

- - SYNOPSIS - -

**A NEW PATENTED GASTROINTESTINAL TRACT BASED HUMAN HEALTHCARE SYSTEM**

U.S. PATENTS: US 8,491,495 B1, US 8,915,863 B2, US 8,926,526 B2, US 9,215,997 B2, US 9,955,922 B2

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**SYNOPSIS OF THE 5- PATENT SYSTEM**

These five patented capsule devices, methodologies and systems, when combined, address as many as 34 symptoms in various combinations, associated with as many as 53 major human health diseases, for which no cures are known and only symptoms are treated. This comprehensive system and methodologies constitute a new human healthcare system. These 53 major human diseases are known, acknowledged, and cited by medical professionals to have their origin in the human gut, which is also the origin of the various 34 symptoms. Each of the patented capsules represents a different process that is essential to researching, exploring, discovering, bracketing, diagnosing, and treating at the source, the actual causes of these 53 major human diseases. After creating statistical profile mapping of the gut microbiome and their cascaded byproducts, bracketing and treating the causes of the diseases at the precise locations in the gut, then associating some 3,000 strains and species of microbes with their specific endotoxins should result in a very high probability of discovering for the first time in history the actual causes of these 53 major human diseases, and it then becomes feasible to lead to the actual cures of the diseases, some of which, were identified over 8,000 years ago. Each of these five patented inventions is also a subsystem that performs independent functions, all of which is essential to constitute an overall patient diagnostic and treatment system. The human gastrointestinal tract and its microbiome is believed to be the most sophisticated system, with the most independent and dependent variables, spanning the full spectrum of science and engineering disciplines, known to mankind. The inaccessibility of the small intestine where the most important phenomena occur, and the thousands of species and strains of microbes, of which many have never been identified or characterized, creates a number of probabilities of one in trillions for conventional statistical medical research methodology. The gut ecosystem consists of many symbiotic, coincident, codependent, sequential, transient, time and space dependent processes with feedback, which renders statistical research means virtually impossible, if not an absurd waste of money and resources. Current "studies" correlating symptoms, diets, diseases and genetics with each other is largely a huge waste, because they are all coincidental with the same unknown variables! Each invented capsule performs unique functions, such that when all combined, should reduce the number of variables to a tractable number. Thus, the few remaining principal, strong variables, along with diet and other control protocols, should allow construction of models of the basic causative mechanisms and actual causes of the diseases, for which, then cures become feasible and eminent.

**CAPSULE A, PATENT NO. US 8,491,495 B1 Human Intestinal Tract Research and Diagnostic System to Evaluate Patients and Advance Medical Science and Bioengineering and to Determine Processes in the Gut and Causes of Diseases 7-23-2013**

This capsule is designed to obtain simultaneously gut microbe species and their byproducts along the entire GI tract, such that a global understanding, and perhaps model, of the many roles of the gut microbiome. Numerous and different processes occur along the entire gastrointestinal tract (GI Tract, or gut) of all animals. The processes taking place downstream are functions of what happens upstream, and in a cascade manner. While knowledge has been gained on processes and magnitudes of some variables within discrete portions of the gut, there is no known variable for which continuous data are available within the gut. Such discontinuities

render most of the processes and their variables along the gut guesswork at best. Capsule A, is a device, process, and methodology that permits several variables of the gut to be monitored continuously, and other critical ones on a fine grid such that continuous interpolation of data is relatively precise. This means that every conceivable gut process variable can be plotted from  $x = 0$  to  $x = L$  for the first time in history of mankind. Such a graph constitutes a profile. In addition, these hundreds of graphs include microbe species/strains and the chemical substances they are associated with for a variety of reasons. Therefore, each human will have unique profiles, but commonality in various ways that are significant in bracketing and diagnostics to lead to accelerated treatment and cures. This constitutes a new tool for gastroenterologists to scope the entire GI tract in a holistic manner, overcoming the limitations of colonoscopy, and endoscopy, among others.

**CAPSULE B, PATENT NO. US 8,915,863 B2 In Vivo Device and method for Researching GI Tract Processes, Microbes, and Variables Associated with illnesses and Diseases 12-23-2014**

Capsule B is a research tool, methodology, and an interactive system to explore, discover, identify, and characterize cause and effect relationships of all types, ranging from food allergies and autoimmune system responses to drug effects, and elimination of symptoms and causes of diseases. Capsule B can deliver substances and deploy them at any point  $x$  and time  $t$ , thus, has the capability to perturb the autoimmune system and measure responses at any point  $x$  and time  $t$  in the gut, thereby totally eliminating the mixing pot methodology of analyzing expelled feces, which can never lead to accurate conclusions because of the trillions of probabilities for any one test, and by virtue of mixing, destruction of evidence of point-specific phenomena. This methodology also eliminates all of the enumerable problems of administering drugs that must pass through the stomach and enter the body over a long distributed path of 25' with distributed implications including loss of gradient, concentration, and integrity of drugs. Every person's gut is unique!

