Phase 2 Clinical Trials

On: DigestaCure® AUTOIMMUNE-X®

in standard low dose form of 8 to 12 - 500mg capsules daily.

Study's Objectives:

1. **EFFECTIVENESS:** To demonstrate average healing time periods necessary to produce significant or total therapeutic improvement, in persons suffering with "incurable" autoimmune diseases, via the administration of the natural product **DigestaCure® AUTOIMMUNE-X®** in standard low dose form.

2. **SAFETY:** To confirm the **safety and non-toxicity of DigestaCure® AUTOIMMUNE-X®**, as outlined in the **PHASE 1 SAFETY DATA.**

TYPES and NUMBER of PERSONS BEING STUDIED: This study is comprised from the standardized data submitted from **186 persons** of all ages and both sexes, suffering at varying levels with autoimmune symptoms and diseases, prior to taking **DigestaCure® AUTOIMMUNE-X®**. Persons come to take **DigestaCure® AUTOIMMUNE-X®** because they refuse to take pharmaceutical medications for their conditions, or because their medications are not working and/or causing further problems.

COVER SUMMARY OF PROCEDURE: 186 Persons suffering with autoimmune symptoms and diseases taking **DigestaCure® AUTOIMMUNE-X®** were encouraged to take dosages consistently, communicate with the DigestaCure® Support Team when questions arose, and submit the standard electronic progress reports during the healing process. Data received, minus personal information, was compiled, analyzed, and categorized into the charts and conclusions outlined. Each person was assigned a case number based on the date of their last submission. Copies of the original electronic submission reports, minus personal information, are found in Section C.

COVER OVERVIEW: Outlined in over 600 published scientific studies, conducted by over one thousand independent researchers, scientists, MDs, PhDs, and natural healing practitioners, on the active ingredients in Aloe Vera, selectively being used in a proprietary stabilized concentration in **DigestaCure® AUTOIMMUNE-X®,** have illustrated astounding diverse therapeutic potential for over 5 decades. These published studies, on file with the International Aloe Science Council (IASC), have been virtually ignored by drug-based establishment medicine while millions have suffered unnecessarily with chronic degenerative autoimmune diseases. We are hopeful that the foresight and sincerity of the new administration will lead to a full investigation into the validity of these known healing properties.

COMMENTS FROM PHASE 2 STATISTICIANS: Considering the fact that every condition addressed in this study is currently classified as "incurable" by the pharmaceutical/medical establishment, consistent small improvements in any of these conditions is inarguably profound. The improvement levels submitted and outlined here are beyond massively significant. Due to previous, combined personal and patient experiences with this natural formulation, we must state here that we are not at all surprised by the findings in the **PHASE 2 TRIAL.** Upon learning of their existence, we requested these Progress Submission Forms from the company for the purpose of review. (See forms in Section C). Flavianny Santos, CCRC (Certified Clinical Research Coordinator), Andrea Larsen, Medical Research Coordinator/Licensed Nutritionist.

CONCLUSION: It is the opinion of the professionals compiling these findings, that the **PHASE 2 CLINICAL TRIAL** has the potential to change the direction of modern medical treatment away from the emphasis on the harmful drug-based methodology, which has recently been designated as the ***Third Leading Cause of Death**, to a harmless and effective natural therapeutic approach. *Johns Hopkins University

PHASE 3 and 4 CLINICAL STUDY data is presently being compiled from standard electronic progress reports, and patient case files of numerous Medical Doctors and Natural Healing Practitioners using DigestaCure® AUTOIMMUNE-X in their practices.

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SUMMARY OF PHASE 2 CLINICAL TRIALS on DigestaCure® AUTOIMMUNE-X®

