CAUSE NO. D-1-GV-07-001386

STATE OF TEXAS, Plaintiff, vs. MANNATECH INCORPORATED; MANNA RELIEF MINISTRIES; THE FISHER INSTITUTE; SAMUEL L. CASTER, Individually; and REGINALD McDANIEL, Individually, Defendants.	§ § § § § § § § § § § §	IN THE DISTRICT COURT OF TRAVIS COUNTY, TEXAS 353 JUDICIAL DISTRICT

Filed In The District Court of Travis County, Texas
JUL -5 2007 3:45 P.M.
At
Amalia Rodriguez-Mendoza, Clerk

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW THE STATE OF TEXAS, acting by and through Attorney General Greg Abbott ("State"), and files Plaintiff's Original Petition, complaining of and against MANNATECH INCORPORATED, MANNA RELIEF MINISTRIES, THE FISHER INSTITUTE, SAM CASTER, Individually, and REGINALD McDANIEL, Individually, ("Defendants"), and would respectfully show the court the following:

AUTHORITY

1. This action is brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §431.060, §431.047, and §431.0585 of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. §431.001 *et seq.* ("TFDCA"). Section 431.060 of the TFDCA specifically provides that the Attorney General, to whom the Commissioner

of the Texas Department of State Health Services ("TDSHS") reports a violation of the TFDCA, shall initiate and prosecute appropriate proceedings. In addition, §431.047 authorizes the Attorney General to seek injunctive relief under certain circumstances and recover any costs and attorney fees incurred in obtaining that relief. This action is also brought pursuant to §431.0585, which authorizes the Commissioner of Health to refer matters to the Attorney General to seek civil penalties in favor of the State for violation of §431.021 of the TFDCA and regulations pursuant to that Act.

2. This action is also brought under the authority granted to the Attorney General by §17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.* ("DTPA"), upon the grounds that Defendants have engaged in false, misleading, or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by, §§17.46(a) and (b) of the DTPA.

PARTY DEFENDANTS

3. Defendant MANNATECH INCORPORATED ("Mannatech"), a Texas corporation, is doing business in Texas at 445 S. Royal Lane, Suites 200 and 800, Coppell, Texas, 75019, and may be served with process through its registered agent, Corporation Service Company, 701 Brazos St., Ste. 1050, Austin, Texas, 78701.

4. Defendant MANNA RELIEF MINISTRIES ("MannaRelief"), is a Texas corporation doing business at 3017 Red Hawk Dr., Grand Prairie, Texas, and may be served with process through its registered agent, George Reninger, at 530 South Carrier Parkway, Grand Prairie, Texas, 75051.

5. Defendant THE FISHER INSTITUTE, is a Texas corporation doing business at 580 Decker Dr., Irving, Texas, and may be served with process through its registered agent, John W. McCuistion, at 580 Decker Dr., Ste 100, Irving, Texas, 75062.

6. Defendant SAMUEL L. CASTER ("Caster"), is Chairman and Chief Executive Officer of Defendant MANNATECH INCORPORATED, and works at 445 S. Royal Lane, Suite 800, Coppell, Texas, 75019, and may be served with process at that address.

7. Defendant REGINALD McDANIEL ("McDaniel"), was formerly the "Medical Director" of Defendant MANNATECH INCORPORATED, and currently holds a similar position with Defendant MANNA RELIEF MINISTRIES. On information and belief, Defendant McDANIEL also generally controls the operations of Defendant THE FISHER INSTITUTE. Defendant McDANIEL resides at 4 Woodland Dr., Mansfield, Texas,76063, and may be served with process at this address.

VENUE

8. Venue of this action lies in Travis County pursuant to §431.047(c) and §431.0585(d) of the TFDCA by virtue of the fact that Defendants are engaged in the business of manufacturing, offering to sell, and selling unapproved new drugs and/or misbranded or adulterated foods in Texas.

PUBLIC INTEREST

9. Because Plaintiff STATE OF TEXAS has reason to believe that Defendants MANNATECH INCORPORATED, MANNA RELIEF MINISTRIES, THE FISHER INSTITUTE, SAM CASTER, Individually, and REGINALD McDANIEL, Individually, have engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE OF TEXAS has reason to believe that Defendants have caused and will continue to cause injury, loss, and damage to the STATE OF TEXAS, and its citizens, and will also cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings

are in the public interest.

ACTS OF AGENTS

10. Whenever in this petition it is alleged that Defendants MANNATECH INCORPORATED, MANNA RELIEF MINISTRIES, THE FISHER INSTITUTE, SAM CASTER, Individually, or REGINALD McDANIEL, Individually, did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was performed by agents or employees of Defendants and in each instance, the agents or employees of Defendants were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of Defendants.

TRADE AND COMMERCE

11. Defendants MANNATECH INCORPORATED, MANNA RELIEF MINISTRIES, THE FISHER INSTITUTE, SAM CASTER, Individually, and REGINALD McDANIEL, Individually, have, at all times described below, engaged in conduct which constitutes "trade" and "commerce" as those terms are defined by §17.45(6) of the DTPA.

NATURE OF DEFENDANTS' CONDUCT

12. Defendants MANNATECH INCORPORATED, MANNA RELIEF MINISTRIES, THE FISHER INSTITUTE, SAM CASTER, and REGINALD McDANIEL operate an elaborate scheme designed to promote the sales of Mannatech's dietary supplements. Defendants market and sell such dietary supplements as a way to cure, mitigate, treat, or prevent diseases, illnesses, or serious conditions, despite Defendant Caster's admission that the products do not cure any disease, and despite the fact that this marketing violates both federal and state food and drug laws, as well as the Texas Deceptive Trade Practice - Consumer Protection Act. Defendants are aware that such

marketing techniques are illegal, and try to distance themselves from responsibility for these illegal disease claims for their dietary supplements in numerous ways, including: substituting the word "glyconutrients" for the name of Mannatech's products; setting up alternate websites; claiming that third parties who they have no control over are making the illegal claims in books, videos, and other marketing materials; using testimonials to make claims that Defendants' products cure, mitigate, treat, or prevent diseases; and employing the facade of a disciplinary policy for associates making illegal disease claims, all the while enabling the system under which the claims are made.

13. Defendants' products are dietary supplements under federal law and are regulated as foods in Texas pursuant to Chapter 431 of the Health and Safety Code, known as the Texas Food, Drug, and Cosmetic Act ("TFDCA"). By law, claims cannot be made that dietary supplements are intended to cure, mitigate, treat, or prevent disease. Only drugs approved by the Federal Food and Drug Administration ("FDA") can be represented to have intended uses to cure, mitigate, treat, or prevent disease.

14. The FDA, by affidavit, states that it has not approved any new drug applications for Defendant Mannatech. Moreover, the FDA further states that it has not approved any new drug application for the products[1] marketed by Mannatech or its affiliates or for Manapol or glyconutrients. Therefore, Defendants cannot legally market any of their products as drugs by making claims that these products can cure, treat, mitigate, or prevent disease. (See Exhibit 1 attached).

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[1]Ambrotose, Glycentials, Phytomatrix, CardioBalance, GI-Pro, GI-Zyme, ImmunoSTART, Man-Aloe Classic, MannaCLEANSE, Ambrostart, Manna-C, Mannatonin,Glyco-Bears, Manna-Bears

15. Defendants know that their products are not approved as drugs and know that it is illegal for them to make claims that these products are intended to cure, mitigate, treat, or prevent disease. Nevertheless, they continue to employ their deceptive scheme for monetary gain, earning in excess of $400 million in 2006. In particular, to further their sales, Defendants make disease claims, directly or indirectly, at corporate events, on corporate or affiliated websites, and through marketing material, websites, and sales presentations of Defendants' associates.[2]

Corporate Events

16. Defendants host at least four corporate conventions each year - the event in Texas is called "MannaFest" - to promote their products. One essential element of each of the events is a time set aside for testimonials, often referred to by Mannatech as "Life Experiences." These testimonials, which are generally made by Mannatech's associates and their families and friends, make numerous claims that Mannatech products have cured, mitigated, treated, or prevented diseases. The whole purpose of the testimonials is to create a frenzy and motivate associates to sell even more products, in large part through the relaying of deceptive claims set forth in the testimonials. Moreover, as explained below, the testimonials are recorded on video so that associates may later use them to assist in the sale of Mannatech's products. The following testimonials are just a few examples of the type of illegal disease claims about Defendants' products that are made at these corporate events:

A. Testimonial 1: A woman testified that her four year old son was initially

[2]In addition to selling directly through its website, Mannatech also sells its products through a Multi-Level Marketing structure, which utilizes thousands of affiliates - or associates - around the country to sell Mannatech's products.

developing normally according to all the markers, but eighteen months after his well-child check, he started presenting bizarre behavior. He soon lost basically all language ability and all ability to make eye contact. In October, 2004, he was diagnosed with autism. In March, 2005, the woman testified that he started on "the product" (i.e. Mannatech products). In three days he started talking. Today, according to the woman, he has normal eye contact, social skills, and dramatically improved language. Now he has no sensory issues, he eats well, and sleeps well.

B. Testimonial 2: A man testified that he was diagnosed with Non-Hodgkin's B-cell Lymphoma a little over one year ago. The oncologist told him cancer had spread to eight places in his body and that they could not cure it, but with treatment could give him as many years as he could. He started doing research and a dear friend and chiropractor gave him some information about "glyconutritionals" (i.e., Mannatech products), which he started taking. He testified that after five months, his lab work started looking better. He continued to improve, and in June the doctor told him that maybe he didn't have lymphoma after all. The last lab work indicated seven spots were cancer-free, and the one remaining spot (originally the size of a racquetball) was now size of a pea.

