

Background and History of Laminine

WHAT IS LAMININE?

Laminine is an amino acid peptide which has all the required nourishment to sustain life. (An **amino acid** is the building block of protein in which each is linked together through peptide bonds; and a **peptide** is an amino acid compound that consists of 2 or more amino acids).

There are *over 100 amino acids* that occur naturally, but only twenty of them are involved in making up a protein, and are classified as either *non-essential* or *essential*. Non-essential amino acids are so named because they can be synthesized in the body. These include alanine, arginine, aspartic acid, asparagine, cysteine, glutamic acid, glutamine, glycine, proline, serine, and tyrosine. Essential or *indispensable* amino acids cannot be synthesized in the body and can only be obtained through food. These become the rate-limiting factors for the synthesis of certain proteins in the body. The essential amino acids are histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine.

Before the production of the supplement known as Laminine, no other companies had developed and marketed a combination of amino acids, peptides, and growth factors required to sustain robust health.

THE HISTORY OF LAMININE:

In 1929 a Canadian doctor, Dr. John Ralston Davison, theorized that an injected extract from fertilized hen eggs could be helpful for a number of his cancer patients. Davidson spent well over a decade developing and researching his theory. He published a number of studies on his discovery in the Canadian Journal of Medicine, however, when Dr. Davidson passed away in 1943, his research on fertilized hen eggs quickly and quietly came to a halt and was lost.



It wasn't until almost 50 years later that the pursuit of fertilized hen egg extract was revived by Norway's foremost expert on egg research, Dr. Bjodne Eskeland.

Dr. Eskeland also hypothesized that incubated, fertilized hen eggs contained a special combination of amino acids, peptides, and protein fractions that could help provide an incredible array of health benefits when consumed by humans.

In theory, these partially incubated, fertilized eggs – specifically 9-day-old fertilized eggs – contain all the nutrients required to start a new life. This includes vitamins, minerals and proteins, as well as important defense factors, growth factors, hormones and other biologically active components. While not much was known about the growth factor at the time, the high level of oligopeptides (small peptides) found in Laminine allows for rapid transport across the membranes of the gastrointestinal tract in order to provide effective benefits from these amino acids.

Manufacturer of Laminine:

Laminine's parent company, LifePharm Inc., researched what was being done with this key ingredient, also called YTE or Young Tissue Extract, that had demonstrated so many health-associated benefits. LifePharm contacted the team of scientists in Norway working with YTE, and now have exclusive rights for distribution of this product under the brand name "Laminine" and have it manufactured exclusively for them.

A patented process extracts the critical nutritional fluid from the white of an egg at the protoembryonic stage (only the egg-yolk is present and no developing chicken), so the manufacturer called it **Proto-Embryonic Stage Extract (PESE)**. The extract not only provides a mechanism of rapid transport of very critical nutrients, but also

contains Basic **Fibroblast Growth Factor**, which is probably responsible for the amino acids and peptides being utilized in the right manner, by "directing" their use by the body. This growth factor is also responsible for nurturing the body's own **stem cells** both differentiated, and undifferentiated (undifferentiated stem cells can rebuild any of the tissues of the body). Common amino acid formulations do not contain this growth factor, and may not be utilized by the brain in the most efficient manner.

A team of scientists lead by Dr. Alex Martin, a leading doctor in the study of nutritional supplements, at the LifePharm institute of technology went to work to develop what they termed "the perfect supplement". Using PESE as a base ingredient, they looked at the symptoms caused deficiencies in most by our diets, and the toxins in our environment, and then evaluated methods to "super charge" the PESE for modern day use. Skin and hair, health, moods (depression), memory loss, fatigue and cardiovascular health are most commonly affected by today's lifestyle. These symptoms and how Laminine addresses them are covered later in this booklet.

Having a perfectly balanced, natural, transport mechanism with PESE LifePharm knew that the added amino acids will not only find their way to the right areas of the body, but would be guided properly to perform their function efficiently. The manufacturer then added the amino acids most critical for the health of your skin, hair, memory function, cardiovascular health and restoration of energy, from natural plant protein and marine protein. These protein ingredients from land ("phytoproteins" or plant proteins from the yellow pea), sea (marine protein sources from shark cartilage) combine to form and enhance the powerful symbiotic relationship of the base ingredient in Laminine that is called **OPT9**.