IN MONTH 1 OF THEIR TREATMENT, 62 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 0% TO 100% WITH AN **AVERAGE OVERALL IMPROVEMENT OF 24.19%** (1500% / 62 = 24.19%) WITH 15 PERSONS (24.19%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 2 OF THEIR TREATMENT, 40 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 0% TO 90% WITH **AN AVERAGE OVERALL IMPROVEMENT OF 31.50%** (1260% / 40 = 31.50%) WITH 8 PERSONS (20.00%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 3 OF THEIR TREATMENT, 37 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 0% TO 100% WITH AN **AVERAGE OVERALL IMPROVEMENT OF 38.91%** (1440% / 37 = 38.91%) WITH 6 PERSONS (16.21%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 4 OF THEIR TREATMENT, 14 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 10% TO 100% WITH AN **AVERAGE OVERALL IMPROVEMENT OF 42.14 %** (590% / 14 = 42.14%) WITH 0 PERSON (0%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 5 OF THEIR TREATMENT, 8 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 10% TO 100% WITH AN **AVERAGE OVERALL IMPROVEMENT OF 71.25%** (570% / 8 71.25 = %) WITH 0 PERSON (0%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 6 OF THEIR TREATMENT, 6 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 30% TO 100% WITH AN **AVERAGE OVERALL IMPROVEMENT OF 60.00%** (360% / 6 = 60%) WITH 0 PERSONS (0%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 7 OF THEIR TREATMENT, 5 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 40% TO 100% WITH AN **AVERAGE OVERALL IMPROVEMENT OF 64.00%** (320% / 5 = 64.00%) WITH 0 PERSONS (0%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 8 OF THEIR TREATMENT, 4 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 50% TO 100% WITH AN **AVERAGE OVERALL IMPROVEMENT OF 87.50%** (350% / 4 = 87.50%) WITH 0 PERSONS (0%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 9 OF THEIR TREATMENT, 3 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 50% TO 70% WITH AN **AVERAGE OVERALL IMPROVEMENT OF 56.66%** (170% TOTAL / 3 = 56.66%) WITH 0 PERSONS (0%) NOT YET SHOWING IMPROVEMENTS.

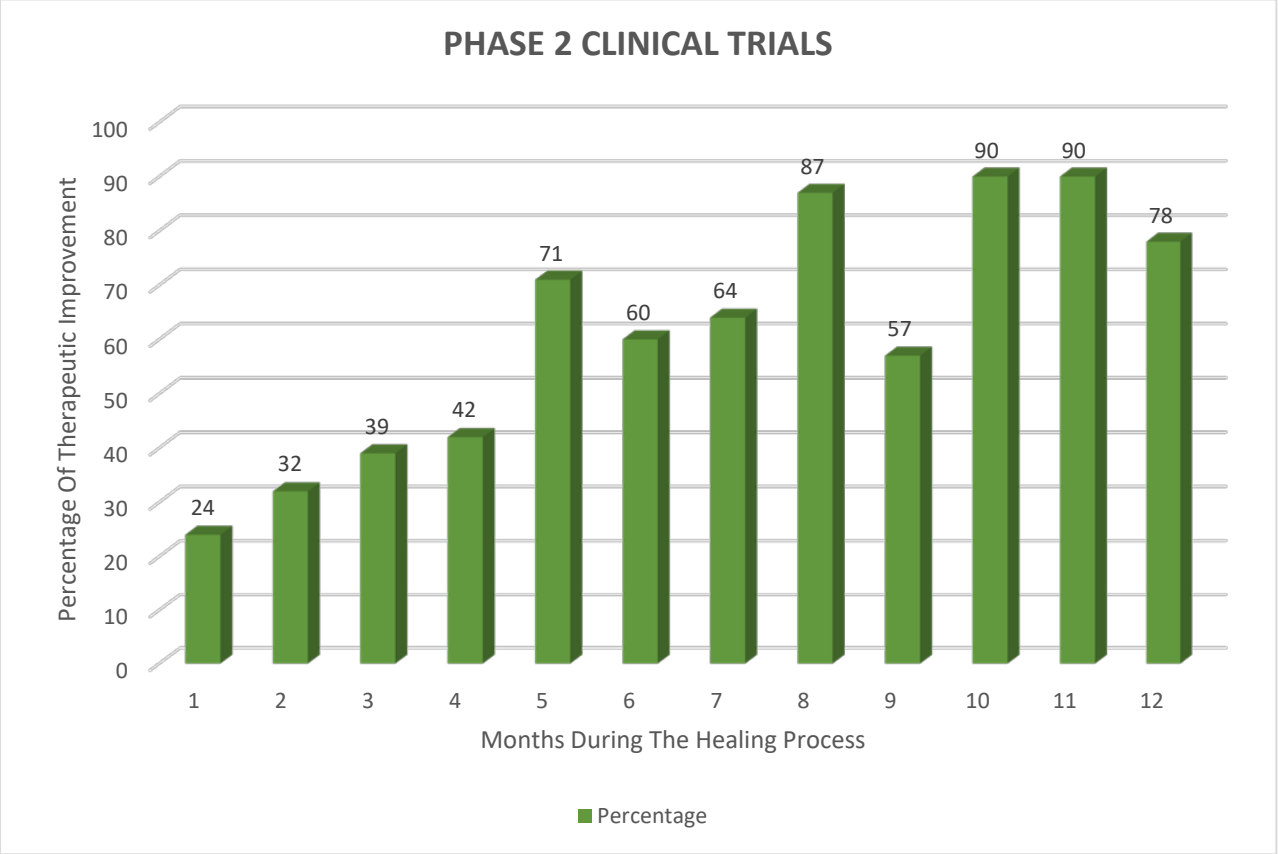
IN MONTH 10 OF THEIR TREATMENT, 1 PERSONS SUBMITTED A REPORT STATING OVERALL THERAPEUTIC IMPROVEMENTS, OF 90%. YIELDING AN **AVERAGE OVERALL IMPROVEMENT OF 90.0%** (90% TOTAL / 1 = 90.0%) WITH 0 PERSONS (0%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 11 OF THEIR TREATMENT, 1 PERSONS SUBMITTED A REPORT STATING OVERALL THERAPEUTIC IMPROVEMENTS, OF 90%. YIELDING AN **AVERAGE OVERALL IMPROVEMENT OF 90.0%** (90% TOTAL / 1 = 90.0%) WITH 0 PERSONS (0%) NOT YET SHOWING IMPROVEMENTS.

