NUTRITIONAL PRODUCT FOR PERSONS INFECTED WITH HUMAN IMMUNODEFICIENCY VIRUS

FIELD OF THE INVENTION

The present invention relates generally to a liquid enteral nutritional product which has been formulated to address the nutritional needs of persons infected with human immunodeficiency virus (HIV).

BACKGROUND OF THE INVENTION

A profound wasting disease in humans associated with *Pneumocystis carinii* pneumonia was first described in the United States in 1981. The investigation of the symptoms associated with this disease ultimately focused public health and political structures on a disease described as acquired immunodeficiency syndrome (AIDS). AIDS is defined by infection with the human immunodeficiency virus (HIV), and by the onset of several opportunistic infections, syndromes, and/or malignancies. These include, but are not limited to, tuberculosis, *Pneumocystis carinii* pneumonia, Salmonella bacteremia, Kaposi's sarcoma, *Mycobacterium avium intracellulare*, herpes simplex, toxoplasmosis, cytomegalovirus (CMV), dementia complex, and wasting syndrome.

The cell types infected by HIV play a role in defining the efforts of the virus on patterns of infection, and ultimately the effect of the disease on the metabolic and nutritional state of a person infected with HIV. The immune system develops several types of cells to deal with infection, including B and T lymphocytes, which produce antibodies and directly attack the invading pathogen. These cells and others, including macrophages, monocytes, and other cell types involved in the immune response, communicate through protein factors which they secrete (cytokines) and/or through the types of proteins and glycoproteins they display on their surface.

Health care professionals dealing with HIV-positive and AIDS patients face a multitude of management issues, including control of opportunistic infections and malignancies. Two major factors underlying how a patient may respond to the therapies required to manage the disease are: (a) the nutritional status of the patient early in the infectious process, and (b) the ability of the patient to take in and tolerate adequate nutrition.

There is disclosed herein a liquid nutritional product for enteral feeding which is formulated, on the basis of the latest and most compelling research, to meet the specific nutrient needs of persons infected with HIV. This calorie and nutrient-dense, low fat nutritional product contains enterotrophic peptides, a fat source high in omega-3 fatty acids, and fiber. Enterotrophic peptides appear to modulate a particular receptor pathway in cells which reduces the expression of apoptotic genes and alters the phosphorylation of cell division control protein. The peptides significantly reduce the expression of the apoptotic-associated gene, amyloid beta precursor protein, and apoptotic rescue protein. (This protein is a marker for the induction of cell death). This nutritional regimen results in a reduction in the rate of intestinal cell death.

These formula components promote changes in the gastrointestinal tract that result in improved nutritional and physiological status for a HIV-infected person. The vitamin and mineral profile of this nutritional product provides for repletion of the nutrients for which HIV-positive persons have been shown to be at risk of depletion or deficiency. The nutritional product also contains β-carotene.

The nutritional product of the present invention is acceptable total enteral support and may be consumed, either orally or by tube feeding. Flavor variety, Orange Cream and Chocolate flavors are disclosed herein, promotes compliance when the nutritional product is used as an oral supplement or as a total oral diet when a person's condition precludes intake of solid foods.

DISCUSSION OF PRIOR ART

There has been a great deal written about nutritional support of persons infected with HIV.

Villous atrophy of the small intestine may be detected early in the course of HIV infection and in the absence of enteropathogens, so it has been postulated that the intestinal tract may be severely affected by HIV. The histological appearance of villous atrophy seen in HIV infection is unlike the classic villous atrophy seen in gluten-sensitive enteropathy or tropical sprue because the enterocytes appear normal and there is no increase in intraepithelial lymphocytes. This resembles the villous atrophy seen in graft versus host disease of bone marrow transplantation, and this raises the possibility that an immune response within the mucosa may be responsible. Griffin, "Human Immunodeficiency Virus Infection and the Intestine", *BAILLIERE'S CLINICAL GASTROENTEROLOGY*", Vol. 4, No. 3, pages 657–673 (1990). Apoptosis of crypt cells in AIDS patients was reported soon after the disease was identified. Kotler et al., "Enteropathy Associated with the Acquired Immunodeficiency Syndrome", *ANNALS OF INTERNAL MEDICINE*, Vol 101, No. 4 pages 421–428 (1984).

Trujillo et al, "Assessment of nutritional status, nutrient intake, and nutrition support in AIDS patients", *JOURNAL OF THE AMERICAN DIETETIC ASSOCIATION*, Vol.92, No.4, pages 477–478 (1992) reports observations that hospitalized AIDS patients can consume only 70% of estimated basal energy needs and 65% of protein needs, which does not account for the increased needs of hypermetabolism associated with acute infection or any physical activity. Patients with AIDS have moderate to severe metabolic stress similar to that found in other critically ill patients. This stress, coupled with the anorexia and malabsorption associated with the disease, promotes malnutrition. Irrespective of any possible specific relationship between nutrition and the HIV disease process, malnourished patients will be debilitated and unable to function optimally. Malnutrition in general affects five areas of functionality: reproductive competence, immunocompetence, work performance and/or behavioral performance and cognition. *THE FASEB JOURNAL*, Vol. 5, No. 10, pages 2329–2330, at page 2330 (1991)

Food-borne infections must be scrupulously avoided in immunosupressed patients, because what would be a minor incident for a healthy person might become life threatening. HIV infected patients are 300 times more susceptible to salmonella than healthy persons if they ingest contaminated food. Dwyer, "Nutrition Support of HIV+Patients", *HENRY FORD HOSPITAL MEDICAL JOURNAL*, Vol. 39, No. 1, pp. 60–65, at page 62 (1991). Kotler, "Nutritional Effects and Support in the Patient with Acquired Immunodeficiency Syndrome",