C. Testimonial 3: A woman shared a story about a friend of hers who had severe chest pain at home and passed out and was rushed to the hospital. The doctors told the family that she had to be put into a comatose state or she

would die from a stroke or massive heart attack. They put her into a comatose state and sedated her heavily. She got pneumonia and then developed staph in her lungs. After one week, the doctors told the family that she wasn't going to make it and took her off the medications. A friend of hers that is a Mannatech associate finally got the doctors to give her "the product." She started on products at 5:00 Wednesday night. By 5:00 on Thursday morning she was making facial motions. At 8:00 that morning the nurse called two of her sons in and they couldn't believe what was going on – she was blinking her eyes and she did it on command. On Friday she started speaking a few words. In total, she was in ICU for one week, was in the hospital on a regular floor for another week, and spent two weeks in rehabilitation. She's now back to work, she has her life back, and her family and children have their mom back.

17. In addition to the testimonials, at each of Defendants' corporate conventions, Defendants dedicate a large area of the convention facility to vendors and other persons to sell promotional materials designed to help Mannatech's associates promote Defendants' products. Defendants, who obtain a financial benefit from these vendors, know or have reason to know that many of the marketing materials that are sold make illegal claims that Defendants' products cure, mitigate, treat, or prevent disease. A few examples of the illegal disease claims for Defendants' products made in materials sold at Defendants' MannaFest and similar conventions include the following:

A. Defendants facilitated the offering for sale of a CD titled "Back from the

Brink" by Michael Schlachter, M.D. This CD provides example after example of how "glyconutrients" (i.e. Mannatech's products) cured, treated, or mitigated diseases, including but not limited to toxic shock syndrome, heart failure, asthma, arthritis, Lou Gehrig's Disease, Attention Deficit Disorder, and lung inflammation. Examples of these claims include:

1. "We administered 25g of this glyconutrient at 9PM that third night. The same amount was repeated four hours later. By eight o'clock the next morning, without any change whatsoever in therapy except for the addition of the special glyconutrient formula, Greg's pulses returned. Greg's legs and arms were now warm. Only hours before, they were ice-cold. By morning, the severe metabolic acidosis, which indicated dying cells, had all but reversed. I had never seen anything like this. A few hours earlier, Greg was at the point of death. Now, Greg was at the point of recovery. This formula had reversed what we had been told in medical school would be an irreversible process."

2. "My first introduction to this glyconutrient formula came from a physician friend, Dr. Blaine Purcell, who had been telling me of some of his patients with asthma, who no longer needed steroids for therapy. These patients had been on lifelong steroids. Now, in my experience, being a pulmonary specialist, when a person with asthma requires lifelong steroids, they can't function without them. They practically suffocate without them. Dr. Purcell went on to say that his asthma patients were eliminating the steroids largely due to this glyconutrient."

3. "My second case was a gentleman who suffered from heart failure, arthritis, and asthma. Scripps Clinic gave him the prognosis that he would have to live with his illness and get ready to die. ... I put him on a solid program of glyconutrients and scheduled an appointment to see him in six weeks. Five and a half weeks later, this man practically burst into my office to tell me he was feeling great and that he did not need to see me. He proceeded to do a knee bend, and proclaimed that if he had tried that six weeks ago, he would have fallen to the ground and not been able to get up. A few weeks later when I rechecked his heart function, it had improved from one-third normal to entirely normal. To add to this, his asthma symptoms were also resolved."

4. The Brink CD concludes with:

"Thank you for listening to the "Back from the Brink" audio program. This information you just heard could dramatically affect the quality of your life as well as the lives of your loved ones. Since research shows that these biological sugars are very likely missing from your diet, they are now available to everyone through nutritional supplementation. You may be wondering how to order this special glyconutrient formula for you and your family. The same formula that Dr. Schlachter used and continues to use with his patients. Since this formula has been patented, it's available through only one company only. To order, please get back with the person who shared this important health breakthrough with you. And remember, glyconutrients are for everyone, whether you feel great and want to enhance your health even more, or whether you're struggling with a health condition. Your body depends on these glyconutrients."

B. Defendants further endorse the making of a disease claim to cure, treat, or mitigate Down syndrome for their products through a book offered at their conventions titled, **A Gift Called Michelle**, which includes a forward by Defendant Reginald McDaniel, who at the time the forward was written was the Medical Director of Mannatech. At MannaFest 2006, Michelle, a Down syndrome girl who is the subject of the book, was in attendance signing copies of the above book. The book also includes "before and after" pictures of Michelle, including an "after" picture of Michelle with Defendant Caster.

1. The McDaniel forward makes the following claims:

"I requested to hear from other parents with significant improvements in children with Down syndrome which resulted in over 50 positive responses with the addition of micronutrients to the diet...Each child's genes know what to do with elements and nutrients, if the right and sufficient nutrients are added back into the diet. The same results were reported from parents with children having: cerebral palsy, leukodystrophy, fragile-X syndrome, autism, and a wide range of gene caused malfunction and development based alterations in cellular synthesis, physical damage to the brain and the neuromuscular system, other organs that include types of muscular dystrophy and other rarer enzyme or glycoprotein gene defects that include hemophilia."

2. Excerpts from the book, which has been endorsed by both Defendants McDaniel and Caster, include:

   a. p. 9. "...we were introduced to glyconutritionals through a friend. Almost immediately Michelle was transformed from a chronically sick child to a well, asthma and ADHD-free child....In 2001 *Las Vegas Magazine* ran a feature article called "Beating the Odds in Vegas," about a man who had a near-death experience from streptococcal toxic-shock syndrome but who returned to health from giving him aggressive amounts of glyconutitionals....Suddenly it became evident that these supplements were changing more than health. They were changing the features of a chromosomal disorder!"

   b. p. 20. "When essential sugars are missing from our diets it weakens our immune system and opens it up to cancer, diabetes, heard disease, AIDS, allergies, asthma, hepatitis-C, fibromyalgia, ADHD, and eighty-five other autoimmune diseases."

   c. p. 25. "I have witnessed first hand the body's healing powers when glyconutritionals were taken for someone who suffered from lupus, cancer, autism and of course asthma and seizures....The person with lupus had suffered for years with the disease. She was in the final stages of the disease when someone introduced her to the product. She has been symptom free now for years. The person with cancer was diagnosed with an inoperable form of cancer. After taking the product he shocked his doctors when the tumor shrank and disappeared. Within two weeks of taking the product, the young man with autism stopped his screaming, and started to engage in social conversations."

   d. p. 26. "Michelle's facial features had indisputably changed since taking the supplement. The features associated with Down Syndrome had dramatically softened and the folds on her lids had nearly disappeared....In short, her appearance changed as much as her health."

3. In addition to the forward by Defendant McDaniel, Defendant Caster has also endorsed the book. In a September 10, 2006 Fort Worth Star-Telegram article, Defendant Caster is quoted as saying that he has read the book and has no problem with its assertions because, "if you read the document ... what [the mother] basically quantifies is all the quality-of-life improvements that have come as a result of the intervention of

glyconutrients."

C. Another CD offered at Defendants' convention was titled "The Road to Recovery - A Cancer Survivor's Story," which tells Dr. Michael Currieri's story about his recovery from tongue cancer thanks to Mannatech's products. Excerpts from the CD include:

1. "I took home the material that they had offered me, some brochures and some scientific data, some audio tapes...and read through the material, listened to the tapes, decided to attend a meeting that a doctor was hosting, a meeting about glyconutritional products...I went to a meeting, found out how I could obtain the products, and began taking the products, a fairly high dosage of it. I talked to the doctor who had hosted that meeting, told him my situation, and he recommended the dosage that I should take...About ten days after I started taking these products... I felt a shift in my body...I continued taking the products and the following month, when I got my new lab results in, came a wonderful surprise: that the T-cells and B-cells were both in the mid-20's, which prior to that, they had been around 1, and my natural killer cells, which had been around 300-500, were now above 56,000."

2. "I recommend it to everyone...had I known abut a product like this and been on it, I would not have had to go through this in the first place. So, preventative maintenance, it's a whole lot better to prevent in the first place than to try to cure it afterward, and I would hightly recommend this for everyone to protect yourself, protect your loved ones. It's proven science, I'm living proof of that."

3. The CD concludes with

"Okay, after hearing that, if you'd like to have additional information on the glyconutritionals, the phytochemicals, the plant steroids or anything, get with the person who gave you this tape. Thank you very much for listening."

"Glyconutrient" Sham

18. The above testimonials and promotional materials also demonstrate another sham that Defendants continuously employ in an attempt to avoid liability. Defendants instruct their associates not to refer to Mannatech's products by name when making certain claims, but instead to refer to

them generically as "glyconutrients." The associates are taught that once they have peaked the interest of potential customers with these illegal health claims, they can direct the customer to the "only company that makes these patented glyconutrients" - Mannatech. Defendants created and perpetuate this "glyconutrient" sham in the hopes of avoiding liability because Defendants know that the disease claims that are being made for their dietary supplements are illegal and that such claims make their products unapproved new drugs or misbranded foods.

Corporate Websites

19. Defendants also use multiple websites to further market their dietary supplements as drugs in violation of federal and state law. For example, Mannatech maintains its corporate website at www.mannatech.com. At this website, you can find information about Mannatech's products and can order the products. For the most part, the portion of www.mannatech.com that is accessible to the general public avoids making illegal health claims. But this website includes a password protected area, accessible only to Mannatech associates, that includes other information that enables and assists associates in promoting Mannatech's products by making illegal disease claims. For example, the www.mannatech.com backpages include links to videos of the testimonials that are given at Mannatech's corporate conventions, like those described above. Defendant Mannatech, at the insistence of Defendant Caster, has even indexed the testimonials and made them sortable by disease, making it as easy as possible for its associates to use the illegal testimonials to peddle Mannatech's products.

