Medical Amelioration of Down's Syndrome Incorporating the Orthomolecular Approach

Henry Turkel, B.A., M.A. (D.Sc.), M.D.1

In 1959, before the U.S. Food and Drug Administration lapsed into insanity, I filed a new drug application for a combination of food factors and medicines I called the "U" Series, from the Greek prefix eu, a prefix selected for somewhat the same reasons, I assume, that Pauling selected the prefix ortho: to indicate normalization of abnormal factors in the cells.

By 1959 I already had 19 years of experience with the "U" Series in treating Down's syndrome patients.

Down's syndrome (mongolism) is one of the most disabling congenital disorders compatible with an almost normal lifespan. Mongoloids comprise the largest group of the institutionalized retarded. My feelings in 1959, therefore, were those echoed by a doctor of the Montana Physicians' Service in February 16, 1972: "Most certainly had Doctor Turkel's approach to this most unfortunate human malady met with even partial

¹ 8000 W. Seven Mile Road, Detroit, Mich. 48221.

success, it would have represented a major contribution to medical science and, obviously, would have gained wide recognition and general acceptance."

In other words, I expected the FDA to obey the laws governing it at that time and to approve the manufacture and interstate distribution of the "U" Series as a prescription drug (FDA Law: 1938). What went wrong?

To explain I must backtrack to 1935, my third year of medical school, when I did research in diabetes, arteriosclerosis, and allergies. I discovered that patients with these diseases all had one thing in common: accumulations of fats, water-soluble substances, and/or minerals.

I devised combinations of standard medicines. For diabetes, I prescribed lipotropic substances like betaine-cho-line tartrate, choline-methionine tartrate, inositol, unsaturated fatty acids, and dessicated liver. Brewer's yeast had been used to ameliorate diabetes since the early 19th century. However, lipotropic substances alone could not remove the fats responsible for arteriosclerosis because these fats were sheathed by minerals. I therefore prescribed carotene (vitamin A not yet being available) to

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decalcify mineral deposits. Other contents added for this purpose were thyreoglobulin and organic iodine.

For vasodilation, I gave nicotinic acid and pentylenetetrazol, together with L-glutamic acid as a nutrient. B-complex vitamins and minerals were included for their important metabolic functions and additional Pyridoxine as a coenzyme.

The need for ascorbic acid was especially emphasized by my research under Kahn, who developed the complement fixation syphilis test. Guinea pigs were sensitized to proteins in this study. Given adequate vitamin C, the guinea pigs survived a situation that otherwise produced fatal anaphylactic shock.

Theophylline was given at first, but I later substituted aminophylline magnesium glycinate, which was less nauseating. Rutin was added to preserve the integrity of the capillaries.

As antihistamines became available, they were promptly included to alleviate respiratory congestion and to eliminate fluids. Other substances, such as zinc and 3, 5, 3' Ltriiodothyronine were also added as they became available. A diuretic was prescribed twice weekly, on consecutive days, to help eliminate dissolved metabolites.

All of these substances were supplied simultaneously to obtain the synergistic effect.

This was my background in the treatment of genetic diseases when I became more involved with instruments I developed for tissue biopsies and bone-marrow infusions. Because of certain safety features of these instruments, such as a trephine tip and double needles, they became the standard instruments of the U.S. Armed Forces during World War II. During that war, as consultant to the Surgeon General's Office, I instructed medical and paramedical personnel to the use of the bone-marrow infusion instruments under combat conditions.

That is how it happened that in 1940, after an exhibit at a medical convention; I was approached by the father of a mongoloid and asked to treat his child. Quite a bit is now known about the

cause of mongolism, but in 1940 we were still as ignorant about the reason why some infants were born mongoloids as we still are, in general, about any treatment (Erbe, 1974).

We now know that in 98 percent of the cases of Down's syndrome, the cause is a prenatal mutation. The chromosomes are unequally divided during either meiosis or mitosis. If the mutation occurs in germinal cells prior to conception, the zygote is trisomic and the affected individual develops as a severely involved mongoloid.

If the mutation occurs during any stage of the development prior to organogenesis, only the cells derived from the one with 47 chromosomes contain the trisomy. This latter is the origin of mosaicism. Examined cells may or may not reveal the trisomy as it may be in an unexamined structure, or may have been discarded by the individual. Even apparently normal persons may be mild mosaic mongoloids, without being so stigmatized, because that diagnosis is not made unless there is a degree of mental retardation.

