## "Fungi Officinalis Project"

"Let food be thy medicine and medicine be thy food."

Hippocrates (460 B.C.)

## **Summary**

According to Hippocrates, the spiritual father of every doctor, food should be our main medicine. However, global warming, pollution with soil impoverishment and overpopulated world forced mass food production. This process leads to nutritional deficiencies and junk food rich in saturated fats and carbohydrates, good for energy supply only; that is often a source of disease both when there is enough and even more when there is a shortage. It is not by chance to believe that almost all tumors originate from epigenetics, i.e. they are due to the two environmental factors mentioned: pollution and bad/insufficient nutrition. The individual factor or so-called "lifestyle" (for instance smoking) is an additional cause. Therefore, as doctors we cannot follow the Hippocratic dictates on food, not being able to arrange prevention for a healthy diet, often expensive, treating most (avoidable) diseases such as chronic ones and many neoplasias only at the end when these occur, through necessary and expensive chemotherapy drugs, with highly relevant social economic and personal costs. Unfortunately, culturally and economically our societies base oneself on disease and not on health, with the interested approval and media support by Big Pharma. The economic and social Elites are well aware of this and it is no coincidence that the Healthy Diet with Medicinal Mushrooms (M.M.) is currently exclusive to wealthy and cultured people. Medicinal Mushrooms so called also Chinese mushrooms as Shiitake, Maitake, Ganoderma etc, are some species of mushrooms, used in feeding by Chinese immigrant in US (from which the name) and traditional in oriental diet, with hystorical or scientifical evidences of health and pharmacological actions. Unfortunately, knowledge and culinary tradition, frequently in addition to the money, is not for all. Is a scientific evidence that in recent decades polluted and low nutrient food, are among the major causes of the exponential growth of chronic diseases and cancer in the most developed countries as well as in the poorer ones called "in developing countries". In fact in those countries, in addition to the economic impossibility of accessing healthy and sufficient food and to the medical treatments and prevention programs, there is a so high level of soil, atmospheric and water wasting, that we are witnessing to a great cancer epidemic in younger people (Report "Global cancer statistics 2020 " WHO).

The connection **food-pollution-cancer** put together rich and poor countries, old rich and young poor people, the whole world. The association feeding with mushrooms=healthy is tightly connected to the mass presence inside the fruit body (cell wall) of branched-chain Polisaccarydes and Proteoglycan with unique and relevant immunomodulation action basic in prevention throught feeding (Immunocompetence). But the action against cancer/degenerative diseases is synergistic, needs more in quantity and quality and involves a lot of other actors presents (but in few quantities) only in mushrooms, like **Ergothioneine, Ergosterol, Vitamin D2**, trace elements and minerals (**Selenium, Germanium** etc). Those molecules are subject of the enrichment method "**Fungi officinalis**" (see later) together to others like alkaloids terpenoids vitamins etc etc. already present in the 20 species of **Medicinal Mushrooms** (MM) selected by the method.

In short, the problem seems only technical: find a new cultivation method for a new product: a nutraceutical at the same time nutrition as a pharmacological action. Nevertheless, things are not quite like this, the problem is "Philosophical" and regards how we face Nature or Gaia from Lovelock hypothesis (1996) of a living Earth. If as a species want to dominate the Nature (this Era is called Anthropocene rightly for impact), we are seeing the results with Global Warming, Cancer by polluted environment and Covid Pandemic; at the opposite we have to accept changing and the evidence that we cannot win this challenge in competitive terms. Respecting our biological

limits but trying to prevent by reducing the environmental impact both individual and collective, doing the right thing: consume less and consume the right, improving quality and ecosustainability. Let us take example from mushrooms that feed on and through waste with excellent energy balance, recreating themselves and all living beings at no cost. From technical point of view, we have all the possibilities, what we lack is the philosophical approach that we must borrow from the fungal symbiosis, that I believe have found in "Fungi officinalis project".

Furthermore, it was not ethically acceptable for a doctor like me, at the beginning of this story, that cancer is only a question of money and information (denied).