20. Mannatech maintains another website at www.glycoscience.com which purports to "provide information on nutritional saccharides - glyconutritionals - that form the scientific underpinnings for Mannatech's product line..." This website is accessible to the general public as

well as to Mannatech associates, and contains a number of "scientific studies" and papers that Defendants use to try to support their claim that "glyconutrients" (i.e. Mannatech's products) can cure, treat, mitigate, or prevent diseases. Defendants and their affiliates heavily rely on these studies to give Mannatech's products an air of legitimacy and to support the sale of their products. The vast majority of these studies and papers were prepared by Mannatech employees or affiliates, are not peer reviewed, have not been published or are published by Mannatech or entities closely affiliated with Mannatech, and have little, if any, scientific value. Some of the studies referenced on the glycoscience.com website are legitimate studies that have been published in recognized journals. Those studies, however, are generic studies that have been done in the field of glycobiology and provide no support for the claims being made by Defendants. Many doctors in the field of glycobiology have strenuously objected to Defendants using their work to mislead consumers into believing Mannatech's products can cure diseases. Nevertheless, Defendants continue to encourage associates to use the studies in order to convince their non-medical and unsophisticated customers that Mannatech's products have these incredible curative properties.

21. Even if all of the studies were scientifically valid studies and supported the proposition that Defendants' products could cure diseases, Defendants still cannot rely upon these studies to support their claims that their products cure, mitigate, treat, or prevent any diseases because their products are dietary supplements and not drugs. If Defendants want to rely on any of these studies to make disease claims for their products, Defendants must apply to the FDA for approval of any drug prior to it being marketed for that intended use. Defendants have not done so. Nevertheless, Defendants continue to promote and heavily rely on "studies" with titles like:

A. Glyconutritionals: Implications in Cancer;

B. Glyconutritionals: Implications in Rheumatoid Arthritis; and

C. Glyconutritionals: Implications in Asthma.

Defendant's Patent

22. Defendants' patent for its products, obtained in 2005, clearly demonstrates that Defendants' intended use for their products are to cure, mitigate, treat, or prevent diseases. The patent identifies many diseases that Mannatech claims its products cure, mitigate, treat, or prevent. Attached as Exhibit 2 is an excerpt from Defendants' patent, which is a list of more than fifty diseases or conditions that Defendants assert can be cured, mitigated, treated, or prevented by Defendants' products. These are generally the same diseases that Defendants and their associates promote the use of their dietary supplements to cure, mitigate, treat, or prevent in violation of federal and state law. The patent protection obtained by Mannatech is for products with intended uses that would make the products drugs, and therefore have to be approved by FDA. Again, FDA has not approved any drugs for marketing by Mannatech or any Defendant. Mannatech and its associates heavily rely on its Mannatech's patent for credibility and validation.

23. Defendants purport to have a policy that prohibits associates from using the patent in the marketing and promotion of Mannatech's products. But Defendants are well aware that associates continue to use the patent to support their illegal disease claims, yet Defendants refuse to take any reasonable action to prevent such conduct.

Associate Websites

24. Defendants also promote their products as drugs that can cure, treat, mitigate, or prevent numerous diseases in violation of federal and state law by allowing Defendants' associates to make such claims at sales presentations and on their websites. Defendants, including Defendant

Caster, are fully aware that associates are making illegal claims, yet they refuse to take any reasonable enforcement action against the associates to get the associates to stop making such claims. A couple of examples of illegal marketing claims made by Mannetech associates that has gone unchecked include the following:

A. The website www.glycohealthservice.com, which belongs to a Mannatech associate, and is used to promote Defendants' products, includes:

1. A transcript of "Back from the Brink" (which, as discussed above contains multiple illegal claims) and
2. An Open Letter by Dr. Rayburne W. Goen (a prominent Mannatech Associate). Excerpts of the letter include:

a. "Amazing to me was the dramatic response of Lupus by restoring these glyconutrients. Lupus is a disease from an overactive immune system, when the immune system actually attacks its "own" body cells. ("mis-communication") On the other hand, I have seen reports that taking glyconutrients dramatically increases low immune function as in AIDS or Cancer."

b. "A few of the disorders which have been shown (in reports or published articles in Medical and Scientific journals) to be benefitted or restored to normal health, (without interfering with appropriate drug therapy as indicated) are: Asthma, Rheumatoid Arthritis, Osteoarthritis, Systemic Lupus, Fibromyalgia, Chronic Fatigue Syndrome, Multiple Sclerosis, Peripheral Neuropathies, Attention Deficit-Hyperactivity Disorder, Down Syndrome, Diabetes, Muscular Dystrophy, Cancer, Ulcerative Colitis, Crohn's, Alzheimer's, Parkinsonism, Hepatitis C, and AIDS, as well as a whole host of others."

c. "Check it out. [This Company] is the only source of an oral form of these eight monosaccharides, any combination of which is 'composition patented or patent-pending' worldwide.. [The Company's] Science and Research labs are second to none in the field of pharmaceutical grade nutrients (nutraceuticals)."

B. Another Mannatech associate website used to promote Defendants' products, www.livingsugars.com, includes:

1. Numerous testimonials with pictures and descriptions, including Down syndrome, subglottic hemangioma, skin rash, severe burns, birthmarks, cerebral palsy, severe allergies, anorexia, MS, and skin cancer. These same pictures and testimonials are found on numerous other websites.
2. Statements that imply that the last four Nobel Prizes have been won in connection with the study of glyconutrients, including the 1999 Nobel Prize which went to Dr. Gunter Blobel. Dr. Blobel has previously sent a cease and desist letter to Mannatech in 2004 to get the Defendants to stop using his name and research in the promotion of Defendants products. Dr. Blobel, along with two other Nobel laureates, Dr. Paul Greengard and Dr. Paul Nurse, filed a complaint with the New York Attorney General's Office over the use of their names by Mannatech.

C. The website of another associate, www.healthtestimonies.com, includes an audio recording of four different marketing products which feature various doctors. These recordings, all of which include multiple illegal testimonials, are listed under a page titled "Dr Reports." Combined, the four presentations, each of which is approximately 30 minutes, are represented to contain testimonials for a total of 24 conditions which are identified on the website as: Arthritis, Asthma, Attention Deficit Disorder, Brain Aneurysm, Brest

Cancer, Cancer, Cataract, Cerebral Palsy, Diabetes, Diabetic Blind, Fibromyalgia, Golf Ball Brain Tumor, Heart Failure, Lou Gehrig's Disease, Low Back Pain, Micro Valve Prolapse, Muscular Dystrophy, Osteoarthritis, Peripheral Neuropathy, Progeria, Prostate Cancer, Retinopathy, Rotor Cuff Pain, Streptococcal Toxic-Shock Syndrome. The website has another page titled "Products" which specifically includes the names and marketing materials for Mannatech's products.

Third Party Marketing Materials

25. As noted throughout, there are many individuals and companies who have produced and sell promotional materials to be used as an aid to selling Mannatech's products. Many of these promotional materials can be found on associate websites, can be purchased at Mannatech corporate events, and can be purchased from vendors over the Internet. For example, www.glycotools.com is a website that is exclusively dedicated to selling Mannatech sales aids, including dozens of CDs, DVDs, brochures, and other promotional materials. This website is owned and operated by Dupli-Pack, which is also a prominent vendor at Mannatech's corporate events. The same products that are available over the Internet are generally available at Mannatech's conventions. Many of the products sold on the website include very specific and illegal disease claims. Some of the promotional materials even include descriptions or titles which in and of themselves consist of illegal testimonials or disease claims. For example, the following promotional materials and descriptions are available on the website:

A. How I Conquered Cancer – "After taking the nutrients for a short period of time, his tumor started to shrink and it eventually disappeared altogether."

B. The Spectrum of Autism & Glyconutrients – "These 2-CDs contain interviews with 11 experts. It also contains stories of children who have recovered / are recovering, and the parent's journey utilizing Glyconutritionals."

C. Pass It On – "It mentions over 30 major illnesses and catastrophic maladies. It also contains 8 powerful testimonies, four of which have never been seen before."

Defendants are well aware that these websites exist and are aware that they are selling marketing materials that are illegal for Mannatech associates to use. This is evident by the fact that the glycotools.com website includes a link to mannarelief.org and the mannarelief.org website (as described below) includes a link to glycotools.com. Moreover, Defendant McDaniel is featured on a number of the promotional materials sold on these websites, including as a speaker on several CDs or DVDs (including the "Pass It On" DVD) and has written forwards or introductions for written materials. Despite their knowledge, Defendants have failed to take reasonable steps to prevent the sale or use of these materials, and even encourage their use by allowing these companies to sell their products at Mannatech sponsored conventions.

Defendant's Compliance and Training Policies

26. Defendants represent that they maintain strict training and compliance procedures to ensure that no illegal claims are made about Mannatech's products. For example, Mannatech has written "Associate Policies and Procedures," a copy of which Mannatech claims to give to each new associate. The Associate Policies and Procedures include the following provisions:

A. Advertising (paragraphs 2.1.1-2.1.2) - The policies state that an associate may only advertise on the Internet using the "MannaPage" which are provided by Mannatech and may only utilize Mannatech-produced sales materials.

B. Advertising (paragraph 2.7) - Associates are strictly prohibited from creating, selling or distributing sales aids that are not Company-approved materials for use in the U.S.

C. Generic Materials (paragraph 2.10) - Associate may use generic materials that do not mention or directly allude to Mannatech or its products.

D. Use Educational Materials (paragraphs 2.11.1- 2.11.3) - The policies provide that educational material (i.e. published scientific and peer-reviewed articles or papers approved by Mannatech) are strictly prohibited from being mentioned, unless the American Nutraceutical Association or equivalent has certified the presenting associate. The papers may NOT be discussed, but only mentioned if the specific disease condition is asked about or commented on during the meeting and may be displayed if they are physically separate from the dietary supplements.

E. Testimonials at Meetings (paragraph 2.12) - At opportunity meetings, the host may allow attendees to make public statements concerning improved health they have personally been witness to after use of Company products, if certain written or spoken disclaimers are made. At educational meetings, the policies provide that a testimonial segment is not allowed, but then allows the "communicating" of only personal first-hand knowledge of health improvement.

F. Product Claims and Misrepresentations (paragraphs 2.25, 2.25.5, 2.25.6) An Associate is prohibited from 1) making or alluding to any medical or other

prohibited claims regarding the prevention, treatment, cure or mitigation of any disease from the use of Company products; 2) using disease-specific names or written testimonials in promotion of the Company or its products; 3) audio, video and written testimonials cannot be used when discussing the opportunity or the products.