Chromosomes consist of thousands of genes that, through their enzymes, produce thousands of different normal metabolites. The products of an chromosome therefore excessive interfere massively with normal prenatal development. Unlike a single-gene defect, in which a specific abnormal substrate reaches a level that penetrates the placental barrier and is eliminated by the mother, a trisomic defect produces thousands of normal metabolites specific that remain unmetabolized because of the lack of consecutive enzymes. The metabolites, being the result of excessive but normal enzymes, apparently are not eliminated by the mother and are, therefore, distributed throughout the entire fetal organism and deposited within organs and tissues. There they interfere massively with adequate nutritional intake and waste elimination. A form of congenital malnutrition results. During gestation even nutrients that cross the placenta cannot efficiently

penetrate the massive accumulations of unmetabolized metabolites—each individually within the normal range—produced by the trisomy.

Thus, Tan et al. (1974) state that the simplest postulate to explain the abnormalities of Down's syndrome "is that the extra chromosome results in a linearly proportional increase of those products controlled by genes on chromosome 21. This increase then produces an imbalance between the products determined by chromosome 21 and the gene products determined by other chromosomes..."

This imbalance may result from the metabolic accumulations of fats, fluids, and minerals that can be seen when one examines the mongoloid and studies his x-rays. Since proper nutrition is absolutely essential for normal structural development and function of organs and tissues, the malnutrition of the mongoloid fetus and infant causes all structures to develop at a rate that is slower than normal. The underdeveloped brain causes mental retardation. The respiratory system is susceptible to infection. Congenital heart defects reduce the efficiency of the circulation. Delayed bone development causes bony articulations of joints to be widely spaced. The delayed development of the nasal bridge causes the excessive overlying skin to produce the characteristic epicanthal folds. Inefficient digestion and excretion produce additional accumulations of wastes-a vicious cycle.

When I treated my first mongoloid patient 34 years ago, the reasons for the accumulations of fats, fluids, and minerals were unknown. But I did know that all living cells require proper nutrients in optimal quantities for the specific cell to develop normally. As a medical student, I elected a course in dietetics. It became obvious to me that nutrients were important therapeutic agents in the treatment of disease, and this line of reasoning extended not only to the physical diseases, like diabetes, arterio-sclerosis, and allergies, but also to so-called mental illness including retard-

ation, which I perceived as medical problems, not amenable to "talk therapy" alone (Turkel, 1957).

The method I used to control genetic disease in the 1930's and 1940's, removal of the harmful expression of the genes by removing the accumulated metabolites, was a procedure later recommended by Haskins, in his address to members of the American Council of Learned Societies in January, 1969, when he predicted that "should such control ever become possible, the resultant psychological shock for us could be at least as great as that produced by the first atomic explosion" (Haskins, 1970).

Of course, if and when such "control" is made possible by Orthomolecular methods, the medical bureaucracy does its best to censor all references and denigrates its value. Examples are the APA's references to Orthomolecular psychiatry, the AMA's attitude toward the dosages of vitamin C that Pauling recommends to prevent and cure colds and toward vitamin E.

When Shute was asked why vitamin E was not accepted by the medical establishment, although he had treated more than 30,000 cardiac and other patients with this vitamin, he pointed out that in 1955, when he arranged to exhibit his evidence, the AMA mysteriously withdrew permission (Bricklin, 1974).

Removal of the harmful expression of the excessive genes was the only way that a mongoloid patient could possibly have been treated in 1940. In fact, at that time it was not even known that excessive genes were the cause of the observed accumulations. Since nothing was known about the cause, I had to refer back to previous experience with diabetic, allergic, and arteriosclerotic patients.

I prescribed this same series of medicines, to which nutrients were now added, because of the retardations seen in mongoloids, and also digestive enzymes because of their underdeveloped digestive organs.

Quantitative ratios of the "U" Series must be determined by individual examination of the patient and must be adjusted according to his response (see Chart 1).

Readers familiar with the FDA's stereotyped response to medical treatments that emphasize the importance of nutrients for amelioration of serious medical disorders will quickly comprehend how it has come about that the FDA provided me with a monopoly in the treatment of Down's syndrome with the "U" Series. According to the FDA, a combination of standard medicines is a "new drug," and as such must be approved by that agency for interstate shipment.

