CENTER FOR Science IN THE Public Interest

April 8, 2014

A Summary of the Science Linking Food Dyes with Impacts on Children's Behavior

A possible link between food ingredients and adverse behaviors such as hyperactivity was first raised in the 1970s, and while it attracted the attention of scientists as well as the public, the Food and Drug Administration (FDA) largely dismissed it. Over the past 40 years, dozens of studies have demonstrated that food dyes and other ingredients can prompt adverse behavioral responses in children.

Recently, even the FDA has acknowledged the growing body of evidence. After evaluating the numerous studies implicating artificial dyes in behavioral disorders, the agency concluded in 2011 that:

> Exposure to food and food components, including artificial food colors and preservatives, may be associated with adverse behaviors, not necessarily related to hyperactivity, in certain susceptible children with ADHD and other problem behaviors, and possibly in susceptible children from the general population.[i]

FDA official Mitchell Cheeseman cited that finding in an article responding to criticism of the agency's inaction on food dyes.[ii] The agency, however, still has not pursued regulatory action to protect the public by banning dyes or requiring a notice on labels warning that the dyes may cause adverse behavioral reactions. That contrasts with the British Food Standards Agency, which has encouraged the food industry to stop using certain food dyes; lists food establishments with products free from these food dyes; and advises consumers to eliminate certain food dyes from the diet of children showing signs of hyperactivity or ADHD.[iii] The European Parliament requires that foods throughout the European Union (EU) that contain certain food dyes bear a warning notice, "may have an adverse effect on activity and attention in children."[iv] As a result of those actions, few foods marketed in the EU contain some of the dyes most commonly used in the United States (including Red 40, Yellow 5, and Yellow 6).

Meanwhile, the evidence continues to mount. Three separate meta-analyses, including one sponsored by an arm of the food industry, have concluded that dyes can trigger hyperactivity or ADHD symptoms in sensitive children.[v] A recent review concludes that "food colour elimination is a potentially valuable treatment approach for ADHD."[vi] While the number of children with ADHD who are adversely affected by food dyes is not known, dyes nevertheless contribute an entirely preventable amount to the enormous costs to society of ADHD in children, estimated to be between $36 billion and $54.2 billion (in 2005 dollars, assuming a prevalence of 5 percent).[vii] Indeed, removing dyes from the food supply may be one of the only public health measures that could be deployed to reduce behavioral problems in children.

New Scientific Reports Bolster Decades of Evidence

Sonuga-Barke EJ, Brandeis D, Cortese S, Daley D, Ferrin M, Holtmann M, et al. "Nonpharmacological Interventions for ADHD: Systematic Review and Meta-Analyses of Randomized Controlled Trials of Dietary and Psychological Treatments." [viii]

- This meta-analysis of six non-pharmacological treatment options for ADHD found artificial food color exclusion to be the most effective.
- It concluded that excluding artificial food colorings from the diet, unlike most of the other treatment options, produced statistically significant reductions in ADHD symptoms in individuals selected for food sensitivities even when the analysis was limited to studies where the individual making the assessment was considered blind to treatment.
- The analysis found that the effect of excluding artificial colors from the diet on ADHD symptoms was similar in magnitude to what was reported in a previous meta-analysis (by Nigg, see below).

Nigg JT, Lewis K, Edinger T, Falk M. "Meta-Analysis of Attention-Deficit/Hyperactivity Disorder or Attention-Deficit/Hyperactivity Disorder Symptoms, Restriction Diet, and Synthetic Food Color Additives."[ix]

- Published in 2012, this meta-analysis, funded by the International Life Sciences Institute, an arm of the food industry, found that a restriction diet (which excluded certain items from the diet, including but not limited to food dyes) reduced ADHD symptoms in approximately 33 percent of children with the disorder. It estimated that 8 percent of children with ADHD may have symptoms related to food dyes.
- The study also found that in objective, computerized measures of attention, a significant effect was associated with FDA-approved food dyes and that those effects were not explainable by publication bias.
- The researchers deemed the findings "too substantial to dismiss."

Stevenson J, Buitelaar J, Cortese S, Ferrin M, Konofal E, et al. "Research Review: The Role of Diet in the Treatment of Attention-Deficit/Hyperactivity Disorder – An Appraisal of the Evidence on Efficacy and Recommendations on the Design of Future Studies."[x]

- This research review examined studies of dietary interventions for ADHD, concluding that "(a)rtificial food colour elimination is a potentially valuable treatment."

Other Significant Studies and Meta-analyses

Schab DW, Trinh N-H T. "Do Artificial Food Colorings Promote Hyperactivity in Children with Hyperactive Syndromes? A Meta-Analysis of Double-Blind Placebo-Controlled Trials."[xi]

- Published in 2004, this meta-analysis analyzed nearly three decades worth of research and found that the studies "strongly suggest an association between ingestion of (synthetic food dyes) and hyperactivity."
- It estimated that the magnitude of the effect of dyes is about a third to a half the deterioration in behavior that would occur if medications were withdrawn from children being treated for ADHD.