27. Mannatech also represents that it has a disciplinary process that includes a Compliance Committee that meets on a regular basis to decide cases of reported policy violations. Mannatech reports that associates that are found to have violated one or more of Mannatech's Associate Policies and Procedures may be required to complete additional compliance training or may be subject to probation, fines, suspension, or termination of their associate agreements.

28. While Mannatech tries to create the appearance that it strictly prohibits illegal drug claims through its written policies and procedures, Defendants' conduct clearly tells a different story. First, Mannatech's policies and procedures outlined above specifically allow conduct that is prohibited by the TFDCA. For example, Mannatech's policies allow at least limited personal testimonials at both opportunity meetings (i.e. meetings to sign up new associates) and educational meetings (i.e. meetings designed to sell products). Such personal testimonials, even with a disclaimer, constitute false advertising and are prohibited by the TFDCA.

29. Mannatech's policies and procedures on the use of "educational materials" and "generic materials" also directly facilitate and perpetuate the "glyconutrient" scam discussed above. While Mannatech Associates are "prohibited from making or alluding to any medical or other prohibited claims regarding the prevention, treatment, cure or mitigation of any disease from the use of Company products," this policy, like the policy on testimonials, provides the "stamp of approval"

for associates to advertise and market Mannatech's products using disease claims. For example, the policies and procedures allow the "mention" and display of scientific papers with claims regarding the treatment or cure of diseases, if the specific disease condition is asked about or commented on during the meeting. The policies also allow all generic materials to be used, regardless of the claims, as long as the name of the product or company is not mentioned (i.e. if "glyconutrients" is supplemented for Mannatech's product). But such representations, both orally and on display, constitute false advertising under Texas law because the representations are being used to advertise and sell Mannatech's products.

30. Moreover, regardless of its written policies and procedures, Defendants' conduct actually encourages associates to make illegal drug claims, rather than deterring illegal claims. For example, many of the people brought in by Mannatech to "train" associates regarding Defendants policies and procedures are the very same Mannatech associates that are known to make some of the most egregious disease claims. Rather than training associates on how to comply with the law, the trainers often train new associates on how to try to avoid the law.

31. Defendants' compliance program is also ineffective, in part, because rather than actively monitoring associates, Defendants rely on "self-regulation" (i.e. the reporting of violations by other associates or consumers). Moreover, even when a complaint is reported, Defendants fail to take any reasonable action to discipline violating associates, especially if the associates are high ranking associates who make a lot of money for Defendants. On occasion, Defendants take "disciplinary action" against Mannatech associates in the form of a written or verbal warning to stop making illegal disease claims. But such disciplinary action is only illusory, intended to create the impression that Defendants take real enforcement action. In fact, Defendants fail to follow up on

such warnings to ensure that the associate has stopped making illegal claims, or take any further action to deter associates from making illegal health claims. Some associates have received multiple warning letters from Mannatech, but continue to make illegal claims without repercussion.

32. Moreover, Defendant Caster refuses to allow any more serious enforcement action to be taken against high ranking associates. For example, on at least two occasions, Defendants' Compliance Committee has met and made a recommendation to terminate and/or suspend for a significant period of time a high ranking associate because of egregious illegal disease claims. In each case, however, because the associate was a highly productive associate, Defendant Caster has overruled the Compliance Committee's recommended punishment and instead given the associate a slap-on-the-wrist.

Defendant MannaRelief

33. In order to further perpetuate Mannatech's illegal scheme, Defendant Caster and his wife, Linda, also started a nonprofit organization in 1999, Defendant Manna Relief Ministries, that purports to distribute Mannatech's products to "health challenged children" around the world. While Defendant MannaRelief may in fact distribute Mannatech's products to people around the world, Defendants and their affiliates largely use MannaRelief as a marketing tool and use its website www.mannarelief.org to promote Mannatech's products as method to cure, mitigate, treat, or prevent diseases. For example, the www.mannarelief.org website contains the following claims:

A. "We brought to completion the year long survey of 30 children and a few adults with HIV/AIDS. A couple of adults commented that they didn't believe they would be alive this year had it not been for these products."

B. "One experience in particular had a profound effect on his decision to launch

the organization. In 1999 Caster began sending Mannatech's glyconutritional products to orphans in Romania, where the harsh winters had a debilitating effect on the children. The orphanage staff said the first year the children were on the nutritional products, the incidence of disease dropped dramatically."

C. Although they have now been removed from the website, www.mannarelief.org formerly included a number of testimonials, including testimonials for all of the following diseases: ADHD, ADD, Asperger's Syndrome, anaplastic astrocytoma, autism, blood disorder, blindness/partial, Burkitt's lymphoma, cancer, cerebral palsy, coma, cystic fibrosis, Down syndrome, dyslexia, dysgraphia, Diamond Blackfan Anemia, eye tick, hydrocephalus, improved coordination, metastatic osteosarcoma, neurofibromatosis, quadriplegia, and retinoblastoma.

D. The website continues to have a link to Glycotools.com, which as explained above, sells promotional materials for Mannatech products, many of which contain specific disease claims.

34. Moreover, Mannatech associates will often promote a charitable event for MannaRelief as a hook to get people to attend meetings. The meetings will then turn into a sales presentation for Mannatech products and the Mannatech business opportunity.

35. In addition to furthering Defendant Mannatech's illegal scheme, Defendant MannaRelief has independently violated federal and state law by making illegal disease claims, because even when products are given away for free, state and federal law prohibit claims that the

product can cure, treat, mitigate, or prevent diseases.

Defendant Fisher Institute

36. Defendant Fisher Institute, which is a nonprofit corporation, represents itself as an independent medical research organization whose "primary objective is to explore the extent, if any, to which nutraceuticals, glyconutritionals, phytonutritionals, functional foods, and/or other natural substances may provide integrative and complementary health and wellness support." In fact, upon information and belief, Defendant Fisher Institute serves no legitimate charitable purpose, but instead is run and controlled by Defendant McDaniel and his wife Candace for the benefit of Mannatech and its associates. As a result, Defendant Fisher Institute is little more than a sham charity[3] with the sole purpose of providing "scientific" support to the illegal health claims made about Mannatech's products. Virtually all of Defendant Fisher Institute's revenue comes from selling publications to Mannatech associates. In particular, Defendant Fisher Institute publishes and sells its own "journal," titled the "Proceedings of the Fisher Institute for Medical Research." Upon information and belief, almost all of the articles published in the "journal" are written by Defendant McDaniel or other

[3]Even the method by which Defendant McDaniel gained control of the Fisher Institute was fraudulent. The Fisher Institute was incorporated in 1977 by Sherrill Edwards, Phil Gramm, and Henry Gilchrist, with the purpose of studying and promoting free market economic theories. In 1991, Edwards, who at the time was the only person still involved in the corporation, died of cancer. At the time of his death, the Fisher Institute had no assets, and Edwards widow and executrix, Virginia, filed the proper paperwork to dissolve the corporation. Shortly thereafter she was contacted by Defendant McDaniel, who had apparently been treating Edwards' cancer with alternative remedies, and Defendant McDaniel expressed an interest in continuing to operate the institute. Virginia died shortly thereafter without acting on Defendant McDaniel's request. Approximately a year after her death, Virginia's son-in-law Thomas Corboy was contacted regarding reinstating the corporation. Mr. Corboy, who was lead to believe the corporation would continue with the same mission and purpose, agreed to a friendly lawsuit to reinstate the charter. A lawsuit was filed, without the notice required by law to be sent to the Attorney General, and the corporate charter was reinstated.

persons affiliated with Defendant Mannatech, usually with no disclosure of the connection. And very few, if any, of the articles or studies are scientifically valid, randomized, double-blind, peer-reviewed studies. In addition to being sold on Defendant Fisher Institute's own website, copies of the "journal" are also available for sale on www.glycotools.com and other websites that sell promotional material to Mannatech associates.

Defendant McDaniel

37. Defendant McDaniel is one of the original developer's of Mannatech's original product, Ambrotose. Although Defendant McDaniel is no longer an employee of Mannatech, he has been involved with Mannatech since its inception and continues to play a prominent role with Mannatech. Defendant McDaniel served as the "Medical Director" for Mannatech until mid-2002. At that time, he was forced to resign from Mannatech because of pressure from the FDA. Even so, rather than sever ties with Defendant McDaniel, Defendant Caster gave Defendant McDaniel a similar position with MannaRelief. Defendant McDaniel also has a similar position with Defendant Fisher Institute. Moreover, Defendant McDaniel continued to receive compensation from Mannatech, in the amount of $25,000 per month, for several years following his resignation. Defendant McDaniel is also the fifth largest shareholder of Mannatech.

38. Today, through his position with MannaRelief and the Fisher Institute, Defendant McDaniel is still a prominent player in Mannatech's illegal scheme through his presence at corporate events, his contributions to third party marketing materials, and his almost constant speaking circuit at events and meetings hosted by Mannatech associates. As demonstrated by his removal from Mannatech, Defendant McDaniel has a long history of making illegal health claims. Defendant McDaniel continues to makes such illegal claims in his speaking tour. Defendant McDaniel goes

so far as to prescribe certain dosages of Mannatech products for certain diseases.

Defendant Caster

39. Defendant Caster is one of the original founders of Defendant Mannatech and is still one of the largest shareholders. Except for a brief period in 2001, Defendant Caster has been intimately involved with Mannatech since its founding, serving in various roles, including President, CEO, and Chairman of the Board. Currently Defendant Caster serves as CEO and Chairman of the Board for Mannatech.

40. Defendant Caster is also one of the founders of MannaRelief and has been intimately involved in MannaRelief since its inception. Defendant Caster currently serves as the Chairman of the Board for MannaRelief.

41. Defendant Caster is very involved in the day-to-day operations of both Mannatech and MannaRelief. He has knowledge of all aspects of Mannatech's and MannaRelief's business practices, including all of those detailed above. Despite Defendant Caster's knowledge of the illegal conduct described herein, and despite his authority to prevent such illegal conduct, he has taken no steps to prevent the illegal conduct. To the contrary, Defendant Caster has orchestrated the illegal scheme being perpetrated by Defendants, and has hindered the efforts of any person attempting to rein in the practices of Mannatech and its associates.