In 1959; after a presentation of my findings at a meeting of the AAAS, when I first applied for new drug approval, the law stated only that a new drug must be safe (Harvey, 1962). The agency was also responsible for the labeling of medications, presumably to assure accuracy. The "U" Series was safe even in the opinion of federal agencies like the FDA and NIH. At that time the objection to

CHART 1

CONTENTS OF MEDICATION COMPRISING THE "U" SERIES OF DRUGS

UMORPHOID - A	(BREAKFAST)	LIPNFOID - B	(AT BEDTIME)
Thyroid Globulin	(BREAKFAST)	is Uppenid A but Enteric Coated	(AT BEB HITE
Organic Iodine	66 mg	is ophobia A but Entene obated	
			(PBN)
	25.000 Linits	UPNEOID – C Naphazoline Hydrochloride	0.05%
Vitamin E	10 mg	Pyrilamine Maleate	
	IBREAKEAST LUNCH DINNER	Chlorpheniramine Maleate	0.25%
		Methyl Paraben	
Cluterie Asid	200 mg	Propyl Paraben	0.01%
	50 mg		(LUNCH)
Nicotinic Acid			
UPEPTOID - A	(BREAKFAST, DINNER)	Thiamin Mononitrate (B ₁)	
Betaine-Choline Fartrate		Riboflavin (B ₂)	
		Calcium Pantothenate	
		Para Aminobenzoic Acid	
		Pyridoxine (B ₆)	
	/5 mg	Niacin	
UPEPTOID – B	(DINNER)	Niacin UTROPHOID - C Ealio Acid	(DINNER)
Betaine Hydrochloride			
Papain		Cyanocobalamin (B ₁₂)	
		Calcium	
		Cobalt	
		Copper	
		lodine	
Desoxycholic Acid		Iron	10 mg
UPNEÓID – A	(BREAKFAST, LUNCH, DINNER)	Magnesium	1mg
Phenylpropanolamine Hydro	chloride	Manganese	1.25 mg
Pyrilamine Maleate		Molybdenum	0.1 mg
Rutin		Zinc	
Ascorbic Acid	100 mg	Bone Meal (Breakfast, Lunch, Dinner)	200 mg
		Glutamic Acid (Breakfast, Lunch, Dinner)	
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DO NOT ADD ANY VITAMIN "D" AS A SUPPLEMENT - IT IS CONTRA INDICATED TO THE "U" SERIES DRUG.

SUGGESTED STARTING DOSAGES

3 months to 2 years	1/6 to 1/3 of Full Dosage
2 years to 6 years	1/3 to 1/2 of Full Dosage
6 years to 10 years	1/2 to Full Dosage
10 years and over	Full Dosage

If the patient's age indicates a dosage size which would be intermediate between those available, it is suggested that the patient be placed on the larger size since the dosages are figured on the minimal level.

SUGGESTED SUPPLEMENTARY MEDICATION

1. All patients may receivé, at the physician's discretion, L. Triiodo-Thyronine as follows:

3 months to 2 years	5 mcg daily with breakfast
2 years to 6 years	10 mcg daily with breakfast
6 years to 10 years	12.5 mcg daily with breakfast
10 years and over	25 mcg daily with breakfast

Edematous patients must receive a potent diuretic for two consecutive days each week during the entire course of the treatment as follows:

3 months to 2 years	1/6 to 1/4 size Dosage
2 years to 6 years	1/4 to 1/2 size Dosage
6 years to 10 years	1/2 to 3/4 size Dosage
10 years and over	3/4 to Full size Dosage

Non-edematous patients in whom excessive calcification or indication of accumulation of mineral deposits is seen on x-rays should receive similar dosages of diuretics as above at the physician's discretion.