## Presentation

If we were properly informed, we could know that we already have an example in the world that demonstrates how it has been possible to defeat cancer with epidemiological evidence (together to change economic and culture attitude of the society) through feeding population with mushrooms, this is the case of Japan. In fact, since 70' years, Japan had the greatest incidence (and prevalence of course) of gastric cancer of the world. An observation of farmers that cultivated and ate mushrooms, showed a lower incidence of cancer. It was the first 90' years and was the beginning of the large public campaign to introduce mushrooms in the daily diet of the Japanese people. After 30 years Japan is the nation with the lower incidence and prevalence of gastric cancer and of the all nutrition-related cancers of the world (S. Zhang et al., 2020), furthermore with the highest average life and in good quality of the world. This is, also, the reason that are so widespread mushrooms dishes in Japan with both cultural and consequently economic success, due to the technical cultivation improvement so to become one of the world leaders on the field. Mushrooms carry the same richness as meat but they do not pollute, indeed, they fight it also feeding on our residues such as plastic and tar, always-remaining edible! (Paul Stamets, Mycoremediation). Coming back to Japan, this nutritional action on cancer, with epidemiological evidence due only by feeding with mushrooms, has been the only one modern successful action of Public Health in the humanity, with the greatest medical evidence for numbers, but for this has been hidden to the world public opinion. The answer is because this information is against the economical and social predominant model based on disease and separation between feeding and drugs, which is convenient to Big Pharma. To fight this we have to return to the Hippocrates teachings: nutrition=care. However, to do this we should have a new kind of mushrooms that eaten at normal quantities, will have always the same protective action (standardization and food safety) but not guarantee by commercial medicinal mushrooms. Starting right from Japanese and Korean Patents about forms of mineral enrichments (selenium), Dr Bagnato came the idea of a method to enrich but also to develop these molecules positively involved in cancer/diseases struggle, maintaining the potential (psychological and nutritional) and the form of food.

**Fungi Officinalis** (F.O.) was the answer, a functional food which born as such and available to everyone, rich and poor, young and old people, with which to raise population immunocompetence against cancer and diseases, so implementing primary prevention, but also taken in low quantities as nutraceutical with the power of a drug even though remaining food. To break the axiom disease=drugs through feeding, cracks Big Pharma cultural monopoly focused just in negative as a struggle against diseases with drugs, which makes prevention underestimate. It is a paradigm problem and F.O. is the tool that can get us through it. Like Hippocrates teachings, as mushrooms do since 1,5 billion years, is a synergic metabolism in Symbiotic Planet (Lynn Margulis, 1998) that can save us.

Mushrooms, among all that becomes food (animal and plant), for their power to modulate genetic/epi-genetic expression in the development of the fruit body adapting itself to

the needs of environmental symbiosis, are the best suited to enrich themselves with properties and metabolites that promote human health. We have already mentioned the role that mushroom consumption has historically represented and represents for most of the world population, especially in Japan and China, given the growing demand for the favorable cost-benefit ratio on human health: a good, healthy, nutritious and safe food at low cost. This is the reason for collaboration agreements between China and various African State in mushrooms cultivation: technologies that ensure immunocompetence and food for population in exchange for raw. This great world movement on medicinal mushrooms (among 60 billion dollars revenue for defect) it seems to be unstoppable driven by Chinese power. Further research led to isolate molecules and drugs from fungi used in and with chemotherapy, in Japan with important clinical results, little publicized in the international scientific literature. Nevertheless, the action on cancer was already known by the same pharmaceutical companies since a long time before, so much that many of the first chemotherapeutics used in cancer therapy (Busulfan, Irofulven, Ciclosporin, etc etc) belong or are directly pharmaceutical derivatives of mushrooms. Medicinal mushrooms, known all over the world, have the paternity of use to TCM (Traditional Chinese Medicine): they were special food for the emperor (Ganoderma lucidum or Reishi in Japanese) which assured him long life and sexual potency (Cordyceps sinensis). Medicinal mushrooms is a worldwide phenomenon in constant rise; known as "Chinese Mushrooms" in US they are used as special foods, rich in vitamins, noble minerals and proteins (enzymes) and low in saturated fat and calories. They are used for diet and versus obesity, especially in children obesity (very important public health problem in US), and have been proposed to the health authorities of many states at the base of a new "Food Pyramid" in US.