Regulation by Texas Department of State Health Services

42. Defendant Mannatech has been licensed as a food manufacturer since 1996 by the Texas Department of State Health Services (or its predecessor, the Texas Department of Health). Defendants are responsible for knowing both the federal and state laws that regulate the dietary supplements that they manufacture and distribute. Defendants' regulatory history clearly

demonstrates that Defendants are well-aware that it is illegal to make any claims that dietary supplements can cure, treat, mitigate, or prevent diseases. In fact, as detailed below, Defendants have been notified by TDSHS that the conduct outlined above contravenes state and federal law. Despite these warnings, Defendants have continued to allow and encourage the illegal conduct.

TDSHS 2006 Inspection and Warning Letter:

43. TDSHS issued a warning letter to Mannatech Incorporated on September 21, 2006, to inform Mannatech of the adverse conditions found during a physical inspection of Mannatech's facilities conducted on July 13 and 17, 2006. The letter also detailed numerous unapproved disease claims for dietary supplements TDSHS discovered in a review of websites, advertising and promotional materials, scientific literature, and other information used by Mannatech Associates to advertise, offer for sale, and sell Mannatech's glyconutrient products. TDSHS determined that these adverse conditions and the unapproved disease claims made for Mannatech's glyconutrient products violate Chapter 431 of the Texas Health and Safety Code (TFDCA). The adverse conditions and unapproved disease claims result in violations of the prohibited acts listed in §431.021 of the TFDCA.

44. In addition, TDSHS also re-stated in the letter its oral and written request from July 17, 2006 for the distribution records for Mannatech's glyconutrient products which is authorized under §431.044 of the TFDCA. Mannatech has continued to refuse to produce these distribution records, in violation of §431.021(g) of the TFDCA.

45. In particular, the September, 2006 letter summarized the following violations found by TDSHS:

A. TDSHS determined that the "Back From the Brink" audio CD described

above makes numerous illegal drug claims, including claims regarding Toxic Shock Syndrome, ADD/ADHD, asthma, pneumonia, and ALS.

B. TDSHS determined that the "Conspiracy Against Our Children," audio CD described above makes illegal drug claims regarding the ability of Defendants products to treat, cure, or mitigate ADD/ADHD.

C. TDSHS determined that the audio CD, "The Road to Recovery, A Cancer Survivor's Story," which is described above, makes illegal drug claims, including specific dosages used, regarding cancer.

D. TDSHS concluded that a promotional DVD titled "Pass It On," which features Defendant McDaniel, makes claims that 30 illnesses were improved or cured by Defendants' products, including sarcoma cancer, severe allergies, PMS, arthritis, Sturge-Weber syndrome, and diabetes.

E. TDSHS determined that a pamphlet, "Restore Your Cells, Restore Your Health," was used to promote and sell Mannetech's glyconutrients. The pamphlet includes illegal disease claims in the form of testimonials and "before and after" pictures which purport to show "ill, handicapped" children being turned into "healthy children." The pamphlet includes claims representing that the products can cure cystic fibrosis, anemia, seizures, brain damage, cognitive dysfunction, cancer, endometriosis, bladder infections, degenerative joint disease, depression, fibromyalgia, irritable bowel syndrome, multiple sclerosis, severe psoriasis, lupus, polycythemia vera, and autoimmune disease.

F. TDSHS found that the book, "A Gift Called Michelle" described above, including the forward written by Defendant McDaniel, makes numerous illegal disease claims regarding Down Syndrome, cerebral palsy, leukodystrophy, Fragile-X Syndrome, autism, muscular dystrophy, and hemophilia from taking Mannatech's glyconutrient products.

G. TDSHS also concluded that a book written by Defendant Caster's wife, Linda, Undeniable Destiny, promotes Mannatech's glyconutrient products to treat or cure various health problems. For example, the book includes a passage, "[a]t Mannatech National Events the testimonies of people's miraculous recoveries from various health problems became overwhelming both in number and in substance. We would sit literally for hours and listen to one story after another of life-changing experiences."

H. TDSHS reviewed Defendant MannaRelief's website, www.mannarelief.org, and concluded that it included unapproved disease claims that promote Mannatech products to treat or cure diseases. Unapproved disease claims cannot be made for Mannatech's glyconutritient products without violating the TFDCA, even if the products are given away. TDSHS also noted that the MannaRelief website has a direct link to www.glycotools.com which offers for sale "Dr. Reg's Famous Cancer Lecture" on video by Defendant McDaniel, which also makes unapproved disease claims for Mannatech's glyconutrient products.

I. TDSHS further noted that the website www.glycotools.com also markets

many other promotional materials that are used by Mannatech associates that contain Mannatech glyconutrient product testimonies on a variety of health issues, including cancer, fibromyalgia, depression, ADD, ADHD, AIDS, cystic fibrosis, weight loss, and many additional diseases.

J. TDSHS also reviewed the website www.mannapharmacists.com and determined that it also makes unapproved disease claims for Mannatech's glyconutrient products by claiming that the "blood pressure drugs no longer will be needed" when taking Mannatech's glyconutrient products.

K. TDSHS also reviewed the following website of Mannatech Associates, Hal and Shirley Mesler of Michigan, www.glycohealthservice.com, as representative of Mannatech associates' websites and the illegal claims that are made. TDSHS determined that the Mannatech associates' website made unapproved disease claims that Mannatech's glyconutrient products could treat or cure Toxic Shock Syndrome, asthma, Lou Gehrig's disease, heart failure, arthritis, and fibromyalgia.

The September, 2006 warning letter detailed how all of the above materials made illegal disease claims, and how such claims made Mannatech's glyconutrient products unapproved new drugs or misbranded foods.

46. In addition to the illegal disease claims noted above, the September, 2006 warning letter also detailed other violations of the TFDCA. For example, TDSHS's inspection of Mannatech's warehouse revealed a pallet of cases and bottles labeled "Mannatech Distribution Center...Sugars for Asthma Study...Study #HS0307C...Phytaloe." TDSHS was informed that this

product was used in a study conducted by the Research and Development department and this was left over product from the study. TDSHS requested this study on July 13, 2006, but Mannatech refused to provide the study. Mannatech has no approval from FDA to manufacture or test any drug to treat asthma and Mannatech's dietary supplements cannot make any claims to prevent, treat, mitigate, or cure asthma.

47. TDSHS' inspection of Mannatech also revealed numerous observed violations of the TFDCA on the labels and in labeling and advertising by Mannatech. Those observed violations were detailed in a report that was provided to Mannatech as part of the September, 2006 letter.

TDSHS Inspection December 14, 2005:

48. TDSHS, in a December 22, 2005 letter, provided Mannatech with a copy of a complaint from a customer who had been misled to believe that Mannatech's products would help him to feel better during his chemotherapy treatment for cancer. Mannatech responded to the complaint by providing a detailed explanation of its "self-regulation" compliance and training policies.

TDSHS Complaint Investigation Aug. 1, 2002:

49. On February 6, 2002, the Smithville police called TDSHS to refer a complaint about Max Brache, a Mannatech associate. The complainant had cancer and had surgery to remove a tumor on her leg. She was also receiving chemotherapy, but the Mannatech distributor had her stop taking her chemotherapy and purchase $1,100.00 worth of Mannatech products to give her body the tools it needed to heal itself from the cancer.

50. TDSHS sent a letter, dated June 5, 2002, to the President of Mannatech to notify him of the complaint against Mannatech. TDSHS stated that a distributor promoted various Mannatech

products for the treatment of cancer, encouraged the complainant to cease current chemotherapy and only take Mannatech products, and promoted a dosage far in excess of the dosing instructions on the product label. TDSHS indicated that these representations constituted false advertising under the TFDCA. Such false advertising also misbrands the Mannatech products which results in additional violations of the TFDCA.

TDSHS Complaint Investigation June 24, 2002:

51. On April 24, 2002, TDSHS received a complaint from a consumer stating that she had received an unsolicited e-mail, dated February 1, 2002, from Mannatech associates, Steve and Sylvia McCuistion. The e-mail's subject stated "Scientific Am News!! AMBROTOSE BEATS Cancer!" and indicated that the "Scientific American news article FURTHER VALIDATING Mannatech's proprietary patent granted/pending Glyconutrient Complex AMBROTOSE!" The e-mail then stated that this Mannatech product changes cancer cells and can inhibit tumor growth.

52. The e-mail from these Mannatech associates was sent to an unknown number of "undisclosed-recipients" and begins by making another disease claim by thanking Dee Hergenreter, a Mannatech leader, who has helped "save 1000s of lives by helping Dr. Tim Hollingshead's daughter...rid herself of the many perils of DOWN SYNDROME!!!".

53. On June 6, 2002, TDSHS sent a letter to the President of Mannatech regarding the complaint about an e-mail from Mannatech associates that made claims for the treatment and cure of cancer and Down Syndrome. TDSHS indicated that these unapproved disease claims constituted false advertising under the TFDCA. Such false advertising also misbrands the Mannatech products which results in additional violations of the TFDCA.

TDSHS Letter Notifying Adverse Conditions, dated September 21, 2001:

54. TDSHS issued a letter to Mannatech on September 20, 2001, to inform Mannatech of the adverse conditions found during the August 13, 2001, and August 15, 2001, detention of misbranded dietary supplements, MVP with Ambrose Complex and GlycoLean Accelerator. The letter indicated that the adverse conditions found misbranded Mannatech's glyconutrient products by failing to include required information on labels, by making unapproved disease claims for dietary supplements in Mannatech's website, and in advertising and promotional materials used by Mannatech. TDSHS determined that these adverse conditions, including the unapproved disease claims, made for Mannatech's glyconutrient products violate Chapter 431 of the Texas Health and Safety Code (TFDCA). The adverse conditions, including the unapproved disease claims, result in violations of the prohibited acts listed in §431.021 of the TFDCA.