3. Additional Supplement, Calcium Pantothenate, pyridoxine, zinc, magnesium and teething lotion.

SOME OF THE INDIVIDUAL DRUGS WITHIN THE "U" SERIES MAY BE SUBSTITUTED BY PHARMACOLOGICALLY-EQUIVALENT DRUGS, SUCH AS THE VASODILATORY PENTYLENE TETRAZOLE MAY BE REPLACED BY VASODILAN OR OTHER SIMILARY-ACTING DRUGS.

the only effective medical treatment for the amelioration of a dreadful disease was that I had not provided "suitable" labeling (Yakowitz, 1960). At no time did the FDA ever specify the type of labeling that would be satisfactory. In correspondence with the FDA in 1960, I was informed by Mr. Yakowitz of the Bureau of Enforcement that it was doubtful that the "U" Series could benefit mongolism because "the condition is caused by a defect in the basic cell structure (an abnormal number of chromosomes). This finding, considered together with the long history of inability of medical science to find a treatment or cure for mongolism suggests that this condition is beyond hope of successful treatment by the kind of preparations that you wish to recommend for this purpose." (Emphasis mine). He also stated that "the proposed mixture of pentylenetetrazol with nicotinic acid is regarded as unscientific." It is not reported who considers it unscientific since this very same combination was approved for other pharmaceutical companies.

At this time, the FDA was stalling on the approval of new drugs, waiting for a "hard case" (Barnes, 1967). This came in the form of the thalidomide tragedies that gave the medical staff of the agency the power of public hysteria needed to urge Congress to pass "bad law"—the 1962 Amendments requiring "proof" of efficacy, arbitrarily determined by the FDA, a test that aspirin could not have passed if introduced as medication after 1962. Ironically; the trouble with thalidomide was **not** its lack of efficacy as a tranquilizer, but rather its danger to the fetus.

In a 1963 letter (Lockhart, 1963), the FDA admitted, "It is our opinion that it may be impossible to write suitable labeling for the efficacy of this product; in view of the cytogenetic basis of mongolism, we recommend that you abandon work on this application," thereby preventing other physicians from obtaining the "U" Series for the treatment of mongolism. No doubt the FDA is correct in stating that it may be impossible to write labeling for the role played by each nutritional factor: as Roger J. Williams has pointed out, the action of food factors is synergistic (Williams, 1973). The catch, therefore, is that I must write suitable labeling for the drug's effectiveness, but FDA regulations-are so worded that it is impossible to write acceptable labeling.

The FDA, also in 1963 (Smart, 1963), invited me to submit more evidence, but stated, "Because of the fundamental nature of mongolism, and because a number of preparations being used by Dr. Turkel have been experimented with in this condition without success, we think it will be difficult for Dr. Turkel to prepare a rational plan." Thus, I was invited to apply for approval to investigate the drugs (IND), but was simultaneously warned that it would be "difficult" for me to come up with a plan that the FDA would approve.

Then suddenly, only one year after the new law requiring "proof of efficacy" was passed, the FDA terminated all further investigation, with the order: "You should immediately recall the drug from all clinical investigators and discontinue administering it to human beings" (Lar-rick, November 26, 1963).

Because the "U" Series could no longer be investigated in the United States, my thoughts paralleled those of Sabin, who gave over the first use of the oral polio vaccine to Russia when it was blocked in the United States for 10 years. Approached during a convention of military surgeons by an official of the Japanese National Institute of Mental Health, Dr. Makoto lida, in 1964, I was asked about the "U" Series. We spent a day together discussing the manufacturing process and use of the "U" Series.

In the meantime, I could not believe what was happening in our country. I could not have foreseen that by 1974 scientists would be complaining that, under the laws passed in 1962, it would have been impossible for the FDA to approve aspirin, quinine, or penicillin. Obviously, something was wrong with the law, or the FDA's interpretation of it,

so that it is now necessary to spend some 10-15 years and untold millions of dollars to obtain new drug approval, not to mention what Senator Hartke has called "a deferred bribe"; the promise by a large drug company of a lucrative position to a key member of the FDA after he leaves the agency (Hartke, 1974).

I forgot about the Japanese and continued with my own battles. By December 12, 1966, the FDA was clearly tiring of my persistent attempts to obtain new drug approval of the "U" Series. Hodges of the Bureau of Medicine wrote (1966): "It is extremely unlikely that this product will ever meet the stringent requirements of the Federal Food, Drug and Cosmetic Act, as amended." The agency informs Congressmen, Senators. physicians, and parents that I can comply if only I will, but it has admitted privately that it has prejudged the case, apparently from the beginning in 1959. The agency has even gone so far as to convince a Court of Appeals that the application is incomplete as regards the safety of the medicines because no level of toxicity was obtained on the animal studies. That is to say that none of the animals given the most massive dosages were persuaded to die. At the worst, they vomited (U.S. Court of Appeals, 1970). If this is indeed the case, then it is true that the "U" Series will never meet the stringent standards set by the FDA-because the medicines are too safe.