**Dr Maurizio Bagnato**, the proposing MD and inventor of the Method, is a passionate scholar and researcher in Integrated Medicine (MTC, Acupuncture, Homeopathy, Phytotherapy, etc.) and the mushroom world. Being also a Mycologist, he has worked for 20 years as a Medical and Myco-toxicologist Head of the Mycological Inspectorate of ASL (Italian National Health Service Unit), currently appointed Legal Medical Director in Hospital. Right because of these studies and of the clinical experience gained, he developed a modern integrated approach in trying to solve the symptoms of diseases working both on the clinical side and on the causes. He used techniques and doctrines of the Eastern and Western traditions with medical evidence of integrative medicine: f.e. in cancer patients with medical Cannabis for pain and Psylocibin from Fungus Psylocibe for depression (latter only in literature because in Italy is still forbidden) and by naming this new medical discipline "Micomedicina" (Mycomedicine). At the beginning, lacking of medicinal mushrooms fit for purpose was the reason for further Fungi officinalis conceptual elaboration. Stopped by institutional constraints but wanting to continue research, in 2009 Dr Bagnato founds Associazione Internazionale di Micomedicina ONLUS (International Association of Mycomedicine NPO) of which he is and he has been the President until now. The association goal is to inform and to improve the consciousness in the population about the potential of mushrooms for health; meanwhile Dr Bagnato continues his clinical activity on patients and research on Mushrooms and Medicine. The term Mycomedicine comes from the way mushroom has function and interact with other living beings in the form of anabolic exchange (symbiosis) or of annexation and catabolic destruction (parasitism). Life is a continue pendulum between these two opposite as Yin and Yang of MTC. The same ambivalence of Drug: on the one hand it cures on the other hand it kills you. Health now is only a question of cost/benefit ratio: how much are you willing to pay in terms of general health (inherent toxicity and side effects) to solve the problem with drugs now? Are you sure that cost/benefit ratio of this pharmacological choice now, in medium/long-term, is the right thing you can do for your inside and outside environment health? It wouldn't be better to prevent with foods than cure with drugs? The answer is obvious, such as consideration that it is only an

information problem and conscious choice. A great problem, instead, that regards stakeholders political and economical choices. We do not talk about the great problem of drugs abuse and antibiotic resistance, but are tightly connected. Without detracting from the great merits of drugs and scientific research for human health, sometimes with random discoveries, like in the case of Penicillin, that I underline is a mushroom. Anyway, when needed take the pill! Nevertheless, that is not the point. The point is what direction we want to run across now, pro-life or pro-death? Life physiologically needs to be fed with a single vitality direction, such as breast milk for growth of the baby, our first food, through positive words and thoughts and natural healthy food; drugs are not only toxic for the body but also for mind and soul because they evoke sickness and thoughts of death. Only by rising immunocompetence of the population through mushrooms (F.O.), can drugs work when needed: Covid teaches us! In fact in Japan, where is the most immunocompetent population in the world even if the oldest, Covid did not cause as many deaths as in Italy which is second oldest country in the world. This is another reason why terminal cancer patients and the irreversible advanced chronic diseases were targeted by Mycomedicine, i.e., those no longer responding to active pharmacological treatments, but those sometimes responsive to the call of life and spirituality helped by Fungi, as Dr Bagnato saw in over thirty years clinical holistic practice. After his meeting with Palliative Care and his naturally holistic approach, Dr Bagnato has elaborated a new vision of Palliative Care, genuinely holistic, through integrated medicine therapies (Cannabis/Psilocybin, Homeopathy, Phytotherapy, Acupuncture etc) and Mycomedicine together with "mushrooms (F.O.)" with medicinal properties that provide energy and specific antitumor-antidegenerative action, reinforcing the structural body and by activation of detoxification mechanisms. However, at this point he faced the harsh reality: these medicinal mushrooms (M.M.), although available with difficulty (e.g., the Shiitake), hardly reached such levels of active substances as to allow their therapeutic use in food doses. Least of all they could be defined functional food, above all for the variable levels of these substances: they lacked standardization and reproducibility or rather specific procedures and strains. Hence the idea of "building" the Funghi officinali /Fungi officinalis ® (F.O.) to meet the need for standardization and reproducibility of effects not possible with common medicinal mushrooms, that works in primary prevention as food but also as nutraceutical/supplement in secondary prevention and finally as a (new) drug in patients who cannot otherwise be treated. In 2015 together with the Italian Patent Application, the ONLUS of Micomedicina identifies more clearly the Holistic Palliative Care field (through Mycomedicine) modifying the statute and the name in "Mycomedicine association (NPO) for Holistic Palliative Care (HPC)" targeting Micosalus Centers as the residential communities where to provide Holistic Palliative Care services with Fungi.