55. Additional violations observed by TDSHS were detailed in a report that was provided to Mannatech as an attachment to the September, 2001 letter, and included but were not limited to:

A. Product literature and Mannatech's website www.mannatech.com made claims, both direct and implied, that these products may be used to treat diseases and/or symptoms of diseases, including a product brochure entitled, "What Do I Take For...", subtitle, "Guidelines for Use of Mannatech Products" that states that the product, Ambrotose Complex, may be a treatment for "viruses," "people who are ill," "genetic errors of metabolism," and "diabetics." The brochure also stated, "Those who have health challenges may discern improvement in specific signs and symptoms;"

B. The product description for Phyt-Aloe Complex associated the product with

a disease by referring to "The National Cancer Institute" and "persons undergoing radiation therapy or chemotherapy;" and

C. Mannatech's website www.mannatech.com, under the page heading "Introduction" stated that its products may be used to treat "persons with compromised health, maybe even with a specific disease condition."

FDA's Findings of Claims to Treat, Prevent, Cure, or Mitigate a Disease

56. The FDA, like the TDSHS, has notified Mannatech on multiple occasions that its marketing materials make illegal drug claims. For example, on December 27, 2000, FDA sent a letter to Mannatech to respond to a submission pursuant to 21 U.S.C. 343(r)(6), Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act for the product ImmunoStart. FDA determined that numerous claims by Mannatech suggest that ImmunoStart is intended to treat, prevent, cure, or mitigate diseases, including a claim that it will "fight infection and disease."

FDA concluded that these claims to treat, cure, prevent, or mitigate disease cannot be made for products under 21 U.S.C. 343(r)(6), dietary supplements. FDA determined that such claims make these products drugs and drugs require approval by FDA pursuant to 21 U.S.C. 321(g)(1)(B).

57. Again, on February 28, 2001, FDA sent a letter to Mannatech to respond to submissions pursuant to 21 U.S.C. 343(r)(6), Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act for the products Ambrotose Powder, Ambrotose Capsules, and Ambrotose Capsules with Lecithin; Manna-C Capsules; MannaCleanse Capsules; and AmbroStart Drink Mix. Again the FDA determined that certain claims made by Mannatech suggest that these products are intended to treat, prevent, cure, or mitigate diseases. For example, Mannatech's marketing material claimed that:

A. Ambrotose Powder, Capsules, and Capsules with Lecithin to "...delay the

onset of various degenerative conditions";

B. AmbroStart Drink Mix "Helps lower serum cholesterol levels in individuals with elevated cholesterol;" "Aids in control of diabetes. Insulin-requiring diabetics often need lower amounts of insulin when they consume a diet high in soluble fiber," and "...prevent the growth of disease-producing bacteria...help alleviate lactose intolerance."

FDA concluded that these claims to treat, cure, prevent, or mitigate disease cannot be made for products under 21 U.S.C. 343(r)(6), dietary supplements. FDA determined that such claims make these products drugs and drugs require approval by FDA pursuant to 21 U.S.C. 321(g)(1)(B).

VIOLATIONS OF THE TEXAS FOOD, DRUG AND COSMETIC ACT

58. Based on the findings in paragraphs 1 through 57, incorporated by reference herein, Defendants have manufactured and/or introduced into commerce or caused the introduction into commerce unapproved new drugs and/or misbranded foods; have misbranded drugs and/or foods in commerce or caused the misbranding of drugs and/or foods in commerce; falsely advertised these foods and/or unapproved new drugs or caused the false advertising of these foods and/or unapproved new drugs; and failed to produce distribution records in violation of the Texas Food, Drug and Cosmetic Act.

59. Defendants manufacture and sell products that are drugs within the meaning of §431.002(14) of the TFDCA because these products are intended to cure, mitigate, treat, or prevent disease although Mannatech labels these glyconutrients as dietary supplements. Mannatech is licensed as a food manufacturer by TDSHS and is not licensed to manufacture or distribute drugs.

60. Defendants' products are additionally classified as "new drugs" within the meaning

of §431.002(25) of the TFDCA because TDSHS is unaware of any evidence that establishes that these drugs are generally recognized as safe and effective for their intended uses. New drugs must be approved by FDA before they may be marketed. The FDA, by affidavit, states that it has not approved any new drug applications for Mannatech or Mannatech, Inc. FDA also finds that there is no valid new drug application on file for any of the following products: Ambrotose, Glycentials, Phytomatrix, CardioBALANCE, Gl-Pro, Gl-Zyme, ImmunoSTART, Man-Aloe Classic, MannaCLEANSE, Ambrostart, Manna-C, Mannatonin, Glyco-Bears, Manna-Bears, Manapol, and glyconutrients. (See Exhibit 1 attached).

61. Defendants' drugs are also misbranded under the terms of the TFDCA. Section 431.112(e)(1) of the TFDCA states that a drug is deemed to be misbranded unless its labeling bears adequate directions for use, unless the drug has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services.

62. By federal regulation, 21 CFR § 201.5 "adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended." Defendants advertise and sell drugs that fail to bear adequate directions for their intended uses since adequate directions for use by a layperson cannot be written for an unapproved drug under the terms of §431.112(e)(1) of the TFDCA.

63. Accordingly, the sale, delivery, offering for sale, holding for sale, or giving away of any new drugs by Defendants without an FDA approved new drug application violates §431.114(a)(1) of the TFDCA. The introduction or delivery for introduction into commerce or causing the introduction or delivery for introduction into commerce of any article in violation of §431.114 of the TFDCA is prohibited, under §431.021(e) of the TFDCA.

64. Section 431.021(a) of the TFDCA prohibits the introduction or delivery for introduction into commerce or causing the introduction or delivery for introduction into commerce within the State of Texas of any misbranded drug, such as Defendants' products which are intended to cure, mitigate, treat, or prevent disease and/or whose label and/or labeling is not in conformance with state and federal standards, and the misbranding or causing the misbranding of any drug in commerce. Since Defendants' drugs are misbranded under Texas law, Defendants are in violation of §431.021(a) and/or (b) of the TFDCA.

65. Defendants' advertising of unapproved new drugs is false within the meaning of §431.182 of the TFDCA because such advertising is misleading in numerous particulars as set out above. In addition, because FDA has not approved these drugs, they are illegal to market and any advertising is therefore false.

66. Such representations for unapproved new drugs by Defendants constitute advertising within the definition set out in §431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendants' drugs. Section 431.005 of the TFDCA provides that the selling of drugs or foods includes "manufacture...offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article..."

67. In the alternative, Defendants manufacture, advertise, offer for sale, and sell products that are foods (includes dietary supplements) within the meaning of §431.002(16) of the TFDCA. Defendants' foods are misbranded under the terms of the TFDCA based upon the disease claims made for these food products and the lack of labels and labeling that comply with §431.082(a), (f), and (g) of the TFDCA. Defendants' foods are deemed misbranded because the labeling is false or misleading and fails to prominently display information and statements required by regulations in

such a manner to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

68. Defendants' advertising of foods is also false within the meaning of §431.182 of the TFDCA because it is misleading in numerous particulars, as set out above, and because disease claims cannot be made for foods, and it is illegal to market these foods with such claims.

69. Mannatech and Sam Caster have also failed to produce for copying distribution records as requested in the July, 2006 inspection pursuant to §§431.042-431.044 of the TFDCA, in violation of §431.021(g) of the TFDCA.

PROHIBITED ACTS UNDER THE TEXAS FOOD, DRUG AND COSMETIC ACT

70. Based on the conduct alleged above in paragraphs 1 through 69, Defendants have committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.001 *et seq.* of the TFDCA:

A. Introducing into commerce or causing the introduction into commerce a misbranded drug in violation of §431.021(a) of the TFDCA;

B. Introducing into commerce or causing the introduction into commerce of an unapproved new drug in violation of §431.021(e) of the TFDCA;

C. Misbranding or causing the misbranding of a drug in commerce, in violation of §431.021(b) of the TFDCA;

D. Falsely advertising or causing the false advertising of drugs in Texas in violation of §431.021(f) of the TFDCA;

E. Manufacturing within this state food that is misbranded in violation of §431.021(h) of the TFDCA;

F. Distributing in commerce or causing the distribution into commerce of a consumer commodity that has a label that does not conform to the provisions of this chapter and of rules adopted under the authority of this chapter, in violation of §431.021(d) of the TFDCA;

G. Introducing into commerce or causing the introduction into commerce a food that is misbranded, in violation of §431.021(a) of the TFDCA;

H. Misbranding or causing the misbranding of a food in commerce in violation of §431.021(b) of the TFDCA;

I. Falsely advertising or causing the false advertising of foods in Texas in violation of §431.021(f) of the TFDCA, and

J. Failing to produce distribution records in violation of §431.021(g) of the TFDCA.

VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT

71. Defendants as alleged above in paragraphs 1 through 70, have in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in §17.46(a) of the DTPA. Additionally, Defendants have violated §17.46(b) of the DTPA as follows:

A. Causing confusion or misunderstanding as to the approval of the dietary supplements and/or drugs manufactured, advertised, offered for sale, and sold by Defendants, in violation of §17.46(b)(2) of the DTPA;

B. Causing confusion or misunderstanding as to the affiliation or connection between Mannatech and the Fisher Institute;

C. Representing that Defendants' dietary supplements have benefits which they

do not have, in violation of §17.46(b)(5) of the DTPA;

D. Representing that Defendants' dietary supplements are drugs and have benefits which they do not have, in violation of §17.46(b)(5) of the DTPA;

E. Representing that Defendants' dietary supplements are of a particular standard, quality, or grade, if they are of another, by, in violation of §17.46(b)(7) of the DTPA;

F. Representing that Defendants' drugs are of a particular standard, quality, or grade, if they are of another, in violation of §17.46(b)(7) of the DTPA; and

G. Failing to disclose that Defendants dietary supplements are not approved by FDA as drugs, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of §17.46(b)(24) of the DTPA.