By these tactics, the FDA has, for the past 15 years, blocked the treatment of mongolism and other genetically-caused disorders.

Rather than look at original objective data, the FDA has preferred to rely on an unsubstantiated report of a badly conducted double-blind study (Bumbalo, 1964). Only 12 children were treated and all of these were administered contraindicated vitamin D. It is merely stated in the report that there were no changes, and this "evidence" is quoted as gospel by the FDA. My evidence that the fifth finger was straightened in several patients—the evidence of x-rays—was refuted by an expert of the FDA, inexperienced

in the medical treatment of Down's syndrome, who quoted what he called a medical "Bible" that called it a permanent defect (HEW Hearing, 1967).

The phenomenal growth experienced by patients like Evelyn and Judy was dismissed as resulting from the extra parental care given to treated children. The double-blind report states, "The weights and heights of all 24 children remained more or less in the same range." This is like saying there was no significant change in the height and weight of Evelyn because what she lost in weight she gained in height. Without specific numbers, we have no way to interpret the assertion that there was no change. I was not given the opportunity to see any of the objective data although I sponsored the study and first heard about the "negative" results from Lock-hart of the FDA, who told me that they were about to be published in the JAMA. Since that time anyone requesting information from the FDA about the "U" Series from the FDA is told that I did not report the Bumbalo study, although to this day I have never seen any of the records (Figures 1, 2, and 3).

As anomalies are reduced, esthetic appearance also improves. Development accelerates and is faster than normal, especially during the first year of treatment. If medication is discontinued prematurely, prior to normalization of excretory organs, new anomalies (i.e., edema, calcifications, premature aging) develop (Chart 3).

Such data, and the many similar facts submitted in the NDA, were meaningless to the staff of the FDA. However, they have convinced many doctors in private practice that they wish to treat their own patients with the "U" Series. Unfortunately, this combination is unlike most other methods of Orthomolecular therapy. When doctors become aware of the time and effort presently involved in the preparation of these numerous contents, they prefer to refer their mongoloid patients to me. For example, the specific items must be ordered, and some, like organically bound iodine (or iodine and

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CHART2

'U' Series aids in speedy development of retarded bones -





DIAGRAMMATIC EXPLANATION OF "STRAIGHTENING" OF THE CURVED FIFTH FINGER.

Uctober 1961

Malnutrition due to metabolic blockages prevents normal development of the proximal and distal inner growth centers of the 2nd phalanges of the 5th fingers. Such an hypoplasia causes by mechanical means a concave configuration of the fifth finger. The elimination of these accumulations with the aid of the "U" Series resolves that malnutrition and the hypoplastic structures are then able to resume their delayed growth --- and with it the concave configuration becomes obliterated.



AMELIORATION OF DOWN'S SYNDROME

FIGURE 1A EVELYN complete



ORTHOMOLECULAR PSYCHIATRY, VOLUME 4, NUMBER 2, 1975, Pp. 102 - 115

FIGURE 1B



AMELIORATION OF DOWN'S SYNDROME

Figure 2 JUDY complete



ORTHOMOLECULAR PSYCHIATRY, VOLUME 4, NUMBER 2, 1975, Pp. 102 - 115

JUDY - Figure 3

IMPROVEMENTS: ESTHETIC STRUCTURAL FUNCTIONAL IMPROVEMENT IS AGE REGRESSION REGRESSION IS PREMATURE AGING



CHART 3A

Henry Turkel, M.D. 8000 W. 8 Mile Road Detroit, Michigan 48221 July 10, 1970 RE: George Oliver Johnston File #73252

SKELETAL SURVEY: 7-10-70

There is mild shortening of the base of the skull. No other cranial vault abnormality is identified.

Chest shows the heart to be somewhat prominent. There is prominence of the pulmonary vascularity. This may be related in part to the patient's supine positioning, however clinical correlation would be necessary to exclude an intracardiac shunt. The lungs appear free of an active disease process.

There is generalized mild bone atrophy. The cortises of the bones are thin. There is generalized diminution in the size of the bones. The comparative views show the patient's skeletal age to be that of an infant of 2 years of age. There is flaring of the iliac wings. Flattening of the acetabulae is present. Bilateral coxa valga. Clinodactyly of the fifth digits of the hands is present.