Laminine[®]

Suggested For Adult Use:
As a dietary supplement, take 1-4 capsules a day.

Supplement Facts		
Serving Size: 1 Capsule		
	Amount Per Serving	%Daily Value
OPT9™ Proprietary Blend	620 mg	*
(Fertilized Avian Egg Extract, Marine Protein, Phyto Protein)		
* Daily Value (%DV) Not Established		

Other Ingredients: Vegetable Gelatin, Silicon Dioxide, Magnesium Stearate

SPORTS NUTRITION

OPT9 and creatine reinforce each other (there is no added creatine in the Laminine product). The net result of using this combination is improved performance, decreased fatigue, and a reduced risk of energy depletion in the muscles.

In 1996, a double-blind trial on the use of PESE conducted at the University of Colorado showed that the group using it experienced a strength increase that was nearly double that of the group using creatine alone. PESE and creatine together were found to outperform creatine and other food supplements in the areas of endurance, training, motivation, and subjective health and well-being, and it has the enthusiastic endorsement of many top athletes. They report recovering faster after training. This is linked to a substantial reduction in lactic acid production, which also contributes to increased stamina.

But what does creatine have to do with OPT9? It appears that creatine and the egg protein fractions that are found in OPT9 reinforce each other, resulting in a prominent increase in effectiveness. This means that bodybuilders and athletes experience greatly enhanced benefits when adding Laminine to their regimen. No wonder the product has the enthusiastic endorsement of so many professional athletes and bodybuilders.

Whether it is a physical or mental challenge you face or just the need to handle everyday demands, Laminine may help.

Benefits may include:

1. A delay in lactic acid production
2. The ability to tolerate longer training sessions.
3. Improved Stamina
4. Maximum Muscular Strength
5. Faster Recovery after training sessions
6. Quicker recovery from physical exertion
7. Better muscle tone
8. Increased muscle strength

MEMORY ENHANCEMENT

The most pronounced effect of artificial sweeteners and MSG in the body is to interfere with this synergistic performance. The manufacturer therefore decided to address this issue when they formulated Laminine.

Memory function is controlled by a well-balanced joint effect of Glutamate and Glycine. Both these amino acids act synergistically together to play a critical role in the ability of two neurons to connect, an important cellular mechanism for learning and memory to take place. PESE is low in these amino acids. Therefore, Laminine enhances these levels in OPT9 by the addition of an isolated vegetable protein (from the yellow pea) to provide extra glutamic acid and with marine protein extract (from purified shark cartilage) to provide extra Glycine. PESE is used to provide additional FGF in the aid of memory. FGF is known to build neurites, the bridges between the neurons and which act as the receptors and transmitters of signals. Research shows FGF also inhibits and eliminates mutant protein genes, in this case, quite possibly blocking the genes responsible for memory loss.

In 1962, it was discovered that that neurologic stem cells reside in certain parts of the brain, often where damage or dysfunction is present. It is also scientifically proven that **Fibroblast Growth Factor (FGF)** feeds and nurtures these stem cells to facilitate the healing of this damage, dysfunction, and scarred tissue. Lately, compelling arguments have been made to inject FGF directly to treat or cure Huntington's disease, Schizophrenia, OCD and Autism.

The synergistic effect of building the neurites, nurturing the stem cells, having the most relevant amino acids and factors to guide where the amino acids go, makes Laminine perform extremely well in memory enhancement.

Another very effective combination in Laminine is the combination of the two ingredients Leucine and Isoleucine. This combination is increased by combining the PESE and the vegetable protein extract. Leucine and Isoleucine provide ingredients for the manufacturing of many essential biochemical components in the body, some of which are utilized to stimulate the upper brain and help you to be more alert and focused.

It's no wonder there have been reports of many positive effects of Laminine with people suffering from Alzheimer's syndrome, ADD, and a general increased memory and mental focus in our busy lives.

