

ACKNOWLEDGMENT OF GRATITUDE AND APPRECIATION

The present doctoral research entitled “*Empowering the Structural Reform in the Health Sector: An Innovative, Synergistic and Business Masterminded Approach*” finds its roots in the deep interdisciplinary approach of reality in different fields, here interrelated: medical sciences, economics of health, pharmacovigilance, health management, care services and medical business administration. Under the “*lights of high debates*”¹ (Thaler & Sunstein, 2008), the research holds as main objective the exploration of a new concept to poke at the integrated satisfaction based on the complex rules of societal performances, continuously linked to the real needs of health status afterthought.

A new era in the medical and care knowledge has, in the advancement of the art, carried us back upon the reconsideration, of nature and societal influence and potential, of such a domain. The start is even the health concept that represents the state of wellbeing put into the key of the general harmonious condition of body, spirit and mind. Prior entering upon the consideration of how Medicare can benefit, through innovation, in the field of treatment management of the manifold and general forms of health and care administration, the attention is called to some of the most important remedial or preventive sides and means of any business, economic sector or health and cure topics, occurring anywhere in the absence of honorable administrators and respectable decision-makers overboard understanding and practice.

As my initiation in the academic research is based on the very technical sense of it, the main objective of research has been directed to finding the right definition of problems, formulating hypothesis prior to hint solutions, recording in detail, collecting, comparing and evaluating good practices and large databases, supporting and supplying references prior to reach conclusions, checking specific ratiocinations to see if they fit objectives and hypothesis helped making deductions on an innovative and original work that wants itself to contribute to the “*existing stock of knowledge advancement*” as Redman and Mory nicely stipulated (Redman & Mory, 1923)². My endeavor of developing such a research accords with importance of the topic.

During these blue times, with people either aging or double way relocating, with simple workers and high specialists - no matter the age and gender - looking for better jobs and a sound life, with companies checking harder than ever higher profits in hot money, far away from their homes, with public authorities lacking more and more power and funds, abilities and interest in humankind wellbeing and health, it may look abnormal to check the world with responsible eyes only to

¹ Richard H. Thaler & Cass R. Sunstein, (2008), *Nudge: Improving Decisions about Health, Wealth and Happiness*, Yale Univ. Press

² L.V. Redman & A.V.H. Mory, *The Romance of Research*, (1933), The Williams & Wilkins Co. in cooperation with the Century of Progress Exposition, Baltimore, p. 10.

correct politicians' work, and finalize a research. If so, it is more about facing the challenges rather than solving the unsolved problems. Per chance the main purpose gets off the ground of a creative contribution to restore the idea of societal community, respectability, self-esteem for the general service, in times when the outstanding decision makers politically consider that the global health remains an "emerging area" for deepening the interdisciplinary study, research and practice. Beyond the effects of globalization, the topics remain hot and highly conceptual, being understood only in the comprehensive meaning of a complete state of physical, mental and societal wellbeing. The achievements of equity in health are nearby, for all people worldwide, emphasizing the transnational health issues, determinants and solutions, and their interactions with the national and local values and systems. Some good results after huge efforts enlighten and warm up the researcher. Following the direction, encouragements came up by the widespread response from scientists at conferences, from professors and central authorities' decision-makers I used to work for as a consultant. Hence I put down all efforts made to enhance certain aspects involving different typologies of managing the health and other sides of the medical science, in countries where I have been connected with, and had various contributions (United Kingdom, France, USA, and Ireland).

The highlights refine and restructure points linked from innovation and added value to health, care, management, business and society. As I considered them importantly linked to some new issues, there were added for analyze, undertaking the general attention: the realistic innovation role of acts and facts, the multidimensional side of artifacts relying to design the appropriate methodology to adhere to for improving the quality of research. Concisely, the intention that the paper's title fits perfectly to the topics came upon as its full content frames into the doctorate's specialization.