IMPRESSION: Findings compatible with mongolism. Skeletal age is two years. The general overall findings are those of generalized paresis with soft tissue and bone atrophy.

Increase in pulmonary vascularity suggests the possibility of an intracardiac shunt.

Richard A. Rideout, M.D. (Signed) RAR/eh

CHART 3B

Henry Turkel, M.D. 8000 West 7 Mile Road Detroit, Michigan 48221 May 27, 1971 RE: George Oliver Johnston File #79577

BODY SURVEY: 5-27-71

There has been significant interval enlargement of osseous structures secondary t« growth. Frontal sinuses are absent. Primary teeth are still demonstrated. There has been no interval change in these findings as compared to previous study. Comparative views of the patient's wrists show the skeletal age to compare closest to the standards for males of 3 years and 6 months. Cardiovascular shadows are similar to the previous study and there is again suggestion of increase in pulmonary vascularity.

IMPRESSION: Significant interval increase in size of the child with interval improvement in skeletal age radiographically. The configuration of the cardiovascular structures is still suggestive of intracardiac shunt.

J. Richard Jaconette, M.D. (Signed) JRJ/bs

Birth		6yrs.3mo.	7yrs. 1 mo
Date	4-12-64	7-10-70	5-27-71
Bone Age		2yrs.	3/2 yrs.
Wt.	3.2 lbs.	16 lbs.	32 lbs.
Ht.	17 in.	32 in.	38 in.

accelerated development during first IOVi months' therapy

hexamine), are difficult to locate in the dosage prescribed. Care must be taken in the composition of certain substances that can nullify each other's action if not put together correctly. Medicines must be weighed, compounded, capsulated, counted, placed in envelopes and labeled; nasal spray and teething lotion are prepared to my specifications in bulk, but then must be bottled and labeled: all very time consuming.

At the same time that I am burdened with this unnecessary work, parents are burdened with extra expenses, including those related to the often long trip to Detroit. Other American doctors are denied the right to treat their patients with medicines they want to prescribe, and children whom parents and doctors want treated are denied the right to treatment. In Japan during the past 10 years more than 3,000 mongoloids have been treated with the "U" Series in 60 university and national hospitals under the auspices of the Japanese National Institute of Mental Health.

Despite the fact that the Japanese were unable to obtain thyreoglobulin, penty-lenetetrazole, and the organic amino-phylline, the first two of which are the most important ingredients for mental progress, and the third for improved general health, the results were as follows: one-third of the children improved significantly both mentally and physically, and another third improved significantly physically only.

Unfortunately, this long-term study that proves both safety and efficacy does not fulfill the requirements of the FDA, which seem specifically formulated to keep Orthomolecular therapies that depend primarily on vitamins out of the reach of patients and their doctors. However, I am convinced that if the American people became more fully aware of the therapeutic potential of Orthomolecular medicine—a term that can be extended to include not only Orthomolecular psychiatry for the treatment of mental illness (or to use Kowalson's term, metabolic dyspercepttion) and amelioration of mental retardation, but also cancer (with vitamin B17, Culliton, 1973) or chronic diseases like diabetes, arthritic or heart disease (vitamin E) —they would storm Congress to force a change in FDA policies, policies that are becoming increasingly hostile to the medical use of nutritional factors. No one is unaffected by these policies, either because a member of his own family is ill or because of consequent unrest in the community.

There are approximately 50-60 million slow learners in the United States (and many additional potentially bright children who suffer from including learning disabilities dvslexia). Illiterate, they cannot support themselves in a manner to which they would like to become accustomed. They are therefore easily led into crime (CA.P., 1967). Many of them may have trisomy G, but their chromosomes are not studied. Many others may have a different genetic disorder that could be ameliorated by the "U" Series or other Orthomolecular therapy. For example, Hoffer (1973) has written, "Over one-third of all murderers diagnosed as insane were pellagrin. One can conclude that had they not had pellagra, there would have been a major decrease in crimes of violence." By denying the value of nutritional factors in the prevention and treatment of serious diseases, the FDA is, in my opinion, not only responsible for much sickness and misery, but also for much of the social disruption and violence we are now experiencing in communities throughout the United States.

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