MOOD ENHANCEMENT AND DEPRESSION

Depression is caused by many internal as well as external factors, including stress. In the brain, the serotonin uptake and release mechanism is affected. Serotonin is an essential neurotransmitter which has been called the "happy chemical", as it is associated with feelings of contentment, well-being and happiness. Serotonin also supports cognitive functions, including memory and learning. The SSRI (Selective Serotonin re-Uptake Inhibitor) market is an \$18 billion dollar per year market providing prescription drugs which have demonstrated the ability to increase serotonin levels within the nerve synapses, thereby causing mood improvement and alleviation of depression. But these benefits do not come without significant expense and some notable side effects. Conversely, Laminine is an all natural product that contains the amino acid Lysine; derived from PESE and natural vegetable proteins. The combination of these two components delivers a higher level of Lysine in the OPT9 than either ingredient would by itself (this is called synergism). Lysine is known to regulate serotonin levels in the brain.

Some 20 million people worldwide experience depression serious enough to warrant being placed on prescription medication (usually an SSRI). Many, an estimated 16 to 30 percent, who take such drugs experience sexual dysfunction as a side effect. Some medical experts believe the true number of people experiencing this side effect may be as high as 78 percent due to the fact that the condition often goes unreported by patients. Clinical studies have shown that Laminine may be beneficial in enhancing libido among those taking antidepressants.

Many people taking Laminine report a pronounced improvement in their mood and an increased ability to manage stress on a daily basis. A greater overall engage with others and desire to accomplish things.

CARDIOVASCULAR HEALTH AND LIBIDO ENHANCEMENT

The PESE and Vegetable proteins provide a very potent dose of Arginine. Arginine is a precursor of nitric oxide and plays a vital role in a variety of biological processes. The inner lining of blood vessels uses nitric oxide to signal the surrounding smooth muscle to relax, thus resulting in increased blood flow. Effects include modulation of the hair cycle, and increased libido. Nitric oxide is also known for growth hormone formation, increasing defense of the internal organs against effects of aging.

REMOVING TOXINS FROM THE BODY

PESE contains *Cysteine*, which is a precursor to glutathione, a powerful antioxidant, receiving much attention today for healthier looking skin. Antioxidants fight free radicals, (free radicals are harmful compounds in the body that damage cell membranes and DNA). Free radicals occur naturally in the body (during the normal energy-producing metabolic processes within our cells), but environmental toxins (including ultraviolet light, radiation, cigarette smoking, and air pollution) can increase the number of these damaging particles. Free radicals are believed to play a role in aging as well as the development of a number of health problems, including heart disease and cancer.

NAC (N-Acetyl-Cysteine) is a powerful anti-oxidant and can help prevent side effects caused by drug reactions and toxic chemicals, and helps to alleviate and break down mucus in the body. NAC appears to have benefits in treating some respiratory conditions, such as bronchitis and COPD. This is very crucial for the body's life functions, as NAC helps the body neutralize toxins, heavy metals, such as mercury from dental amalgam fillings, cadmium and lead from paint, and cigarette smoke. The Sulfhydryl balance has also been linked to enhance resistance to viral infections. NAC is one of the most effective oral chelating agents. Taken regularly over a period of time, NAC will remove many toxic heavy metals from the body. NAC has been shown to be a protective agent in many diseases and conditions in which free radicals play a role. This includes cancer, AIDS, cirrhosis, as well as pollution damage from smoking or other chemicals.

The added potent dose of Glycine, from a natural marine protein source, further enhances the anti-aging effect of glutathione in the body. Glycine from the marine protein also builds collagen, making the skin look healthier and less wrinkled.

SKIN, HAIR, & HEALTH

The manufacturer has added an additional component to OPT9 in Laminine. The added potent dose of Glycine, from marine protein, further enhances the anti aging effect of glutathione in the body. Glycine from the marine protein also builds collagen, making the skin look healthier and less wrinkled.

Hair is composed from protein. L-Cysteine is an amino acid that is known to promote hair growth. It improves hair quality and texture, and it is known to double the length of hair. L-Cysteine also prevents hair from falling out, and it has a detoxifying effect in the body. The PESE and Vegetable proteins also provide a very potent dose of Arginine. Arginine is a precursor of nitric oxide and these effect the modulation of the hair cycle.

THE LECITHIN CONNECTION AND CONTROLLING CHOLESTEROL

Years ago, pioneering nutritionist Adelle Davis recognized the error in the assumption that eating cholesterol-rich foods causes a buildup of cholesterol in the arteries and leads to heart disease. She taught that a 'cousin of the fat family', lecithin, plays a vital role in controlling blood cholesterol levels. Lecithin, found in the human body (and concentrated in the brain), is a fat emulsifier that breaks down cholesterol, preventing its buildup in the body, Lecithin is also found in eggs. While they may provide cholesterol, they also provide the lecithin needed to break cholesterol down.