IN MONTH 12 OF THEIR TREATMENT, 5 PERSONS SUBMITTED REPORTS STATING OVERALL THERAPEUTIC IMPROVEMENTS RANGING FROM 60% TO 90%. YIELDING AN **AVERAGE OVERALL IMPROVEMENT OF 78.0%** (390% TOTAL / 5 = 78.0%) WITH 0 PERSONS (0%) NOT YET SHOWING IMPROVEMENTS.

See the chart illustrating this data below.

The chart below illustrates the progressions of AVERAGE THERAPEUTIC IMPROVEMENT as outlined above.



CONCLUSION: PHASE 2 CLINICAL TRIALS for safety and effectiveness on DigestaCure® AUTOIMMUNE-X® demonstrate astounding therapeutic effectiveness in persons suffering with autoimmune symptoms and conditions, while producing no deaths, injuries, or side-effects. The purpose of this bar graph is to illustrate the fact that the Healing Process builds with time. The 12 month interval is *irrelevant*, for healing time-frames and dosages can be increased for faster and more thorough results.

IMPORTANT NOTATIONS:

1. A substantial percentage of persons who were instructed to raise dosages from 8 to 12 capsules per day at appropriate junctures during the healing process, could not do so due to personal financial restrictions. This obstacle will be overcome once approval and subsequent insurance coverage is in place.

2. Once approved, knowledge of success rates in conjunction with physician direction, encouragement, and ability to control/raise dosages when prudent, will significantly increase positive results and potentially shorten healing time frames.

3. A substantial percentage of participants did not bother to submit updated reports after they healed further, or completely in the process.

What is DigestaCure® AUTOIMMUNE-X®?

Through years of testing and refining, Pristine Nutraceuticals has discovered a combination of extracted, stabilized, and concentrated GRAS materials, in precise proportions, which together may progressively nudge the immune system *out* of the attack-mode of AUTOIMMUNITY, and back into the state of normalcy. This natural, proprietary formula is known as **DigestaCure® AUTOIMMUNE-X®**. As outlined in numerous studies, there are many physiologic modes of action working in unison which allow immunity to return to normalcy.

THE PROBLEM IDENTIFIED:

Under a microscope, we may view the fuzzy coating surrounding the surface of immune killer cells. This fuzzy coating is known as the Glycocalyx. This coating is a **coding system** (a guidance system) which enables the immune cells to communicate with other cells in order to locate the pathogens, and eliminate them. This guidance system is made up of Immune Modulating Components (IMCs) of multiple types. IMCs function like a "GPS SYSTEM" for immune killer cells so that they may HIT their target, the pathogen. When an adequate amount of IMCs are present in the body, the immune cells become very ACCURATE and are able to find and eliminate the pathogens which promote illness and disease.

Autoimmunity: When IMCs are NOT present in the body, the immune cells become very INACCURATE, often unable able to find the pathogens, often attacking the tissues of the bodASy instead! The glycocalyx coding system has broken down, and thus, **Cell to Cell communication** has broken down. This is Autoimmunity. **Autoimmunity is the Failure of the immune killer cells to differentiate (recognize) the body's cells from a pathogen which can trigger an "autoimmune" response in which the immune system attacks its own cells, tissues, and organs.**

When the autoimmune attack strikes the joints, the pharma/medical complex refers to the condition which ensues as "arthritis." When the autoimmune attack strikes the thyroid gland, the terms commonly become "Hashimoto's Thyroiditis" and "Grave's Disease." When the autoimmune attack strikes the digestive tract, terms are commonly issued such as "Crohn's Disease," "Gastritis," and "Ulcerative Colitis," to name a few. All 100 plus autoimmune conditions are simply different areas of damage caused by the attack. All are labeled "incurable" by the Complex, and treated with profitable side-effect laden drugs, which cause damage and death, heal nothing, and of course **fail to address the root cause: Autoimmunity.**

THE SUCCESSFUL HEALING APPROACH:

By simply feeding the body a concentration of the Immune Modulating Components, which the immune system relies upon in order to create the glycocalyx, the immune killer cells can progressively hit the pathogen, and progressively cease from attacking the tissues of the body. **This is the main mode of action which enables us to achieve the levels of therapeutic improvements demonstrated here. To clarify precisely; The Successful Healing Approach; We are *not* treating conditions*, diseases*, symptoms*, or diagnoses.**

WE ARE SIMPLY FEEDING THE IMMUNE SYSTEM WHAT IT IS LACKING, AND ALLOWING THE IMMUNE SYSTEM TO HEAL ITS' OWN ROOT-DISEASE, AUTOIMMUNITY. WHEN IMMUNITY RESTORES TO NORMAL, ACCURATE FUNCTION, IT NO LONGER ATTACKS ANY TISSUE LOCATION IN THE BODY.

Thus The Approach is n*ot* to chase symptoms, but to place immunity in a position to heal the body without risk or harm.

*See list of autoimmune conditions and common autoimmune related symptoms in Section B.

HEALING OBSTACLES:

PERSONS DROPPING OUT OF THE HEALING PROCESS EARLY DUE TO:

1. FINANCIAL ISSUES: Due to the fact that the healing process generally requires several months to achieve optimal therapeutic benefit, an approximate 50% of those who enter the healing process will drop out in the early months, due to financial difficulties in acquiring the natural formulation. Those persons who do not see significant change in the early months make up the approximately half of these drop-outs. Surprisingly, the other half dropping out are often showing significant therapeutic improvements ranging from 20% to 50% at the time of dropping out.

2. REDUCTIONS IN SYMPTOMS ENCOURAGE NON-COMPLIANCE: Due to ***pain*** being the only motivating factor for many, without doctor direction, a significant percentage of persons will terminate the healing process prematurely as symptoms lessen.

PHYSICIAN COMMENTS FROM EXPERIENCE:

1. Individual dosage requirements of the natural formulation **DigestaCure® AUTOIMMUNE-X®**, needed to reach significant or full recovery from autoimmune conditions will vary. Generally, the higher the dosage the faster the recovery.

2. Once the patient has recovered, individual dosage levels required in the effort to maintain healthy immune function (the maintenance level), and to prevent reoccurring immune failure and the subsequent return of autoimmune conditions, may also vary, but in the overwhelming majority of cases, these maintenance levels prove to be merely a fraction of the dosage levels required to achieve disease recovery.

OBSERVATIONS AND INSIGHT:

1. As the data strongly indicates, in general;

a. The longer the patient stays with the healing process, the greater the therapeutic improvement experienced, and …

b. 12 Capsules daily yielded a nearly 15% greater therapeutic improvement across the months of the healing phases, as compared to 8 capsules daily.

SUMMARY OF AVERAGES OF THERAPEUTIC IMPROVEMENTS EXPERIENCED:

99 PERSONS TAKING 8 CAPSULES PER DAY OVER THE COURSE OF THEIR HEALING PERIOD REPORTED A TOTAL OF 3560% IMPROVEMENT, YIELDING AN AVERAGE IMPROVEMENT OF 35.95% PER PERSON. THIS AVERAGE FIGURE IS LOW, DUE TO THE MASSES DROPPING OUT OF THE HEALING PROCESS IN THE EARLY MONTHS, PRIMARILY DUE TO EXPENSE.

47 PERSONS TAKING 12 PER DAY OVER THE COURSE OF THEIR HEALING PERIOD REPORTED A TOTAL OF 1940% IMPROVEMENT, YIELDING AN AVERAGE IMPROVEMENT OF 41.27%. AGAIN, THIS AVERAGE FIGURE IS LOW, DUE TO THE MASSES DROPPING OUT OF THE HEALING PROCESS IN THE EARLY MONTHS, PRIMARILY DUE TO EXPENSE.

NOTE:

THOSE INDIVIDUALS TAKING 12 CAPSULES PER DAY EXPERIENCED A 14.81% GREATER IMPROVEMENT OVER THOSE TAKING 8 PER DAY.

THE 14 PERSONS REMAINING IN THE HEALING PROCESS FROM 8 MONTHS TO 12 MONTHS EXPERIENCED AN AVERAGE THERAPEUTIC IMPROVEMENT OF 77.85%.

THE 7 PERSONS REMAINING IN THE HEALING PROCESS FROM 10 MONTHS TO 12 MONTHS EXPERIENCED AN AVERAGE THERAPEUTIC IMPROVEMENT OF 81.42%.

2. In this **PHASE 2 CLINICAL TRIAL**, all 186 persons responded within 4 months of treatment. Although it did not happen in this trial, The Support Team has reported that on occasion, a tough case has not responded until after 8 months of treatment.

