

HYPERKINESIS
AND LEARNING DISABILITIES
LINKED TO THE INGESTION OF
ARTIFICIAL FOOD COLORS AND FLAVORS

BEN F. FEINGOLD, M.D.

AMERICAN ACADEMY OF PEDIATRICS
NEW YORK HILTON HOTEL
NOVEMBER 8, 1977

Mr. Chairman, Members of the Academy and Guests:

I have been allowed 15 minutes to cover 25 years of clinical observations on food additives and 15 years of observations on behavioral disturbances linked to the ingestion of food additives, more specifically artificial colors, flavors and the antioxidant preservatives butylated hydroxytoluene (BHT) and butylated hydroxyanisole (BHA), and also a group of foods containing a natural salicylate radical.

The basic hypothesis, which involves more than food additives, states: "Any compound in existence, either natural or synthetic, has the capacity to induce an adverse reaction in any individual with the appropriate genetic profile."

Recognizing that any compound under the appropriate conditions can induce adverse reactions, including behavioral disturbances, it becomes necessary to evaluate each compound or class of compounds on the basis of benefit compared with risk. Applying this measure to the food additives, we learn this about the colors and flavors: The colors and flavors are the most pervasive additives in our food supply, involving about 80 percent of our foods. By virtue of this widespread distribution, colors and flavors are the commonest cause of adverse reactions attributed to additives, affecting practically every system of the body. But colors and flavors have no nutritional value whatsoever. If they were removed from our food supply, nothing nutritionally would be lost. Therefore, on balance, the risk outweighs the benefit.

The Kaiser-Permanente or K-P Diet consists of two parts:

1. The elimination of all foods with artificial colors and flavors and the antioxidant preservative butylated hydroxytoluene (BHT) and butylated hydroxyanisole (BHA). We have observed over the last few years that BHT and BHA are of equal importance to the colors in behavioral disturbances.
2. The elimination of a selected group of foods containing a natural salicylate radical.

Our initial observation of a behavioral disturbance linked to the ingestion of food additives was in an adult, a woman aged about 40 whom we observed about 15 years ago. The patient presented with a complaint of angioedema of the face. She was managed with the K-P Diet with a favorable response. About ten days following the patient's response, I received a call from the Chief of Psychiatry of our medical center, inquiring as to what we had done for this patient whom he had in psychotherapy for two years because of her behavioral disturbances, her hostility toward her husband, her peers and others about her. Psychotherapy had failed, but on the diet both her angioedema and her behavior were controlled. The patient confirmed that on the diet she was completely controlled, while any infraction induced a complete return of the entire pattern.

We alerted the staff and found not only other adults but also a number of children. These children presented with somatic or physical complaints, e.g. nasal or skin conditions, etc. In the course of management with the K-P Diet, when that was indicated, the parents frequently reported not only a control of the somatic complaint, but also a favorable improvement in the child's behavior. These children had a behavioral pattern characteristic for the hyperkinetic impulse disorder, at times dating to infancy, characterized by aggression and disruption both at home and at school, conflict with peers, failing at school, and frequently on various behavior-modifying medications. When managed with the K-P Diet, they experienced not only an improvement in the somatic complaint, but also a rapid reversal of the behavioral pattern, requiring no further medication.

In order to confirm what the parents reported, it was necessary to go outside the Allergy Department to obtain patients whose primary complaint was a behavioral disturbance.

The initial group of 25 patients reported at the June 1973 meeting of the AMA in this city represented failures to respond to the conventional procedures in pediatrics, psychiatry and psychology, including various types and doses of behavior-modifying medications. Following our initial report, the question frequently raised included, "How was a diagnosis of hyperkinesis established in these children?", and "How did we rule out non-specific factors, e.g. placebo and Hawthorne effects, increased family dynamics and improved nutrition?".

The first case history in my presentation to the AMA in June 1973, which was rejected for publication, can perhaps very objectively answer some of the questions raised:

A seven year old boy presented with a history of extreme hyperkinesis of several years duration. When at home he stomped around, slamming the doors and kicking the walls and even charging oncoming cars with his bicycle. At school his hyperactive behavior was disruptive, resulting in his inability to learn. Numerous pediatricians were consulted as well as neurologists, psychiatrists and psychologists, including a complete medical and neurological survey at a medical center. Nothing succeeded until the child was placed on the K-P Diet. After a few weeks of dietary control, the child became well adjusted both at home and at school. Infractions of the dietary program led almost immediately to a recurrence of the hyperkinetic behavioral pattern.

As the case history indicated, the diagnosis was made by the various pediatricians and other professionals consulted both in private practice and at the medical center. It is hardly likely that dietary intervention entailed greater family involvement than all the procedures recommended to this concerned family. More importantly, it is now over five years since this patient was initially seen, and his behavior as well as that of the other children in the initial sample continues to be controlled. It is hardly likely that a non-specific effect is operating over the years. It is important to point out that even today the mothers report that the slightest infraction incurs a return of the behavioral pattern; however, recognizing the cause, the family can cope with the transient disturbance.

Since the initial case report, we have now observed about 458 of these children, most of them representing failure to respond to the conventional management recommended by various professionals.

Initially, our favorable response for improved behavior were 30 to 50 per cent, depending upon the sample and the age of the child. Today, with emphasis upon the elimination of BHT and BHA, our success for control of behavior is between 60 to 70 per cent of the children.

Any infraction, either deliberate or inadvertent, induces a reversal of the behavioral pattern within two to four hours, which persists for 24 hours to four days.