FATIGUE & ENERGY

Laminine combines the two ingredients Leucine and Isoleucine (known as branched chain amino acids) from the PESE with an added dose from the vegetable protein extract. Leucine and Isoleucine provide ingredients for the manufacturing of other essential biochemical components in the body, some of which are utilized for the production of energy, stimulants to the upper brain and helping you to be more alert.

Many people today are mildly fatigued, and others are seriously energy deficient. Fatigue is a symptom that accompanies most illnesses, both acute and chronic: it is often an early warning sign that serious health problems are in the process of developing. Persistent, extreme fatigue may be a sign of chronic fatigue syndrome (CFIDS). The Center for Disease Control (CDC) estimates that chronic fatigue syndrome affects between 100,000 and 250,000 people in the United States, but many researchers believe that the disorder is much more prevalent than that. What is certain is that there are many tired people everywhere struggling to get through each day.

Whether you're a professional athlete or a weekend warrior, you could probably use more energy, who wouldn't want to feel more energetic, in order to better face the challenges, both physical and mental, in life. Those whose work demands mental concentration are being sapped of energy just like those who have physically demanding jobs. Whether the task at hand is a tennis match or a chess tournament, increased energy and stamina can lead to a better outcome.

STRESS MANAGEMENT & IMPROVED SLEEP

Use of Laminine promotes a feeling of relaxation effect that may be to some degree attributed to the dramatic decrease in levels of the stress hormone cortisol produced after Laminine's ingestion.

As indicated, Laminine reduces stress-hormone levels dramatically in the body.

When cortisol levels decline, we feel more relaxed. Studies show that virtually everyone who uses Laminine

experiences a greater sense of relaxation and with it, many extra benefits, such as improved sleep.

Elevated levels of stress hormones not only make us feel on edge, but also predispose us to a number of stress-related diseases, which include serious conditions such as hypertension, heart disease, stroke, asthma, irritable bowel syndrome, ulcerative colitis, eczema, and autoimmune disorders. By managing stress-hormone levels, we may be helping to prevent or manage these disorders.

HOW DOES LAMININE WORK & WHAT'S IN IT?

What does Opt9 Contain?

OPT9 contains a natural combination of nutrients, including amino acids, glycopeptides, and oligopeptides that come from fertilized eggs, isolated natural plant proteins (yellow pea), and natural marine elements (purified shark cartilage) that work together to form a *super food* or *nutraceutical* for the support of both the mind and the body.

The Health Benefits of Laminine

Laminine has been associated with a variety of potential health benefits, including: increased strength and vitality, improved stamina and energy, increased libido (in both men and women), reduced stress, improved sleep, quicker recovery after workout and improved muscle tone, increased lean muscle mass, increased alertness and mental clarity, reduced "brain fog", improved mood, improved calmness and happiness (Laminine has been called "the happy pill"), and overall improved sense of well being.

These various effects may all be related to the significant reduction of the stress hormone **cortisol** (by about 50 percent) after the ingestion of Laminine, as well as increases in the happy chemical, **serotonin**. Additionally, Laminine provides the precursors (building blocks) to nutritionally support the production, and maintenance of **laminin** in the body. Laminin is the protein network foundation for most cells and organs in our bodies.

Laminins are an important and biologically active part of the basal lamina, and influence how the cells of our body differentiate (stem cells), migrate, hold together (adhesion) and survive. Laminin has been called the "**rebar of the human body**" much like rebar (strong metal rods) structurally hold together and strengthen concrete used to build buildings and highways.

What exactly is PESE, and how much is known about its benefits?

Proto Embryonic Stage Extract (PESE) is the name the manufacturer has given the ingredient in Laminine that is derived from the liquid whites of partially incubated (9 days old) fertilized organic hen eggs. The cholesterol-containing yolk is excluded. PESE contains the most potent and balanced combination of amino acids, as well as other factors such as **Fibroblast Growth Factor (FGF)**. Amino acids derived from such fluids combined with the growth factors are able to enhance brain function because they are precisely engineered to support the most complex stage of development of a living creature, the beginning of life. This beginning is the most critical stage in our development, just like the take-off is the most complex function in flying an airplane, or the foundation (and structural rebar) is in construction, and is the most essential function in the life of a building.