Along the doctoral research all my efforts were kindly and professionally channeled by the honorable members of the guiding commission to converge, thoroughly, at the goals and assumptions formulated and tracked throughout the research. Based on top innovative issues in order to build a new integrative model in health management, the doctoral thesis has been finalized as a particular contribution given the assessments made and the results obtained. Therefore, richly entitled, I bring my thanks to all people near me for their remarks and exceedingly valuable support and orientation in putting my knowledge in the best possible order and give the actual shape to my research. The members of the doctoral monitoring commission together with the PhD supervisor continuously gave me valuable ideas, directing me in the preparation of this thesis. And for this reason, I am grateful to all. I am equally grateful to all the other academics, scientists and decisions-makers that I met and discussed with, during my participations at international and conferences and seminars, during my professional stages, no matter the country, as a scientist, academic, medical affairs manager or consultant. All their valuable suggestions oriented my research and contributed to enhancing the standards of the present thesis. I thankfully acknowledge the assistance provided by the Bucharest University of Economic Studies and the Doctoral School of Business Administration who accepted me as a grant beneficiary, supporting financially and logistically, my doctoral research and the preparation of the final thesis.

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LIST OF ACRONYMS AND ABBREVIATIONS

- A**
- Advanced Mobile Location (AML)
 - Aged Care Assessment Program (ACAP)
 - Aged Care Assessment Team (ACAT)
 - Australian General Practice Training Ltd. (AGPT)
 - Australian Health Ministers' Advisory Council (AHMAC)
 - Acquired Immune Deficiency Syndrome (AIDS)
 - Antimicrobial Resistance (AMR)
 - Australian Bureau of Statistics (ABS)
 - Australian Institute of Health and Welfare (AIHW)
 - Australian Immunization Register (AIHW)
 - Antimicrobial Resistance (AMR)
 - Australian National Audit Office (ANAO)
 - Australian Nurse Family Partnership Program (ANFPP)
 - Australian National Preventive Health Agency (ANPHA)
 - Asia-Pacific Economic Cooperation (APEC)
 - Australian Prudential Regulation Authority (APRA)
 - Australian Public Service (APS)
 - Australian Public Service Commission (APSC)
 - Antimicrobial Use and Resistance in Australia (AURA)
- B**
- Biomedical Translation Fund (BTF)
 - Blood Borne Virus (es) (BBV)
 - British National Health System (NHS)
 - Business process outsourcing (BPO)
- C**
- Cardio Vascular diseases (CVD)
 - Centers for Service Medicare & Medicaid (CMS)
 - Changes Clinical of National Center for Statistics Health (NCHS)
 - Chronic Care Model (CCM)
 - Classification of Rare Diseases – Orphan Code
 - Classification System Diagnosis Related Groups (DRGs)
 - Committee on Orphan Medicinal Products (COMP)
 - Clinical Training Funding (CTF)
 - Community Health Centers (CHC)
 - Community Services Obligations (CSO)
 - Complications and/or co-morbidities - code CC
- D**
- Database dedicated to information on rare diseases and orphan drugs (ORPHANET)
 - Data Envelopment Analysis (DEA)
 - Dementia Behavior Management Advisory Service (DBMAS)
 - Department of Human Services (DHS)
 - Departments of Health (DH)
 - Department of Social Services (DSS)
 - Diagnostic Imaging Accreditation Scheme (DIAS)
 - Diagnosis groups system (DRS)
 - Diagnostic and Statistical Manual of Mental Disorders (DSM)
 - Disability Adjusted Life Years (DALY)
 - Distinction between hospitalized and treated cases represents the case-mix (DRD)
 - Ductal Carcinoma *in situ* (CDIS)
 - Disability-adjusted Life Year (DALY)
- E**
- Echocardiography (EKO)