In addition to our own observations, there are other reports:

1. The initial attempt at a double-blind crossover study was funded by NIE, directed by Conners and reported in PEDIATRICS for August 1976. In this study Conners states, "The results of this study strongly suggest that a diet free of most natural salicylates, artificial colors and flavors reduces the perceived hyperactivity of some children suffering from the hyperkinetic impulse disorder."
2. In the MEDICAL JOURNAL OF AUSTRALIA of July 17, 1976, Cook and Woodhill reported their clinical observations on 15 children. Ten showed a good response, in some cases dramatically. The authors state the children served as their own controls by relapsing if they infringed on the diet.
3. The second study from Conners' laboratory was double-blind, funded by NIMH. This was reported by Goyette, Conners, et al, who state, "The authors believe that these data firmly establish that artificial colors may be particularly disruptive to young children."
4. Wisconsin Study - The data were taken from the study at the University of Wisconsin, funded by the Nutrition Foundation of New York. This study has received wide exposure in the lay press of this country and has stirred considerable controversy. It even preceded me throughout Australia as I visited the various cities there in September.

Forty-six children were included: 10 children between 3 and 4 years. All ten had a favorable response according to mothers' ratings and 4 out of 7 according to fathers' ratings. I understand this is a good track record for observations in behavior, indicating there must be something there.

Of the 36 children between 6 and 12 years, 4 responded favorably on parental and teachers' ratings as well as all objective studies. This is a remarkable response considering that the children were not controlled at school.

Dr. Harley, the principal investigator, admits the children were difficult to control and that infractions occurred once or twice a week. Once a week may turn them on for 4 days, while twice a week may turn them on completely. Under the circumstances, it is remarkable that any children showed a favorable response.

5. In CLINICAL PEDIATRICS for July 1977 Brenner reports as follows:
"Eleven of 32 children were markedly improved. A placebo effect could not definitely be ruled out, but the startling changes seen in patients who had been followed for years with other forms of therapy suggest strongly that this improvement was genuine."

An ongoing study funded by the FDA has as coinvestigators Dr. Hicks Williams of the Kaiser-Permanente Medical Care Program; Dr. Bernard Weiss of the University of Rochester; and Dr. Sheldon Margen of the University of California at Berkeley. This study is restricted to children 1 to 6 years of age and will focus on colors only, to eliminate as many variables as possible and also to permit absolute control of the children, who at an older age are subject to frequent infractions of the diet.

All investigators have noted an improvement in observed behavior. It is the consensus today that dietary intervention influences behavior.

Now the question is frequently raised, "Is the favorable response due to the elimination of the food chemicals, or is this a non-specific effect?"

Let us analyze the situation.

1. Infants as young as 3, 4 or 5 months of age, with a clinical pattern of sleeplessness, crying, fretfulness, unwilling to be cuddled, a pattern resembling colic, show a dramatic improvement within 24 to 36 hours following the removal of pediatric vitamin drops which contain artificial colors and flavors. The entire pattern recurs within 2 to 4 hours after the vitamin drops are returned. The on and off changes in the clinical pattern, occurring within hours, cannot be labeled as a non-specific effect in these young infants.
2. As I have indicated, practically all the children we have managed failed to respond to conventional procedures, e.g. behavior-modifying drugs, at times in inordinate doses and not infrequently 2 or 3 medications simultaneously; psychological and psychiatric therapy; family counseling; behavior modification; and special classes and individual instruction at school. Every conceivable technique and procedure has been applied to these children, often over a period of years, yet without success. Why should a few weeks, and at times even a few days of dietary intervention leading to complete reversal of the behavioral pattern be a greater non-specific influence than several years of management with various procedures?

And further, of extreme importance is the compelling evidence that challenge of these children, not once but repeatedly and often blindly, is followed within hours by a reversal of the behavioral pattern.

The comment of Dr. Theodore Cooper, former assistant HEW Secretary for Health, is very significant: "Thousands of parents from around the country who report favorable responses to the K-P Diet indicates there must be something there."

The problem of hyperkinesis and learning disabilities linked to the ingestion of artificial food additives and salicylates presents two aspects:

First, the clinical aspect which entails the responsibility for getting the patient well, without risk, without harm and without exploitation. This can be achieved in 60 to 70 per cent of the troubled children through diet management with the K-P Diet. Fortunately, the diet, unlike therapy with behavior-modifying drugs is a benign modality which carries no risk, since it introduces no harmful substances. Actually, potentially harmful chemicals which have never been proved safe are eliminated. Not one of the additives has ever been subjected to toxicological studies to determine their influence upon behavior. There need be no concern over the long-term hazards as one must consider with medications. Even today the long term risks with drugs are not known.

In the current issue of PEDIATRICS, i.e. October 1977, in an article on "Stimulant Drug Therapy in Hyperactive Children", Wolraich reports, "There is no clear effect of stimulant medication on intelligence and academic performance", and further, "At this time the long-term benefits from stimulant medication have not been proven."

If a practitioner rejects dietary intervention for hyperkinesis on the basis of a non-specific effect, he/she must in good conscience abandon a large part of the practice of clinical medicine which is empirical. How many of the day to day procedures of clinical medicine are precise? I am certain as clinicians you will agree that many times a day in your office, in the home and on the phone you are giving non-specific counsel.

The question of our responsibility to industry is frequently raised. I am very well aware of the responsibility to industry and the significance of these observations to industry, yet the primary responsibility is to the troubled children of the world.

The second aspect is the academic problems which entails considerable long and costly research to identify the specific compounds involved, their dosage and interaction, and the underlying mechanisms involved. There is a great need for further research in the field of nutrition, with increased emphasis upon nutrition in all branches of clinical medicine. All this MUST be programmed, but we cannot postpone our clinical responsibility to get these children well. That is the nature of the practice of medicine.