INJURY TO CONSUMERS

72. By means of the foregoing unlawful acts and practices, Defendants have acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

TEMPORARY AND PERMANENT INJUNCTION

73. The State alleges that by reason of the foregoing, Defendants should not continue to operate a food manufacturing establishment, advertise, offer to sale, and sell its products in violation of the laws of Texas. The interests of the State of Texas require a temporary injunction and a permanent injunction to prohibit Defendants from continuing to operate a food manufacturing

establishment and to advertise, offer for sale, and sell their products if they refuse or are unable to comply with standards required by the TDSHS pursuant to their authority granted by the TFDCA. The interests of the State of Texas also require a temporary injunction and a permanent injunction to prohibit Defendants from advertising and selling their products, unless Defendants are in compliance with the DTPA.

74. Unless injunctive relief is granted, Defendants will continue to violate the laws of the State of Texas to irreparable injury of the State of Texas and to the general public.

PRAYER

75. WHEREFORE, Plaintiff prays that Defendants be cited according to law to appear and answer herein; that after due notice and hearing a TEMPORARY INJUNCTION be issued; and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining Defendants their successors, assigns, officers, associates, members, distributors, agents, servants, employees, and any other person in active concert or participation with Defendants from engaging in the following acts or practices:

A. Selling, marketing, promoting, distributing, advertising or assisting or allowing others to sell, market, promote, distribute, or advertise, the sale of any Mannatech dietary supplement by representing, expressly or by implication, that the product can cure, treat, mitigate, or prevent any disease;

B. Selling, distributing, sending, mailing, printing, giving, disseminating, advertising, referencing, or assisting or allowing any other person, entity or business affiliated with Defendants or subject to their control, directly or indirectly, to sell, distribute, send, give, mail, print, advertise, reference, or

disseminate, any materials that in any manner represent, expressly or by implication, that Mannatech's dietary supplements can cure, treat, mitigate, or prevent any disease;

C. Failing to completely remove all claims and testimonials that Mannatech's dietary supplements can cure, treat, mitigate, or prevent any disease from all of Defendants' websites, promotional materials, and advertisements;

D. Shipping products or promotional materials to any other associates, sellers, distributors, or buyers of Defendants' dietary supplements who fail to completely remove all claims and testimonials that Mannatech products can cure, treat, mitigate, or prevent any disease from all of such person's websites, promotional materials, and advertisements;

E. Causing confusion or misunderstanding as to the approval of dietary supplements manufactured and sold by Defendants;

F. Causing confusion or misunderstanding as to the approval of drugs manufactured and sold by Defendants;

G. Representing that Defendants' dietary supplements have benefits which they do not have;

H. Representing that Defendants' dietary supplements have any benefits or characteristics unless Defendants have in their possession at the time such representation is made scientific substantiation for such representation;

I. Representing that Defendants' dietary supplements are drugs and have benefits which they do not have;

J. Representing that Defendants' dietary supplements are of a particular standard, quality, or grade, if they are of another;

K. Representing that Defendants' dietary supplements are drugs that are of a particular standard, quality, or grade, if they are of another;

L. Failing to disclose that Defendants' dietary supplements are not approved by FDA to cure, treat, mitigate, or prevent disease;

M. Failing to disclose that FDA has not determined that Defendants' dietary supplements are safe and effective to cure, treat, mitigate, or prevent disease and that such claims are illegal to make for dietary supplements;

N. Introducing into commerce or causing the introduction into commerce of a new drug not approved by the FDA;

O. Advertising or causing the advertising of new drugs because FDA has not approved them as safe and effective;

P. Introducing into commerce or causing the introduction into commerce a misbranded drug;

Q. Misbranding or causing the misbranding of a drug in commerce;

R. Falsely advertising or causing the false advertising of drugs in Texas;

S. Manufacturing within this state food that is misbranded;

T. Distributing in commerce or causing the distribution into commerce of a consumer commodity that has a label that does not conform to state law;

U. Introducing into commerce or causing the introduction into commerce a food that is misbranded;

V. Misbranding or causing the misbranding of a food in commerce;

W. Falsely advertising or causing the false advertising of foods in Texas;

X. Failing to produce distribution records requested by the Texas Department of State Health Services;

Y. Failing to develop and implement a plan for monitoring and regulating Defendants' websites and the websites of their associates, sellers, or distributors and all advertising and promotional materials to insure that claims to treat, cure, mitigate, or prevent diseases and serious illnesses are not included;

Z. Failing to revise Defendants' policies and procedures for associates, sellers, or distributors to reflect compliance with state and federal laws regarding claims;

AA. Using MannaRelief or any nonprofit entity to further the profits of Mannatech through the promotion and marketing of Mannatech's dietary supplements to cure, treat, mitigate, or prevent diseases or serious conditions;

BB. Advertising, offering for sale, selling or giving away any Mannatech dietary supplement or glyconutrient for the treatment, cure, mitigation or prevention of diseases or serious conditions;

CC. Using The Fisher Institute to conduct and publish scientific research on glyconutrients unless the studies are double-blinded, randomized, and peer-reviewed;

DD. Using MannaRelief, the Fisher Institute, any nonprofit or charitable

corporation, or any other third party to make claims about Defendants' dietary supplements that Defendants could not make themselves;

EE. Using research studies on the use of glyconutrients or any of Mannatech's products to support the use of Mannatech's dietary supplements to cure, treat, mitigate, or prevent disease or serious conditions;

FF. Misrepresenting that the Fisher Institute is an independent scientific research entity;

GG. Failing to disclose the relationship between the Fisher Institute and Mannatech; and

HH. Using testimonials to make claims about Defendants' dietary supplements that Defendants could not make themselves.

76. Plaintiff further prays that this court upon final hearing order each Defendant to pay civil penalties in favor of the STATE OF TEXAS in the amount of $25,000.00 per day per violation of §431.021 of the TFDCA.

77. Plaintiff further prays that upon final hearing this Court will order each Defendant to pay civil penalties in favor of the STATE OF TEXAS in the amount of $20,000.00 per violation of the DTPA.

78. Plaintiff further prays that upon final hearing that his Court order Defendants to restore all money or other property taken from persons by means of unlawful acts or practices, or, in the alternative, award judgment for damages to compensate for such losses.

79. Plaintiff further prays that upon final hearing that this Court order Defendants to pay to the STATE OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE

§402.006(c).

80. Plaintiff further prays that upon final hearing that this court order Defendants to pay to the Office of the Attorney General and to the Texas Commissioner of Health their reasonable expenses incurred in obtaining injunctive relief under §431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees, witness fees, and deposition expenses pursuant to §431.047(d) of the TFDCA.

81. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may show itself entitled.

Respectfully submitted,

Plaintiff State of Texas

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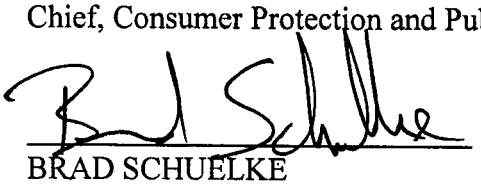

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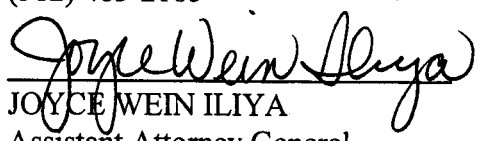

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Declaration of Michael M. Levy

I, Michael M. Levy, declare as follows:

1. I am the Director of the Division of New Drugs and Labeling Compliance, Office of Compliance, Center for Drug Evaluation and Research (CDER), United States Food and Drug Administration (FDA).

2. The responsibilities of my position require that I be familiar with and knowledgeable about the legal requirements of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. §§ 301-97, and the FDA's enforcement policies pertaining to "drugs" and "new drugs."

3. 21 U.S.C. § 321(g) defines the term "drug" in relevant part as "(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C) . . . ."

4. 21 U.S.C. § 321(p) defines the term "new drug" in relevant part as:

   a. Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . or

   b. Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

5. In order to be generally recognized as safe and effective (GRAS/E) within the meaning of 21 U.S.C. § 321(p), a drug must satisfy three criteria. First, the drug must have been subjected to adequate and well-controlled studies that establish that the drug is safe and effective. See 21 C.F.R. § 314.126. Second, those studies must have been published in the scientific literature, so that they are available to qualified experts. Third, experts must generally agree,

based on those published studies, that the drug is safe and effective for its intended use.

6. Even if an active ingredient has been previously approved as safe and effective in another drug product, a drug is considered a new drug if its particular formulation of active and inactive ingredients has not been previously approved or has not been found to be GRAS/E.

7. The FDA is charged with the regulation of drugs for human use. Drugs that are "new drugs" within the meaning of 21 U.S.C. 321(p) must be approved by FDA before they may be marketed. For new drugs, FDA's approval is granted in the form of an approved New Drug Application (NDA) or an approved Abbreviated New Drug Application (ANDA). Among other information, an NDA must contain data from scientific studies conducted both in animals ("preclinical data") and man ("clinical data") that establish that the drug is safe and effective for its intended uses.

8. Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it; except that 21 U.S.C. 355(i) permits, subject to regulations, the introduction or delivery for introduction into interstate commerce of unapproved new drugs solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. The regulations providing for such investigational exemptions are contained in 21 CFR 312.

9. I have access to all New Drug Applications (NDAs) filed pursuant to 21 U.S.C. § 355(b), all Abbreviated New Drug Applications (ANDAs) filed pursuant to 21 U.S.C. § 355(j), and all Investigational New Drug Applications (INDs) filed pursuant to 21 U.S.C. § 355(i), as well as related records.