**CAPSULE C, US 8,926,526 B2 Patient In Vivo Gut Diagnostic and Treatment Tool 1-06-2015**

Capsule C is a patient diagnostic and treatment system. Instead of being tested and having drugs administered and waiting days, weeks or months for often inconclusive results, or being subjected to expensive, painful, or discomforting invasive procedures, Capsule C, like A and B, is no more uncomfortable than swallowing an olive and waiting in a convenient and comfortable environment for data to flow by telemetry continuously into a computerized monitoring system. Data in real time are analyzed and compared with data from Capsules A, and B, and decisions are made in real time as to where and when to deploy and apply treatment measures specifically designed following information obtained from A and B before Capsule C is administered. At such time as Capsule C is administered, substances on board in C are applied at the exact points within the gut in their original concentration and undisturbed form. In this manner, there is no degradation of applied substances, and there are no side effects, such as antibiotic destruction of good bacteria, in any other part of the gut or human body based upon entrance from any other location in the gut except the exact point of deployment. In particular, good microbes or autoimmune system monitors in other parts of the gut or body are not affected. Subsequent follow up tests, if deemed necessary, can be administered using Capsules A or B to determine the characteristics of success with the first administration of substances using C. All of the procedures are accomplished without significant risks, pain, discomfort, or inconvenience to patient, and minimal cost for the healthcare. This methodology can be applied to any part of the GI Tract.

**US 9,215,997 B2 In Vivo Technology System for Human Gut Research, Diagnostics and Treatment 12-22-2015**

The necessary research, exploration, discovery, personal diagnostics and treatments to discover disease causes without this system and methodology would be totally impossible, cost prohibitive, and hospital facility time-

wise impractical, even if it were technically feasible in a lab or hospital. Each of these capsules can be taken and the patient can relax in a monitoring station room of comfort without enduring any invasive procedure and associated discomfort of preps, such as, for endoscopy or colonoscopies. In many of the procedures the patient can just go home and return in a couple of days with a wearable computer based data acquisition and monitoring system. The technical merits of this system are unprecedented in all of medical gut science and engineering because the system being studied is not disturbed in any way and the normal processes of the GI tract proceed normally such that the exact locations and times of malfunctions and their characteristics can be sampled, monitored, analyzed and treated. That is, the capsules are inert and unobtrusive unless commanded. The system not only promises to allow discoveries of causes and cures for some 53 diseases with origins in the gut, but increase the knowledge level of human gut digestive processes decades to centuries ahead of any other conceivable healthcare methodology. Such knowledge of microbial based digestive processes may lead to many other non-medical technologies beneficial to civilization, as well as, healthcare for all other animals.

## **US 9,955,922 B2 CAPSULE DEVICE AND METHODOLOGY FOR DISCOVERY OF GUT MICROBE ROLES IN DISEASES WITH ORIGIN IN GUT 5- 1- 2018**

A special gut microbe and their chemical substances-byproducts simultaneously sampling technology, utilizes swallowable capsules for the purpose of determining roles each gut microbe strain/species among the 1,000 to 3,000 estimated, plays in creating all the byproducts that are consumed by other downstream microbes in a cascade manner, that become biochemical endotoxins at different locations, which in turn drive the autoimmune system into a frenzy, leading to numerous inflammatory symptoms and diseases, for instance. These processes are believed to lead to different named diseases in the respective neurological, cardiovascular, skeletal, and other systems. Prime suspect diseases include Autism, Parkinson's, Alzheimer's dementia, Crohn's, IBS, "Gluten Sensitivities", Celiac, Inflammatory Arthritis, etc. This process should also discover other microbe roles, such as creating impermeable boundary layer gel habitats that selectively filter molecular diverse substances, and encapsulate the villi and microvilli, leading to nutrient deficiencies and malnutrition based diseases over years. Ultimately, this system capability should create a full gut microbiome profile throughout the gut.

### **SCOPE AND IMPLICATIONS**

It should be understood that most all the hypotheses stated herein are just that, without experimental verification by the inventor, but heavily weighted upon extensive literature and state-of-the-art medical research publications with their research methodologies being individually scrutinized. The herein described 5-patent based system is under development. It is noteworthy that many of the subject diseases with origin in the gut are household names, but normally without any association by the general public as to the causes having their origin in the gut. Some of these diseases are believed, based upon respected research papers, to include: Alzheimer, dementia, heart disease, arthritis, diabetes, Parkinson's, Alopecia, obesity, inflammation, cancer, Crohn's, allergies, various immune system, and organ nutrient vitamin and mineral deficiency-based diseases, and many others in addition to the numerous obvious GI tract diseases, such as, IBS, diarrhea, acid reflux, bloating after a meal, etc. Due to the coincidental variable phenomena, many diseases through current research methodology are attributed to the wrong cause, such as, Total Parenteral Nutrition disease being associated with genetics, but given a parental intestinal transplant, the disease is cured. Microbes associated with the mother birth canal often confuse coincidental variables such as genetics. Thus, the coincidental nature of many diseases individually with other symptoms, diseases, genetics, etc., carries a traumatic impact upon medical research based only upon statistical studies, because of the nature of the microbes and their byproducts and their contributions as unknown variables that are never included in statistical based research models, because they are unknown, renders maybe as much as 75% of medical research "studies" today based upon false hypotheses, premises, and experiment designs, which translates to billions of dollars wasted each year in the U. S. alone. Such places a measure of value on the implications of these inventions.