The health benefits of the hen egg have been known for centuries. Recently, further investigation of the mechanism of the development of an embryo in an egg during incubation has revealed the scientific equivalent of the "miracle of life". The potency of the nutrients available to the embryo at the latter stage of development stage has always been assumed to be high, but it was only recently that the chemical structure of the original egg solids for these critical stages was obtained. During this stage, oligopeptides with small molecular weights were identified. These short chains of amino acids are able to cross the digestive barrier without breaking down or changing the ratios and proportions. Peptides are far more potent than other neurotransmitters, requiring only small amounts to produce a profound effect. Heat can destroy these critical protein factors, and Laminine should not be heated over 118 degrees. It should be protected from prolonged exposure to heat, and should never be mixed into steaming hot liquids, or baked into foods.

Additionally, the uptake of the **Fibroblast Growth Factor (FGF)** (present in PESE) by the embryo sharply increases and the FGF present have been isolated through a patented process precisely at the right stage of incubation, extracted and freeze dried to bring the “miracle of life” benefits to humans.

Extracting PESE before the peptides and FGF are “used up” to build organs and bones, allows us to provide this building, repairing, maintenance mechanism of perfectly balanced amino acids, peptides and growth factors to humans. While virtually unknown in the United States until very recently, PESE has been marketed successfully as a nutritional supplement in Scandinavia for many years.

How is Fibroblast Growth Factor (FGF) helpful to humans?

The precise blend of oligopeptides may be seen as building blocks, but without a bridge, or a master builder/director. The role of such a director is fulfilled by a growth factor known as the Fibroblast Growth Factor, or FGF. FGF is prolific in PESE, as well as in the human placenta. A detailed day-by-day study was performed in 1988. Discovered four decades ago in the seventies, and also existing as a peptide, this FGF is critical in the development of embryos, including humans. However, it is not found to be circulating in the human adult bodies. FGF is responsible for building the linings in the blood vessels, creating the infrastructure for the nutrients to flow to critical areas of the brain and organs. Research credits FGF with the potential to directly affect many neurologic disorders because of the ability of FGF to affect the growth of neurites. Neurites are signal senders (Axons) and signal receivers (Dendrites) that are attached to the brain neurons.

Research has also clearly demonstrated that new cell cultures show a dramatic increase in peptide and amino acid uptake in the presence of FGF. This result supports the hypothesis that embryonic growth is influenced by a very precise mechanism, which combines unique combinations of amino acids, peptides and FGF.

Since FGF is not circulating in adults, multiple research projects on the effects of FGF serums to cure neurologic disorders have been carried out. Fundamental to the research is the fact discovered by *Altman* in 1962 that neural STEM cells are formed by the body in response to *abnormalities*, and are resident in certain zones of the brain undergoing biologic stress. The brain is therefore ready to repair the damage, and these cells have shown to differentiate into a wide range of neurons. Neurons derived from such neural stem cells are capable of migrating to various regions of the Central Nervous System.

Use of vegetable proteins

Vegetable protein has an essential amino acid profile, which is very close to that of the ideal protein for human nutrition (FAO/WHO 1985 and 2002). For Laminine, a patented process further isolates these proteins in order to eliminate unnecessary compounds which can neutralize the benefits of the essential amino acids. The result is a compound which is high in Glutamic acid, (further enhancing the cognitive function of the brain), branched chain amino acids (to counter insomnia), Lysine (to control release of serotonin, controlling moods), and Arginine (promoting Nitric Oxide and growth hormone formation). These specially isolated proteins create a synergistically potent composition to enhance brain activity.

Use of Marine Proteins

The high levels of Glycine in the specially extracted marine protein (purified shark cartilage) used in Laminine, combined with a significant amount of hydroxyproline to stabilize the glycine, makes it a primary candidate for a terrific brain food. By itself, Glycine is a neurotransmitter, primarily utilized by the brain to control glutamate levels. In combination within OPT9, it becomes a powerful force to enhance memory function in the brain.