**Fungi Officinalis** produced with this method, are **Patented and Registered by the Italian Authorities** (*Ministry of Economic Development - Italian Patent Register n ° 102015000057159 dep. 10/02/2015 rev.27/02/18 to Bagnato Maurizio, title: "Metodo di produzione di funghi officinali, contenitore per produzione e funghi così ottenuti (Production method of officinal/medicinal mushrooms, container for production and mushrooms as such obtained)"* and in September 2018 issued and registered the **European Patent (EPO)**, the first of the international extensions. After **EPO** Patent was released, in **2019 Russia Patent** and going forward **USA (2020) Australia (2020) China (2021) India (2022)** and next **Canada**. The method consists of a particular **chemical-physical process of cultivation in technologically advanced greenhouses** of 20 species of M.M. commonly cultivated by producers, selected among those with the best scientific references for action on chronic and neoplastic diseases. This is due to the presence of active ingredients, further and naturally enriched at therapeutic doses of fungal substances and metabolites such as Vitamin D2, Ergosterol, Ergothionein, etc and minerals / el. trace in an

organized form (Ge, Se, Cu, etc. over 1500 scientific publications examined), without any genetic modification, until reaching a sufficient level for a strong action on physiological stimulation. The same as and more than a medicine, activating detoxification mechanisms and cellular repair on neoplastic and degenerative or deficient diseases, also stimulating immunity to each individual ration and yet continuing to remain nourished. These mushrooms called "Officinali" because of their behavior, a sort of "pharmaceutic workshop", pharmacy in Latin. The chemical-physical method foresees two phases. The first foresees the chemical enrichment of mushroom substrate, at mycelium seeding, with noble/rare metalloids-minerals like Germanium, Selenium, etc. etc., and egg powder as AA cysteine/cystathionine precursors. The second phase is Physical enrichment formed by two moments: one at the first develop of fruit body through electromagnetic field (EMF) generated by Solenoid that allows metalloid/mineral biological organization beyond transformation of precursors in ERGO. The final moment with treatment of the harvest mushrooms with Pulsed Light (PL) to develop Vitamin D2 in high doses (up to 1000 times more than untreated ones).

Among the metabolically active substances available at sensitive levels in F.O., we mention a few which are already present in medicinal mushrooms (worth to underline this), but not at such levels of any therapeutic action. The **first** is **Vitamin D2**, which is the most commonly used form of Vitamin D in the USA (mixed in milk and butter) instead of the D3 most used in Europe exclusively as a drug. Vitamin D2 has action (when used at high dosages) against neurodegenerative diseases, diabetes and cancer as well as calcium against osteoporosis. This action, as we all know, is shared with D3, compared to which however D2 is better, as shown by US epidemiological studies, for not interacting with the D3 produced by the human body, ensuring normal (US) rations of milk and optimal daily quantity of circulating Vit. D; reaching 1000/2000 IU instead of the 400 IU OMS limit for the risk of side effects such as calculosis and hypercholesterolemia present with D3. Therefore, Vit. D2 present only in fungi is the only one, according to the US authorities (FDA), that can effectively counter the widespread low levels of vitamin D, a real social emergency (also from us), especially in the elderly, women and blacks.