Bateman B, Warner JO, Hutchinson E, et al. "The Effects of a Double Blind, Placebo Controlled, Artificial Food Colourings and Benzoate Preservative Challenge on Hyperactivity in a General Population Sample of Preschool Children."; and McCann D, Barrett A, Cooper A, et al. "Food Additives and Hyperactive Behaviour in 3-Year-Old and 8/9-Year-Old Children in the Community: A Randomized, Double-Blinded, Placebo-Controlled Trial."[xii]

- These two studies were sponsored by the British government and published in 2004 and 2007.
- They differed from earlier studies in that they tested the sensitivity of children in the general population to a dye mixture that also included the preservative sodium benzoate. Several of the dyes used are used in the United States, though several are not, so the study may not be directly applicable in the United States.
- One of the studies concluded that "(a)rtificial colours or a sodium benzoate preservative [or both] in the diet result in increased hyperactivity in 3-year-old and 8/9-year-old children in the general population."
- The British government subsequently urged manufacturers to stop using the dyes tested in the studies (which includes the three dyes most widely used in the United States: Red 40, Yellow 5, Yellow 6). It also advised parents to protect children showing signs of hyperactivity or ADHD from those dyes.
- The editors of the American Academy of Pediatrics' journal, AAP Grand Rounds, stated: "Thus, the overall findings of the study are clear and require that even we skeptics, who have long doubted parental claims of the effects of various foods on the behavior of their children, admit we might have been wrong."[xiii]
- Ultimately, the European Parliament voted to require a warning label that reads "may have an adverse effect on activity and attention in children" on products containing the dyes.[xiv]

Endnotes

i FDA FAC (Food and Drug Administration Food Advisory Committee). "Overview and Evaluation of Proposed Association Between Artificial Food Colors and Attention Deficit Hyperactivity Disorders (ADHD) and Problem Behaviors in Children." 2011a. At http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM273033.pdf

ii Cheeseman M. "Artificial Food Color Additives and Child Behavior." Environ Health Perspect. Jan 2012; 120(1): a15–a16.

iii UK Food Standards Agency. "Products Free From the Colours Associated with Hyperactivity." At http://www.food.gov.uk/policy-advice/additivesbranch/foodcolours/colourfree/#.UlL9gRD0hD4; and UK Food Standards Agency. "Food Additives and Children's Behavior." At http://www.food.gov.uk/policy-advice/additivesbranch/foodcolours/colourfree/#.UlL9gRD0hD4

iv European Union. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. Available online. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF

v Sonuga-Barke EJ, Brandeis D, Cortese S, Daley D, Ferrin M, Holtmann M, et al. "Nonpharmacological Interventions for ADHD: Systematic Review and Meta-Analyses of Randomized Controlled Trials of Dietary and Psychological Treatments." Amer J of Psychiatry. 2013 Mar 1; 170(3):275-89; Nigg JT, Lewis K, Edinger T, Falk M. "Meta-Analysis of Attention-Deficit/Hyperactivity Disorder or Attention-Deficit/Hyperactivity Disorder Symptoms, Restriction Diet, and Synthetic Food Color Additives." Journal of the American Academy of Child & Adolescent Psychiatry 51(1): 86-97.e8, January 2012; and Schab DW, Trinh N-H T. "Do Artificial Food Colorings Promote Hyperactivity in Children with Hyperactive Syndromes? A Meta-Analysis of Double-Blind Placebo-Controlled Trials." J Dev Behav Pediatr. 2004; 25:423-34.

vi Stevenson J, Buitelaar J, Cortese S, Ferrin M, Konofal E, et al. "Research Review: The Role of Diet in the Treatment of Attention-Deficit/Hyperactivity Disorder – An Appraisal of the Evidence on Efficacy and Recommendations on the Design of Future Studies." Journal of Child Psychology and Psychiatry. First published online, February 19, 2014.

vii Pelham WE, Foster EM, Robb JA. "The Economic Impact of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents." J Pediatr Psychol. 2007;32:711-727.

viii Sonuga-Barke EJ, Brandeis D, Cortese S, Daley D, Ferrin M, Holtmann M, et al. "Nonpharmacological Interventions for ADHD: Systematic Review and Meta-Analyses of Randomized Controlled Trials of Dietary and Psychological Treatments." Amer J of Psychiatry. 2013 Mar 1; 170(3):275-89.

ix Nigg JT, Lewis K, Edinger T, Falk M. "Meta-Analysis of Attention-Deficit/Hyperactivity Disorder or Attention-Deficit/Hyperactivity Disorder Symptoms, Restriction Diet, and Synthetic Food Color Additives." Journal of the American Academy of Child & Adolescent Psychiatry 51(1): 86-97.e8, January 2012.

x Stevenson J, Buitelaar J, Cortese S, Ferrin M, Konofal E, et al. "Research Review: The Role of Diet in the Treatment of Attention-Deficit/Hyperactivity Disorder – An Appraisal of the Evidence on Efficacy and Recommendations on the Design of Future Studies." Journal of Child Psychology and Psychiatry. First published online, February 19, 2014.

xi Schab DW, Trinh N-H T. "Do Artificial Food Colorings Promote Hyperactivity in Children with Hyperactive Syndromes? A Meta-Analysis of Double-Blind Placebo-Controlled Trials." J Dev Behav Pediatr. 2004; 25:423-34.

xii Bateman B, Warner JO, Hutchinson E, et al. "The Effects of a Double Blind, Placebo Controlled, Artificial Food Colourings and Benzoate Preservative Challenge on Hyperactivity in a General Population Sample of Preschool Children." Archives of Disease in Childhood. 2004; 89:506-11; and McCann D, Barrett A, Cooper A, et al. "Food Additives and Hyperactive Behaviour in 3-Year-Old and 8/9-Year-Old Children in the Community: A Randomized, Double-Blinded, Placebo-Controlled Trial." Lancet. 2007(Nov 3); 370:1560-7.

xiii Editor's note. "ADHD and Food Additives Revisited." AAP Grand Rounds. 2008;19;17 DOI: 10.1542/gr.19-2-17.

xiv EU Action: European Parliament. European Parliament legislative resolution of 8 July 2008 on the Council common position for adopting a regulation of the European Parliament and of the Council of food additives.