3. The Support Team has also reported that of the toughest autoimmune cases to respond, when the person is willing to take higher daily dosages of 18 to 24 capsules (9 to 12 grams) daily, 4 out of 5 of these most difficult cases seem to turn the corner showing a significant therapeutic improvement within one month on these higher levels.

COMMENT: We believe that potentially limited or damaged receptor sites (enterons) within some patients' small intestinal tracts, may play a major role in the amount of formula necessary to produce improvement from patient to patient. Using higher levels of the immune modulators increases chances of the remaining functioning enterons catching a modulator, subsequently yielding higher levels of therapeutic improvement.

The "Industry-Standard," Double-Blind Placebo Controlled Study Method, is useful to the Industry, *not to the Patient*.

A critical review of the so-called "double blind" study reveals pitfalls, fallacies, and inadequacies of this method of investigation which in the past has created an unwarranted sense of security in many investigators. The "Worsening" of patients' conditions while on placebos is demoralizing to patients and administrative personnel, and the ethics of such a procedure in a patient who is in dire need of active treatment should be seriously questioned.

The use of placebos as treatment in clinical medicine (as opposed to laboratory research) is ethically problematic as it introduces deception and dishonesty into the doctor-patient relationship. The United Kingdom Parliamentary Committee on Science and Technology has stated that: "...prescribing placebos... usually relies on some degree of patient deception" and "prescribing pure placebos is bad medicine. Their effect is unreliable and unpredictable and cannot form the sole basis of any treatment on the National Health Service." Excerpts from: ***UK Parliamentary Committee Science; Technology Committee. "Evidence Check 2: Homeopathy".***

We do not possess the heart, or lack of conscience, to deceive a patient - to place a deteriorating chronically ill person on a placebo sugar pill for 12 months, while watching them deteriorate, and potentially die. Why would we consider doing this when we could simply place them in a position to heal?

In the pursuit for approval of patented drugs, the "double-blind placebo controlled" testing method is touted by the pharma/medical industry as the "gold standard" in study methods. The study goal is to illustrate a marginal "positive" difference in symptom relief, between the placebo and the drug being tested. In the majority of cases, a 10% margin is considered good, and significant enough to gain government approval for the drug, as long as the volume of injuries and patient deaths are on an "acceptable level."

Now it must be noted, that the methods and concoctions utilized by the drug industry has propelled it to the status of ***The Third Leading Cause of Death in the US.** A significant number of these deaths occur during the double-blind studies, both due to the patient succumbing to their illness while on the placebo, and/or patients dying from the direct unwanted effects of the chemical drug. *****Johns Hopkins University

If the industry were using laboratory rats, the double-blind study may be acceptable, but since they are not, it is difficult for anyone who is not benefiting from drug sales to envision a "gold-standard" in regard to the injury or death of patients.

In our humble opinions, healing the patient without harm should be the gold-standard, and healing the patient of diseases listed as "incurable" should be the **Platinum Standard.**

A Platinum Standard Study, involves the administration of an **effective and harmless substance, to ALL study participants.** Whether involving one hundred, or one thousand participants suffering from "incurable" degenerative diseases, a therapeutic success rate of 20% with no substance related injury or death would be unheard of, considered impossible, and feared by the industry. A therapeutic success rate of 50% with no substance related injury or death would change the world. What serious non-biased scientist would argue against any harmless method which elevates and eradicates incurable conditions en masse, without injury?

STUDY METHOD FOR PHASE 2 CLINICAL TRIALS

The Double-Blind PHASE 2 CLINICAL TRIALS data was compiled commencing in early MARCH of 2015 from data submitted over the previous 8 months from 186 persons with autoimmune symptoms and diseases, who were taking DigestaCure® AUTOIMMUNE-X® as directed, for periods up to 12 months and communicated with the Support Team via phone and submitted electronic standardized progress reports during the healing process. The Trial, although not involving a placebo for all the good reasons listed above, was Double-Blind in the sense that:

1. No Participant Knowledge of Clinical Testing:

All persons purchased **DigestaCure® AUTOIMMUNE-X®** on their own. To date, **All** persons were blind to the fact that their submitted data (minus all personal information) would be part of a clinical trial. From our experience, and the reports from others in the natural healing field, significant numbers of skewed reports (in both directions, positive and negative), can occur when participants are aware that their submitted data will be used in the formulation of a published result.

2. No Physician Knowledge of Clinical Testing:

Participants' doctors, in the overwhelming majority of cases, were not aware that their patients were even taking the Natural Formulation, and no doctor was aware that their patient's hard data would be part of a clinical trial. All physicians were blind to the fact that a clinical trial was under way.