The second substance is Organic Germanium (Ge) thanks to the method that makes organic, in a biological state, the inorganic mineral (a metalloid /rare on earth that is found as a by-product of steel and used in electronic components), which is added to the substrate of mushroom cultivation and exposed to particular electromagnetic fields, it is absorbed into the fungal cells becoming an integral part. Organic Germanium (Ge-132 or bis-carboxyethyl germanium sesquioxide) is one of the most powerful antioxidants available in nature due to three molecules of oxygen (from which sesquioxide with reducing valence 6) on which each single molecule is bound. As demonstrated by the studies of **Dr K. Asai** in his Germanium Clinic in Japan where since the 70s thousands of patients have been treated for cancer, the ability of Ge to penetrate human cells in microsomal form and the action of molecules of oxygen on which Ge is bound, produces a stimulation to aerobic glycolysis in the mitochondria of normal cells in which, in the presence of oxygen, pyruvate is oxidized to create energy (ATP). However, in the tissues of cancer patients there is a chronic lack of tissue oxygenation, due in part to tumultuous and disordered cell growth and also to anaerobic glycolysis (fermentation) or rather non-oxidative cleavage of glucose with lactate production which is the preferred fuel for cancer cells (Warburg effect) and blocks cellular respiration within mitochondria by promoting the malefic cancer circuit. Ge's electrical semiconductor capability in mitochondrial ridges could serve as a spark to reactivate the oxidative cycle of pyruvate in the presence of oxygen. Probably enough to be able to change the clinical history of many cancers. It is no coincidence that the studies on the Ge of Dr.

K. Asai, dating back to the 70s, have given the cue for the introduction of Cisplatin in the chemotherapy of many forms of cancer.

The third substance is the Ergothioneine (ERGO), perhaps the most original discovery of the method. In the near future it will be one of the molecules behind the biological therapies of many chronic diseases, particularly rheumatologic and cardiovascular diseases and cancer. It is an amino acid chain typical of the fungal world, in particular present at fairly doses in porcini mushrooms (Boletus edulis). It has a unique feature among all the natural and synthetic molecules: its action is both intra and extracellular at the same time in humans: in fact it has cellular and tissue receptors but also a cell trans-membrane transport system. This feature makes it act both as an antioxidant inside the cell and as anti-inflammatory outside the tissues. Probably the action takes place first in the tissues where there is the highest number of receptors (elastic fibers and/or that act as lining like the endothelium of the vessels, the cartilage, the connective organs etc) that recall ERGO producing a contrast action by accumulation to combat the chronic inflammation of low-grade fats (oxidation of fatty acids), foresight of neoplastic transformation and chronic and acute inflammatory diseases; then it penetrates into the cell and when the intracellular share has been saturated as well as the antioxidant action, remains in the extracellular compartment providing a strong and lasting anti-inflammatory action. The antioxidant action is similar to that of Glutathione (Glut) which is the main antioxidant system of the human body, but compared to this has several advantages: it is ubiquitous, it is practically present throughout the body, especially in areas subjected to greater wear and tear-stress oxidative (blood vessels, cartilages etc. reason of arteriosclerosis and arthritis / osis etc.) while there is Glut, produced and present only in the liver (when that is in good condition!) but in low quantities even for the short half-life (3 hours) and of which the ERGO is a replacement remaining in the time as it has a half-life of 30 days! Researches in the cardiovascular, rheumatological, oncological fields etc are still at the beginning, though very promising, in particular for this dual dose-dependent pathway that allows to recognize the ERGO as the best "Total Cytoprotector" of the human body, as to allow Bruce Ames, famous American doctor and researcher, father and discoverer of cellular oxidation and antioxidants, to coin a new term for the ERGO as "Vitamin of Longevity". When Italian Patent has been deposited (2015) ERGO scientifically was half-known, from that date it has been a scientific explosion of research. One of more active institution is University of Singapore that published a research on hundreds elderly patients for 7 years with Mild Cognitive Impairment (MCI) that show better results (50% reduced odds of having MCI) on cognitive tests with feeding mushrooms almost 200/300 gr /week with high presence of ERGO (Lei Feng et al., 2019). Other publication of the same university shows that elderly that feeding with half cup a day of mushrooms rich in ERGO (around 20 gr./day), had a lower cancer risk of 45% (D.M. Ba et alii, 2021).