10. When a sponsor submits to FDA an NDA, ANDA, or IND for any intended use of a new drug, the existence of that submission is reflected in various records that FDA regularly makes and preserves in the normal course of its regulatory affairs. I have caused a diligent search of the official FDA records referred to in paragraphs 9. Those searches revealed that there is not on file a valid IND, NDA or ANDA for any of the following products: Ambrotose, Glycentials, Phytomatrix, CardioBALANCE, GI-Pro,GI-Zyme, ImmunoSTART, Man-Aloe Classic, MannaCLEANSE, Ambrostart, Manna-C, Mannatonin, Glyco-Bears, Manna-Bears, Manapol and glyconutrients. Nor does Mannatech or Mannatech, Inc., hold an approved NDA, ANDA, or IND for any drug product regulated by FDA.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on June 5, 2007

Michael M. Levy, Jr.
Director
Division of New Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Glyco-1 capsules used in this study were prepared according to Example 6. The purpose of this study was to evaluate the effectiveness of dietary glyconutritional supplementation on the mood states and craving for alcohol in alcoholics. The study was conducted as follows.

Two groups of subjects were recruited from a local alcoholic support group in Little Rock, Ark.: three recovering alcoholics and two practicing alcoholics. Each met the Diagnostic and Statistical Manual 4th Ed. (DSM-IV) criteria for alcohol dependency. In the recovering group, abstinence varied from 2.5 years to six years and 11 months. For both groups, year=of alcohol abuse ranged from 15 to 30 years and ages ranged from 33 to 62.

Assessment tools consisted of a self-rating scale of craving for alcohol which was scored from 0 to 9 and the Profile of Mood States (POMS). The POMS 65 items were divided into five scales: Cognitive, Depression, Energy, Anger/Temper, and Positive Outlook. These assessments were completed prior to taking glyconutritionals and again at the end of the five-week study.

Glyconutritionals were added to each subject's diet: 1 capsule per 10 pounds of body weight for the first day and thereafter 1 capsule per 20 pounds of body weight for the duration of the trial. No other interventions were introduced.

Results indicated that the mean initial alcohol craving of the five subjects had decreased in a statistically significant manner. Likewise, the results also indicated statistically significant improvements in the all of the measured mood states.

EXAMPLE 8

Treatment of Various Disorders with Glyconutrients

The following table summarizes the results obtained when patients were administered Glyco-1 either alone or in combination with one or more of Phyto-1, Glyco-1 with *dioscorea* and PROFILE™. Each patient was administered an initial dose Glyco-1 and any one or more of the respective supplements in the dosages indicated as follows:

SUPPLEMENT	DOSAGE
Glyco-1 (A)	2 capsules, 4×/day
Phyto-1 (B)	1 caplet, 4×/day
Glyco-1 with dioscorea complex (C)	1 caplet, 4×/day
PROFILE ™ (D)	1 tablet, 3×/day

- "E" indicates a topical hydrogel formulation comprising glyconutritionals
- "F" indicates an oral dietary supplement comprising glyconutritionals and herbal extracts.
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- "F" indicates an oral dietary supplement comprising glyconutritionals and herbal extracts.

During each study, patient progress and nutritional or overall health response to administration of a given dietary supplement regimen was monitored For those patients not responding well to initial doses, their dosing regimen was altered and their progress monitored again. It should be noted that in each of the cases, the Glyco-1 at an appropriate dose provided nutritionally effective amounts of the essential saccharide(s) necessary to promote good overall health in a given patient That is, the glyconutrient-containing dietary supplement of the invention is not intended or professed to cure any of the disorders listed below. Rather, the dietary supplement provides a patient the necessary glyconutrients to permit a

patient's own body to heal itself.

TABLE 4

Disorders treated by administration of glyconutrients alone or in combination with one or more of phytonutrients, dioscorea complex and vitamins and minerals.

DISORDER	NUTRITIONAL PRODUCTS ADMINISTERED	TREATMENT RESULTS
aging process or optimal health plan	A, B, C, D	decreased body fat; increased muscle mass and bone density; serum bio-chemistry altered to more healthy values
old stable strokes	A, B, C	restored sensory and muscular control
multiple sclerosis	A, B, C	restored sensory and muscular control
amyotrophic lateral sclerosis	A, B, C	restored sensory and muscular control
muscular dystrophy	A, B, C	restored sensory and muscular control
cerebral palsy	A, B, C	restored sensory and muscular control
macular degeneration	A, B, C	sight restorations
seizures	A, B, C	reduction or elimination of allergies and infections; coordination, learning, memory and appearance improvements
Down's Syndrome	A, B, C	reduction or elimination of allergies & infections; coordination, learning, memory and appearance improvements
systemic combined	A, B, C	antibody and T-cell

immune deficiency syndrome		function restoration
Tay-Sachs	A, B, C	restoration of lost functions
retinitis pigmentosis	A, B, C	sight restoration
color blindness	A, B, C	can see color
Huntington's chorea	A, B, C	restoration or improvement of lost functions
Alzheimer's	A, B, C	restoration or improvement of lost functions
Parkinson's	A, B, C	restoration or improvement of lost functions
inflammatory polyneuropathy	A, B, C	restoration or improvement of lost functions
Closed head traumatic syndromes	A, B, C	restoration or improvement of lost functions
spinal cord injury	A, B, C	restoration or improvement of lost functions
ulcerative colitis	A, B, C	healed ulcers
Crohn's disease	A, B, C	healed ulcers
schizophrenia	A, B, C	improvements in functions
depression	A, B, C	improvements in functions
anxiety reactions	A, B, C	improvements in functions
compulsive disorders	A, B, C	improvements in functions
nervous tics	A, B, C	improvements in functions
restless leg syndrome	A, B, C	improvements in functions
Tourette's syndrome	A, B, C	improvements in functions
autism	A, B, C	improvements in functions
Wegener's granulomatosis	A, B, C	restoration of tissue
Lupus E.	A, B	healing of lesions
Rheumatoid arthritis	A, B	relief of symptoms
thyroiditis	A, B	normalization of antinuclear antibodies
myesthenia gravis	A, B	normalization of antinuclear antibodies
diabetes mellitus	A, B	normalization of glucose and Hgb AIC; restoration of renal functions; healing of ulcers, elimination of infection; elevated lipids normalize; reduced insulin and

		glycomeds
osteoporosis	A, B	reduced pain increased bone density
alcoholism	A	reduction in craving
cocaine	A	reduction in craving
atherosclerosis	A, B	reduced total cholesterol, LDL, and triglycerides and increased HDL; improved patency of vessels and arrhythmia
idiopathic myocarditis (presumed viral origin)	A, B	increased ejection function; restoration of heart size; increased Coxsackievirus antibody levels; and reversal of heart failure
rheumatoid arthritis	A, B	elimination of pain, stiffness, fever, and swelling; restoration of scope of motion, strength and endurance
degenerative arthritis	A, B	elimination of pain, stiffness, fever, and swelling; restoration of scope of motion, strength and endurance
traumatic arthritis	A, B	elimination of pain, stiffness, fever, and swelling; restoration of scope of motion, strength and endurance
juvenile arthritis	A, B	elimination of pain, stiffness, fever, and swelling; restoration of scope of motion, strength and endurance
asthma	A	elimination of shortness of breath and wheezing and improvement of pulmonary function
allergy - nasal, eyes, hay fever	A	elimination of itching, swelling, rash discomfort

silicon breast implant	A, B, C	reduction or elimination of symptoms
environmental toxin syndrome	A, B, C	reduction or elimination of symptoms
agent orange	A, B, C	reduction or elimination of symptoms
Gulf War syndrome	A, B, C	reduction or elimination of symptoms
Hepatitis B & C	A, C, D	normalization of liver enzymes and symptoms
influenza virus	A, C, D	prevention or amelioration; improvement of symptoms
common cold	A, C, D	prevention or amelioration; improvement of symptoms
AIDS	A, C, D	elimination of symptoms; m-RNA of HIV-1 is undetected; restored immune function
herpes	A, C, D	elimination of infestations
warts	A, C, D	elimination of infestations
human papillovirus	A, C, D	elimination of infestations
otitis media (chronic or persistent)	A, C, D	elimination of symptoms and need for antibiotics
leukemia	A, B, C, D	correction of altered chromosomes
lymphomas	A, B, C, D	normalization of tissue biopsies
sarcomas (astrocytomas)	A, B, C, D	normalization of tissue biopsies
adenocarcinomas such as breast, prostate, ovarian, gastrointestinal and lung	A, B, C, D	elimination of metastasis and shrinkage of mass to undetectable level
profound introversion and female impotence	A, B, C, D	restoration of psychological interest and physiological sexual function in the elderly
pain, ulcers and coldness of extremities in diabetes, raynauds, frost-bite, snake-bite	A, C, E	restoration to intact, painless extremity and microvascular circulation

and atherosclerosis		
sun damaged skin, age damaged skin, and radiation damaged skin	A, C, E	lessening of pigmentation, wrinkles, and lost elasticity and restoration of dermis and epidermis
athletic performance	C, F	increased strength and endurance, delayed fatigue, facilitation of recovery in young and aging athletes

In summary, this invention pertains to the field of dietary supplements and nutritional support for promotion and maintenance of optimal good health. More specifically, the invention relates to compositions of carbohydrates as dietary supplements that are essential for the production of correctly structured and, therefore, properly functioning glycoproteins.

Science has recently shown that glycoproteins play a key role in all cellular communication. Many of the cytokines, i.e. cellular "words," do not function properly without an attached glycosyl moiety. The body hydrolyzes complex polysaccharides such as plant carbohydrates into various monosugars and restructures them into oligosaccharides that are then used by the body to build the glycoproteins required by cytokines for cellular communication and, thus, for good health.

This invention will correct the problem caused by modern diets consisting of highly refined foods, from which many essential ingredients have been eliminated during processing, specifically sugars needed for correctly structured and properly functioning glycoproteins.

The above is a detailed description of particular embodiments of the invention. Those of skill in the art should, in light of the preset disclosure, appreciate that obvious modifications of the embodiments disclosed herein can be made without departing from the spirit and scope of the invention. All of the embodiments disclosed herein can be made and executed without undue experimentation in light of the present disclosure. The full scope of the invention is set out in the disclosure and equivalent embodiments thereof. The specification should not be construed to unduly narrow the full scope of protection to which the present invention is entitled.

As used herein and unless otherwise indicated, the terms "a" and "an" are taken to mean "one", "at least one" or "one or more".

* * * * *