Minimal physician encouragement, in conjunction with high negative-reinforcement to participants would presumably significantly nullify any potential "placebo effect."

In Contrast, the overwhelming majority of the doctors who *were* informed by the patients that they were taking The Formulation, discouraged the patient from taking the Formulation with various industry-standard statements such as; *"You are wasting your money with the natural product."* … and; *"There is no cure for autoimmune diseases,"* and; *"The product is a placebo at best,"* were all reported. Another commonly reported *neutral* physician statement was; *"Well, the ingredients can't hurt you".*

Note: All participants' doctors were industry-trained. No participant doctor was trained or instructed by our group, and No participants' doctor was aware that their patient's data would be part of a clinical trial. Consequently, in the overwhelming majority of cases, no doctor encouragement or faith was given to the patient in regard to The Formulation being effective.

STUDY PARAMETERS:

This PHASE 2 CLINICAL TRIAL is based on voluntary data submitted electronically from 186 persons suffering with autoimmune symptoms and diseases, who had begun taking **DigestaCure® AUTOIMMUNE-X®**. The data was sent via a standardized Progress Submission Form. The objective of the Trial was to further demonstrate safety, and average numbers of months necessary to produce significant or total therapeutic improvement in persons taking **DigestaCure® AUTOIMMUNE-X®** in standard low dose form, who had been suffering with autoimmune symptoms and diseases. Each person's report represents one month during their healing period. Progress Submission Forms rejected from **PHASE 2 CLINICAL TRIAL** were: duplicate forms, and forms left incomplete in critical areas such as; number of months taking, dosages being taken, and percentage of improvement experienced (zero "0" was always a checkbox option).

Study History on DigestaCure® AUTOIMMUNE-X®

PAST STUDIES:

PHASE 1 SAFETY DATA demonstrates 100% safety and 100% non-toxicity. The Formulation has been administered to tens of thousands over the last 9 years with no (zero) related deaths or injuries.

THIS STUDY:

PHASE 2 CLINICAL TRIALS for safety and effectiveness involving 186 blind participants have been completed and demonstrate astounding therapeutic benefit against autoimmune symptoms and conditions, while producing no notable side-effects or toxicity.

The GRAS, USDA approved food materials used within The Formulation exhibit no contraindications with medications.

STUDIES UNDERWAY:

Due to the overwhelming evidence of effectiveness demonstrated in the PHASE 2; ... PHASE 3 and PHASE 4 CLINICAL TRIALS are underway.

PHASE 3 CLINICAL TRIALS for safety and effectiveness involving a similar number of participants are underway, and are expected to reaffirm the **PHASE 2** results.

The PHASE 3 CLINICAL TRIAL will be a duplicate in methodology to **THE PHASE 2 TRIAL.**

PHASE 4 CLINICAL TRIAL data is presently being compiled from doctor-patient files of numerous Medical Doctors and Natural Healing Practitioners using **DigestaCure® AUTOIMMUNE-X®** in their practices.

Basic Therapeutic Modes of Action: The specific phytonutrients (mannans) derived from a 20th generation aloe botanical, and concentrated in **DigestaCure® AUTOIMMUNE-X®** are processed and stabilized (preserved in biologically-active form) in a proprietary way that food materials are not normally processed. These include: stabilized long-chain polymannan and polysaccharide molecules, stabilized mannose molecules, stabilized glycoproteins, stabilized glucomannans, stabilized glucopolymannans, stabilized glycolipids, stabilized medium and short chain polysaccharides (oligosaccharides), and stabilized mucopolysaccharides.

For decades, scientists in the field of biochemistry and cellular communication have attempted to break the biological code which enables the trillions of cells that make up our bodies to communicate with each other. This communication between cells is vital for virtually every system, structure, and function within the body. Cellular communication is also vital for proper immune system modulation. It involves the identification of foreign invaders and the exchange of information necessary to maintain the health of each individual cell making up every tissue and organ of the body. Cellular communication is the very foundation of health. When this communication breaks down or becomes hindered, autoimmune disease (self-attacking-self), premature aging, and a multitude of system malfunctions are likely to arise throughout the body.

The Stabilized immune modulating components concentrated in **DigestaCure®AUTOIMMUNE-X®**, in accordance with numerous scientific studies, are believed to normalize immune function through the enhancement of cellular communication, thus eliminating the self-attacking-self response of autoimmunity.