Further and basic step forward to "Fungi Officinalis Project" was the meeting five years ago with Mr. Orazio Tietto, General Manager of "Funghi San Giorgio" from Padua. His great experience in medicinal mushrooms cultivation united to extremely high competence in plant engineering and driving of mushroom farms, with collaborations and achievements all over the world, determined the realization of what I had put only on paper. A solenoid machine was prototyped and samples of Pleurotus spp was realized according to the method. The samples were analyzed by Pharmacology Institute of the State University of Padua and the results were: very interesting, the enrichment method works. In 2020, we found a Startup "Fungi officinalis SrL" an agricultural company of biotechnology innovation, which apply the patented method, with headquarters in Rome where is my property an agricultural land dedicated to the purpose. Planning foresees an experimental production of Fungi officinalis for R&D, adapting the method to every species. Once verified the steps and the stability of the enrichment process on final product,

the results will be notified to **EFSA (European Food Safety Authority)** for necessary authorization as *Novel Food* for Nutritional and Health Claims. All that work will allow us the addition of suffix *officinalis* to the Latin name of the species, as guarantee sign for safety & healthiness but also as evidence of patents rights, technical and commercial, of these new species. In the future, the Startup will transform in Consortium of Producers with guarantee marks Fungi officinalis Brand. Programming provides, in order to contain the very high plant costs for the design and operation of prototypes of both greenhouses and machinery, a production of the enriched (chemical) substrate at Fungi San Giorgio in Padua and their transfer to Rome for the following physical enrichment phase. However, while doing so, the elaborated B.P. requires huge investments and above all the difficulty in finding someone willing to finance R&D.

Anyway, the "Fungi Officinalis Project" now is clearer, composed of two parts: the product part and the human part. Dr Bagnato started a movement and gave a point of view, which is that of mushrooms. The dominant paradigm has been questioned, but it is up to other forces to break it down. About this can be a good example the doctors in ancient China: they were not paid if their client became ill (sometimes it cost his life if the person were the Emperor) and they were starting to be paid again returned in health, so the prevention was convenient. If we do this with Big Pharma, wouldn't it be a paradigm shift?

Dr M. Bagnato would like to carry on the human aspect, dealing with correct information, care and independent research through Mycomedicine Foundation for Holistic Palliative Care with Fungi and disciplines of Integrated Medicine.

We can get rid of illness by promoting a healthy lifestyle and positive behavior, even through the FO. It is not the only change we need to make, but the most important, because eating behavior has always been influenced by our consideration of Nature as something different from us (inferior) to control, subjugate and manipulate and eventually gulp down for the sole purpose of staying alive. When this is under scrutiny because suffering from some disease we resort to drugs (our lifesaving products), which, more often than not, solve just the symptoms, leaving unchanged the cause that continues to produce damage and opens the way to chronic diseases and neoplasms. The root of our problems is the **food / drug dichotomy**; only by solving this, returning to the Hippocratic teachings, we will succeed in actually doing "**Prevention**" and finally understanding that we are part of Nature and we must submit ourselves to its Rules, not vice-versa. This way we could appreciate its gifts like mushrooms and find our place both as individuals and as communities in the "Cycle of Nature". Feeling outside the Cycle of Nature by not respecting the Rules, as when the cells go crazy and lose the rules of cohabitation, is the true and real cause of diseases, first of all Cancer.

We are pleased to share our **philosophy** and the **discoveries** of the method with others interested to the Project only for human elevation by ethical point of view, to save Humanity and the Environment of which we are part.

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