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FDA: Autism hopeless, untreatable

The Food and Drug Administration (FDA), which has never approved a drug as useful in autism, now claims, according to its website, that dietary supplements are "unproven" and that parents who use supplements are the gullible victims of "marketeers."

The FDA website (www.fda.gov/oc.nutritioninitiative/report.html) contains the following statements:

Autism Treatments: Parents of autistic children can be desperate and provide easy targets for unproven therapies. Marketers of dietary supplements for autistic children contend that their products promote more complete food digestion, thereby preventing neuro-toxic molecules that contribute to autism. This is a false and unsupported claim.

Treatments for Behavioral Disorders: Like parents of autistic children, parents of children with behavioral disorders (e.g., Hyperactivity and Attention Deficit Disorder) are vulnerable targets for sham products. These parents want their children to behave normally and want to avoid "drugging" them. Supplements claiming to treat these disorders promise time-tested methods that offer an alternative to drug therapy. These products often claim to contain ingredients that respond to the neurochemical bases of the behavioral problem. In fact, the physiological causes of these disorders are not fully understood and these claims are patently false.

The FDA has failed to do its homework. Its position is absurd and wrongly portrays autistic children as hopeless and untreatable. The editorial in this issue is a letter written to newly appointed FDA Commissioner Mark McClellan, M.D., who is widely regarded as being far more reasonable and open-minded than any of his predecessors. We are awaiting Dr. McClellan's reply to our letter. The FDA must reverse its deplorable, counter-factual position.

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Congress blasts FDA, CDC negligence on thimerosal

In May, after three years of investigation, the U.S. House Committee on Government Reform issued a scathing report charging federal agencies with negligence in failing to recognize and address the dangers of thimerosal-containing vaccines.

The report by the Subcommittee on Human Rights and Wellness is sharply critical of the insistence by Food and Drug Administration (FDA) officials that the risks of thimerosal, a preservative that is nearly 50 percent mercury by weight, are merely theoretical. "Upon a thorough review of the scientific literature and internal documents from government and industry," the report says, "the committee did in fact find evidence that thimerosal posed a risk. The possible risk for harm from either low dose chronic or one time high-level (bolus dose) exposure to thimerosal is not 'theoretical,' but very real and documented in the medical literature."

In fact, the report charges, "Mercury is hazardous to humans. Its use in medicinal products is undesirable, unnecessary and should be minimized or eliminated entirely."

The report charges that the FDA was negligent in failing to require drug manufacturers to conduct adequate safety testing on thimerosal, even though evidence of its toxicity has existed for decades. In addition, it faults both the FDA and the CDC for failing in their "duty to be vigilant" as the number of childhood immunizations climbed, increasing the cumulative mercury exposure of children nearly three-fold in the 1990s and pushing exposure levels to many times those considered safe by the government.

The report also criticizes the FDA for adopting an incremental approach to the removal of mercury from childhood vaccines—an approach that the report notes "allowed

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MMR linked to elevated risk of neurological damage; thimerosal associated with six-fold increase in autism

A study of the measles-mumps-rubella (MMR) vaccine reports "statistically significant increases in the incidence of serious neurologic disorders" following the vaccine, in comparison to another childhood vaccine.

Mark Geier and David Geier used Vaccine Adverse Events Reporting System (VAERS) data for 1994 through 2000 to determine the rate of serious neurologic symptoms reported within 30 days of MMR vaccination, comparing this number to the number of similar complications reported within 30 days of vaccination with the diphtheria, tetanus, and whole-cell-pertussis (DTwcP) vaccine. Among the complications studied were cerebellar ataxia, autism, mental retardation, and permanent brain damage.

Their results, the researchers say, show that "primary pediatric MMR vaccination in children is associated with a marked increase in serious neurologic disorders in comparison to DTwcP vaccination.... These results are remarkable considering that DTwcP vaccination has been found by the scientific and medical communities to be responsible for permanent neurologic sequellae in children."

These findings, Geier and Geier say, are consistent with previous studies showing that the MMR vaccine can cause serious neurological disorders, often resembling symptoms of the diseases the vaccines are intended to prevent. They also cite research indicating that the combined MMR vaccine is more likely to cause severe adverse reactions than the single vaccines for these diseases. Based on their findings, the researchers suggest that live MMR vaccine should be replaced by a killed-virus vaccine, or, if live vaccine is used, that parents should also be given the option to have the components of the MMR vaccine administered at different times.

Previous research by Andrew Wakefield and colleagues (e.g. ARRI 16/3, 16/2, 16/1, 15/4) links the MMR vaccine to a newly identified form of ileocolitis in autistic children.

Thimerosal ups autism risk six-fold

In a related report that updates recent research (see ARRI 17/1), Geier and Geier re-

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