"The most marked biological activities of mannans in mammals are activation of macrophages and stimulation of T lymphocytes." Ian R. Tizard, BVMS, Ph.D., Robert H. Carpenter, CVM, MS, Bill H. McAnalley, Ph.D., and Maurice C. Kemp, Ph.D. *Excerpt from;* ***"The biological activities of mannans and related complex carbohydrates."***

"The key to integrating healthy digestion with a healthy immune system is the oral ingestion of Aloe mucilaginous polysaccharides. Aloe mucilaginous polysaccharides act as a potent anti-inflammatory agent, stopping the damage and leakage of the intestinal wall, thereby taking the stress off the immune system. Aloe mucilaginous polysaccharides stimulate the macrophages, monocytes, antibodies, and T-cells. Phagocytosis (the process of white blood cells engulfing bacteria, viruses, etc.) is dramatically increased to ingest foreign proteins such as the HIV virus. Aloe mucilaginous polysaccharides increase the number and intensity of all immune cells in the body. Aloe mucilaginous polysaccharides have direct anti-bacterial, anti-viral, antifungal/yeast and anti-parasite effects. Chronic yeast growth can be controlled so the normal, healthy flora (friendly bacteria Ed.) can then thrive more easily. Aloe mucilaginous polysaccharides have a remarkable ability to normalize an array of damaging processes, which has the effect of enhancing the immune system function through improved digestion." Dr. John C. Pittman, M.D. *Excerpts from; "****Digestion and The Immune System and Aloe Vera MPS."***

"Aloe mucilaginous polysaccharides are immune modulating, which have a powerful healing effect on many different immune system disorders. Aloe mucilaginous polysaccharides have a direct anti-bacterial and anti-viral effect. Whereas vitamins and minerals can only function outside the cells, mucilaginous polysaccharides are very effective intracellular antioxidants and free radical scavengers. Aloe mucilaginous polysaccharides ARE NOT DIGESTED by the enzyme systems in the human digestive tract; the mannose containing molecules are absorbed by endocytosis, i.e., THEY ARE TAKEN UP INTO THE CELL INTACT. These very large long beads, these very long necklaces (long-chain Aloe polymannans Ed.), have a profound effect in preventing disease and protecting us from various noxious agents in the environment. Ivan Danhoff, M.D., PhD. *Excerpts from; "****Internal Uses Of Aloe Vera.****"*

Avoiding the Potential for Herxheimer (Detoxification or Healing Crisis).

By eliminating these disease causing pathogens slowly and gradually, the patient feels next to nothing:

In relation to the administration of **DigestaCure® AUTOIMMUNE-X®**: A Herxheimer reaction is a symptom or irritation to endotoxin-like substances released by the death of harmful microorganisms within the body, is not life threatening, usually last a few minutes or hours, and is entirely avoidable by simply following the Very Gradual Step-Up Dosage Procedure below.

A Herxheimer Reaction is not a "side-effect," is temporary at worst, and does not cause tissue damage as drug side-effects do. The elimination of harmful disease causing microorganisms throughout the body is the first positive-effect of the healing process, and can be accomplished without discomfort.

Herxheimer Reaction, or "detoxification symptoms" can be an initial concern for "highly toxic" or "super-sensitive" individuals. This can be easily avoided by understanding the following:

Due to the fact that the properties of The Formulation are by nature anti-yeast, anti-fungal, anti-mold, anti-viral, anti-negative bacterial, and anti-parasitic on contact, to avoid symptoms of rapid "die-off," we must simply eliminate these disease causing pathogens slowly and gradually, so that the patient feels little to no detoxification symptoms.

The Very Gradual Step-Up Dosage Procedure: (4 day intervals)

Capsules and Capsule contents can be taken with or without food.
Capsule contents are shaken in a water bottle, half to be consumed in the morning, and half in the evening.
When swallowing capsules; Take "half" the daily dosage in the morning, and half in the evening.

Day 1 through Day 4: Take 1/8 capsule shaken in a water bottle.
Day 5 through Day 8: Take 1/4 capsule shaken in a water bottle.
Day 9 through Day 12: Take 1/2 capsule shaken in a water bottle.
Day 13 through Day 16: Take 1 capsule shaken in a water bottle.

Take 2 capsules per day with water for the next four days.

Take 3 capsules per day with water for the next four days.

Take 4 capsules per day with water for the next four days.

Take 5 capsules per day with water for the next four days.

Take 6 capsules per day with water for the next four days.

Take 7 capsules per day with water for the next four days.

Take 8 capsules per day with water for the next three weeks until evaluated for potential adjustment.

Note: The Standard Dosage Procedure calls for a 1 day interval step-up dosage starting with 1 capsule on Day 1, increasing by one capsule per day until reaching 8 capsules per day on Day 8. This Standard Procedure is the fastest step up procedure recommended. With the Standard Dosage Procedure, our experience is that approximately one person in 20 will "feel" any form of detoxification.

