORGANIC METHYL/ETHYL-THIMEROSAL/DOSE

• WHY WE NEED TO STUDY THE DEVELOPING HUMAN –
  DIFFICULTY IN EXTRAPOLATION OF ANIMAL DATA -
TALKING POINTS

• IS THE DATA REGARDING THE INFANT AND CHILD ADEQUATE TO CONCLUDE THAT THIMEROSAL HAD AN EFFECT? CDC STUDIES, ETC

• IS THIS DATA RELEVANT NOW THE VACCINES DO NOT CONTAIN THIMEROSAL
TALKING POINTS

• STUDIES UNDERWAY OR BEING PROPOSED- US GOVERNMENT, UNIVERSITIES AND PARENT GROUPS – BY THEMSELVES OR TOGETHER

• CURRENT THERAPEUTIC TRIALS BASED ON HEAVY METALS-

CONCLUSIONS
MERCURY AS A NEUROTOXICANT (ANIMAL & HUMAN DATA)

- BIOLOGIC PLAUSIBILITY - MULTIPLE MOAs, KEYS TO UNLOCKING THE BRAIN
- INORGANIC/ORGANIC
- METHYL/ETHYL-?
- THIMEROSAL DOSE RESPONSE?
- PREGNANCY & DEVELOPMENT
WHY WE NEED TO STUDY THE DEVELOPING HUMAN

• EXTRAPOLATION OF ANIMAL DATA TO HUMAN — MOST DIFFICULT FOR DEVELOPMENT—THALIDOMIDE, DES

• WINDOWS OF SUSCEPTIBILITY OF THE DEVELOPING HUMAN — THALIDOMIDE/PCBS

• OF ANY TIME DURING LIFE, THE DEVELOPING HUMAN IS THE MOST SENSITIVE TO MERCURY — IRAQ/MINAMATA BAY

• CO-CONTAMINANTS- A DEVELOPING HUMAN IS EXPOSED TO HUNDREDS OF ENVIRONMENTAL SOME OF WHICH ARE NEUROTOXICANTS, ADDITIVE/SYNERGISTIC/SUPT.
IS THIS DATA RELEVANT NOW
THE VACCINES DO NOT
CONTAIN THIMEROSAL

• RELEVANT TO OTHER COUNTRIES
• UNDERSTANDING OF BRAIN DEVELOPMENT – PARENTS/SCIENTISTS
  RELEVANCE TO MERCURY IN THE ENVIRONMENT
  AND OTHER ENVIRONMENTAL CONTAMINANTS
  GENE – ENVIRONMENT INTERACTION
STUDIES UNDERWAY OR BEING PROPOSED

• US GOVERNMENT - ATSDR
• UNIVERSITIES - CDC
• BY THEMSELVES OR TOGETHER
CURRENT THERAPEUTIC TRIALS BASED ON HEAVY METALS - CHELATION THERAPY

- ORPHAN DRUGS – ALL DRUGS MUST BE STUDIED IN CHILDREN BEFORE USED AS THERAPY-
- THEORETICAL BASED TREATMENTS – XRAYS FOR ENLARGED THYMUS, ANTIBIOTICS FOR PREMATURES. SOME HAVE BEEN SHOWN TO BE BENEFICIAL
- NEED TO STUDY SUCCIMER AND ALL THERAPEUTICS
- WHAT WE KNOW OF SUCCIMER THERAPY AND FDA LABELED INDICATIONS IN CHILDREN
- THE EFFECT OF CHELATION THERAPY WITH SUCCIMER ON NEUROPSYCHOLOGICAL DEVELOPMENT IN CHILDREN EXPOSED TO LEAD, NEJM: VOLUME 344, 1421, 2001
THE EFFECT OF CHELATION THERAPY WITH SUCCIMER ON NEUROPSYCHOLOGICAL DEVELOPMENT IN CHILDREN EXPOSED TO LEAD

- 780 CHILDREN
- BLOOD LEAD LEVELS OF 20-44 MICROGRAM/dl
- RANDOMIZED PLACEBO CONTROLED TRIAL OF UP TO THREE 26 DAY TREATMENT COURSE OF SUCCIMER 1050MG/M SQ. FOR FIRST 7 DAYS AND THEN 700 MG/M SQ THEREAFTER
- STUDY PARAMETERS WERE LEAD LEVELS, IQ, BEHAVIOR, DEVELOPMENTAL NEUROPSYCHOLOGICAL FUNCTION, AND GROWTH
THE EFFECT OF CHELATION THERAPY WITH SUCCIMER ON NEUROPSYCHOLOGICAL DEVELOPMENT IN CHILDREN EXPOSED TO LEAD RESULTS

SUCCIMER

- LOWERED LEAD LEVELS BY 3.7 – 5.3 MICROGRAM/DL
- NO IMPROVEMENT ON COGNITION, BEHAVIOR, OR NEUROPSYCHOLOGICAL FUNCTION
- DECREASED GROWTH BY 0.25CM/12 MONTHS AND 0.35CM OVER 34 MONTHS
- INCREASED INCIDENCE OF HOSPITALIZATION FOR TRAUMA (0 VS 5)
CONCLUSIONS

• MERCURY IS A KNOWN NEUROTOXICANT
• CURRENTLY THERE IS INCONCLUSIVE DATA IN CHILDREN TO SUPPORT THIMERASOL CAUSED NEURODEVELOPMENTAL DELAY INCLUDING AUTISM
• BUT THE WEIGHT OF EVIDENCE IS COMPELLING THAT THIS QUESTION HAS TO BE AND STUDIES MUST BE PERFORMED TO CONCLUSIVELY PROVE OF DISPROVE THIS THEORY, INCLUDING AUTISM.
• RESEARCH OF MOAs, PK/PD, CO-CONTAMINANTS, GENETIC SUSCEPTIBILITY MUST BE PERFORMED AS EXPEDITIOUSLY AND CAREFULLY AS