AMINO ACIDS AND THEIR ROLES

Amino acids are critical to life, and have many functions in metabolism. One particularly important function is

as the building blocks of proteins, which are linear (straight) chains of amino acids. Laminine's unique blend of ingredients combines to produce a complete chain of 20 amino acids. The following is a list of those amino acids and their potential benefits. Amino acids are organic compounds that combine to form proteins. When proteins are digested, amino acids are left. The human body requires a number of amino acids to grow and breakdown food and is a very important part of nutrition.

A complete balance of amino are contained in Laminine and include:

Essential	Nonessential or Conditionally Essential
Histidine	Alanine
Isoleucine	Arginine
Leucine	Asparagine
Lysine	Aspartic acid
Methionine	Cysteine
Phenylalanine	Glutamic acid
Threonine	Glutamine
Tryptophan	Glycine
Valine	Ornithine
	Proline (Hydroxyproline)
	Selenocysteine
	Serine
	Taurine
	Tyrosine

Glycine and glutamine are precursors of nucleotides. Nucleotides are molecules that, when joined together, make up the structural units of RNA and DNA. Please note: Glutamic acid and Glutamine are NOT monosodium glutamate. There is no added MSG in Laminine.

These building blocks of proteins perform various vital roles in the body and help us to remain healthy in many ways.

- Antioxidants helping with combating free radicals and environmental toxins including ultraviolet light, radiation, cigarette smoking, and air pollution.
- Benefits in treating some respiratory conditions, such as bronchitis and COPD. Angina, Chronic bronchitis and Chronic Obstructive Pulmonary Disease (COPD), Influenza, Acute Respiratory Distress Syndrome (ARDS), HIV/AIDS.
- Reducing symptoms of asthma, cystic fibrosis, and emphysema.
- Helping to Improve or Preventing colon cancer.

- Helping to Improve or Preventing cataracts and macular degeneration.
- Helping increase HDL “good” cholesterol.
- Helping increase fertility when taken along with fertility drugs in people with polycystic ovary disease.
- Helping improve outcome in children with advanced cerebral adrenoleukodystrophy, a type of leukemia.
- Helping treat cocaine addiction, schizophrenia, and gambling addictions.
- Reducing lung cancer risk among smokers.
- Decrease Cell oxidation.
- Enhances neurotransmitters in the brain.
- Assist in the formation of tooth enamel.
- Blood coagulation regulation.
- Immune response.
- Increased memory function, cognition, and voluntary movement and learning ability.
- Aid in the elimination of toxic ammonia in the form of nitrogen from the body.
- Improve hair and skin.
- Fight insomnia.
- Increase energy and endurance.
- Regulation of blood pressure under stress.
- Controls release of serotonin and mood improvement.
- Increased vasodilatation which increases blood flow.
- Humans with atherosclerosis, diabetes or hypertension often show impaired Nitric Oxide pathways.

THE ROLE OF PEPTIDES

Small amino acid chain peptides (such as those contained in Laminine), commonly known as oligopeptides, are very easily transported through the intestinal membrane. They are sometimes used as transport mechanisms for drugs.

Peptides are short polymers formed from the linking, in a defined order, of α -amino acids. Proteins are multi peptide chains. Proteins must be broken down to smaller and smaller peptides, and eventually an amino acid, to perform its functions. Dietary intake of peptides and amino acids, which can reach their destination, therefore, can be extremely beneficial. Peptides are the most abundant compounds in the hypothalamus of the brain, and perform vital functions of communicating sensory impulses to the endocrine system (hormone producing glands).

Understanding the mechanisms of the effect of peptides, and the types of peptides, is a complex field and is being studied extensively. Unfortunately, these studies are done in isolation and disregard the whole picture of the many complex mechanisms which exist in our body. Further, these studies are usually focused on a particular amino acid, peptide or other neurotransmitters. While the results identify the final activity with the amino acid/peptide, the mechanism of transport of such critical amino acid/peptides to the final destination is a subject of major arguments. These arguments cast a shadow on the importance of nutritional supplements. Most doctors will tell you that nutritional supplements “cannot hurt”, but stop short of endorsing them. The reason is the lack of evidence that the active ingredients have been formulated in the correct form that can be used by the body.

For more information, please call toll-free: **800-230-7995** or **800-378-1578**

See also: <http://www.StevenPetrosino.com>

Disclaimer: Like all nutritional supplements, this product is not intended to diagnose, mitigate, treat or prevent any disease.