With **The Very Gradual Step-Up Dosage Procedure** outlined above, our experience is that approximately one person in 300 will "feel" any form of detoxification.

Section B:

Immune Dysfunction / Autoimmune Conditions:

Acid Reflux (GERD)

Addison's Disease

Allergies

Alopecia Areata

Amyotrophic Lateral Sclerosis

Anemia

Ankylosing Spondylitis

Anti-GBM Nephritis

Anti-TBM Nephritis

Antiphospholipid Syndrome

Aplastic Anemia

Arthritis (all types)

Asthma

Atopic Allergy

(AIED) Inner Ear Disease

(ALPS)-Lymphoproliferative Syndrome

Bacterial Infections

Balo Disease

Barrett's Esophagus

Behcet's Disease

Berger's Disease (IgA Nephropathy)

Bullous Pemphigoid

Bursitis

Cardiomyopathy

Celiac Disease

Chronic Fatigue Syndrome (CFS)

Chronic Indigestion

Churg Strauss Syndrome

Cicatricial Pemphigoid

Cogan's Syndrome

Cold Agglutinin Disease

Colitis (all types)

Cranial Arteritis

CREST Syndrome

Crohn's Disease (IBD)

Cushing's Syndrome

Degos Disease

Dermatitis

Dermatomyositis

Devic Disease

Diabetes Type I & II

Digestive Dysfunction

Diverticulitis

Diverticulosis

Dressler's Syndrome

Eczema

Eosinophilic Fasciitis

Epidermolysis Bullosa Acquisita

Essential Mixed Cryoglobulinemia

Evan's Syndrome

Fibromyalgia

Fibrosing Alveolitis

Gastritis

General Infections

Giant Cell Arteritis

Glomerulonephritis

Goodpasture's Disease

Graves Disease

Guillain-Barre Syndrome

Heart Disease

Hashimoto's

Hemolytic Anemia

Hemorrhoids

Henoch-Schonlein Purpura

Hepatitis

Hiatal Hernia

High Blood Pressure

High Blood Sugar Levels

High Cholesterol

Hormonal Imbalances

Hughes Syndrome

Idiopathic Adrenal Atrophy

Idiopathic Pulmonary Fibrosis

Idiopathic-Thrombocytopenic Purpura

Infections

Inflammation (general)

Inflammatory Polyneuropathy

Interstitial Cystitis (IC)

Irritable Bowel Syndrome (IBS)

Kawasaki's Disease

Leaky Gut Syndrome

Lichen Planus

Lou Gehrig's Disease

Lupoid Hepatitis

Lupus

Lyme Disease

Meniere's Disease

Mixed Connective Tissue Disease

Multiple Myeloma

Multiple Sclerosis

Myasthenia Gravis

Myositis

Narcolepsy

Neuropathy

Ocular Cicatricial Pemphigoid

Osteoporosis

Parkinson's

Pars Planitis

Pemphigus Vulgaris

Polyglandular-Autoimmune Syndromes

Polymyalgia Rheumatica (PMR)

Polymyositis

Primary Biliary Cirrhosis

Primary Sclerosing Cholangitis

Proctitis

Psoriasis

Raynaud's Phenomenon

Reiter's Syndrome

Rheumatoid Arthritis

Rheumatic Fever

Rosacea

Sarcoidosis

Scleritis

Scleroderma

Sjogren’s Syndrome

Sticky Blood Syndrome

Stiff Man Syndrome

Still's Disease

Sydenham Chorea

Systemic Lupus Erythematosus (SLE)

Takayasu's Arteritis

Temporal Arteritis

Ulcerative Colitis (UC)

Vasculitis

Vitiligo

Wegener's Granulomatosis

Wilson's Syndrome

Common Autoimmune Related Symptoms:

abdominal cramping

abdominal pain

abdominal swelling

abdominal tenderness

abnormal growths

acid reflux

agitation

allergies

anemia

bacterial infection

bloating

blood in stools

burning pain

chronic anxiety

chronic bloating

chronic constipation

chronic depression

chronic diarrhea

chronic headache

chronic insomnia

chronic migraine

chronic nausea

confusion

constipation

depression

diarrhea

digestive problems

drowsiness

fatigue

flatulence

fungal infections

excess gas

gland or lymph problems

hair loss

headache

hemorrhoids

high blood pressure

high blood sugar levels

high cholesterol

hormonal imbalances

immune problems

indigestion

infections

inflammation (general)

insomnia

irritability

joint inflammation

joint pain

loss of muscle tone

low blood sugar levels

memory loss

menstrual problems

migraine

nasal inflammation

nausea

parasitic infections

polyps

rectal bleeding

skin disorders

tissue degeneration

ulcers

vision loss

yeast infections

Section C: PHASE 2 Progress Submission Reports