- European Commission (EC)
- Euro Health Consumer Index (EHCI)
- European Medicines Regulatory Network (EMRN)
- European Union Health Indicators Monitoring (ECHIM)
- European Reference Networks (ERNs)
- European Medicines Regulatory Network (EMRN)
- European Network of DNA, Cell and tissue banks for rare diseases (EuroBioBank)
- European Medicines Agency (EMA)
- European network of population-based registries for the epidemiologic surveillance of congenital anomalies (EUROCAT)
- European Organization for Rare diseases (EURORDIS)
- European Platform for Patients' Organizations, Science and Industry (EPPOSI)
- European Union (EU)
- Exclusive Provider Organization (EPO)
- F** Food and Drug Administration (FDA)
- Freedom of Information (FOI)
- Full-time Equivalent (FTE)
- Fluorescence *in situ* Hybridization (ISH)
- G** General Practice Rural Incentives Program (GPRIP)
- Global Burden of Disease (GBD)
- Gross Domestic Product (GDP)
- Gross National Income (GNI)
- H** Human Development Index (HDI)
- Heads of Medicines Agencies (HMA)
- Health Management Information System (HMIS)
- Health Information Management (HIM)
- Health Information Technology (HIT)
- Health Management Organization (HMO)
- Health-related indicators not included in the MDGs Index (Non MDG)
- Healthy Life Expectancy (HALE)
- I** Information and Communication Technologies (ICT)
- ICT-for-Development Projects (ICT4D)
- International Classification of Diseases and Health Problems (ICD)
- International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- International Classification of Primary Care (ICPC)
- K** Key Opinion Leader (KOL)
- L** Level of diagnosis complexity (NCD)
- Level of the case complexity (NCC)
- M** Master Patient Index (MPI)
- Medicare Benefits Schedule (MBS)
- Medical Science Liaison (MSL)
- Mental Health Drug and Alcohol Principle Committee (MHDAPC)
- Medical Insurance Group Australia (MIGA)
- Medical Research Future Fund (MRFF)
- Medical Services Advisory Committee (MSAC)
- Meticilin Resistant Staphylococcus Aureus (MRSA)
- Minor Use Minor Species (MUMS)
- Millenium Development Goals (MDG) Index
- N** National Agency of Drugs and Medical Devices (ANMDM)
- National Institutes of Health (NIH)
- National Organization of Rare disorders (NORD)
- National Drug Strategy Household Survey (NDSHS)

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- National Health and Medical Research Council (NHMRC)
 - National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
 - National Immunization Program (NIP)
 - National Immunization Strategy (NIS)
 - National Pathology Accreditation Advisory Council (NPAAC)
 - National Partnership Agreement on Essential Vaccines (NPEV)
 - National Prescribing Service (NPS)
 - Non Governmental Organization (NGO)
 - Nordic Medico-Statistical Committee (NOMESCO)
 - O** Organization for Economic Co-operation and Development (OECD)
 - Office of Orphan Products Development (OOPD)
 - Office of Rare Diseases (ORD)
 - Orphan Drug Act (ODA)
 - P** Patent Cooperation Treaty (PCT)
 - Pathology Clinical Committee (PCC)
 - Paediatric Investigation Plans (PIPSs)
 - Paediatric Investigation Plans (PIPSs)
 - Preferred Provided Organization (PPO)
 - Pharmaceutical Benefits Advisory Committee (PBAC)
 - Pharmaceutical Benefits Scheme (PBS)
 - Primary Health and emergency Centers (PHC)
 - Q** Quality adjusted life years (QALY)
 - R** Regenerative Medicine and the Cell Therapy (RMCT)
 - Research and Development (R&D)
 - Rural Clinical Training and Support (RCTS)
 - S** Sexual Transmitted Diseases (STD)
 - Shared Service Center (SSC)
 - System of groups of diagnosis (DRG)
 - Small and Medium-sized Enterprise (SME)
 - Social and Behavioral Change and Communication (SBCC)
 - Socio-Demographic Index (SDI)
 - Statistical Office of the European Communities (EUROSTAT)
 - Sustainable Development Goals (SDG) Index
 - T** The European Core Health Indicators (ECHI)
 - The European Court of Human Rights (ECHR)
 - Total Quality Management (TQM)
 - U** United Nations Children’s Fund (UNICEF)
 - United Nations Development Programme (UNDP)
 - United Nations Social Development Network (UNSDN)
 - Universal Health Coverage (UHC)
 - W** Work Health and Safety (WHS)
 - World Federation of Haemophilia (WFH)
 - World Health Organization (WHO)
 - World Health Organization (WHO)
 - Y** Years of Life Lost (YLLs)
 - Years Lived with Disability (YLDs)

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ARGUMENTATIVE SUMARIZATION IN FAVOR OF DESIGING HEALTH AND MEDICAL CARE AS A SOCIETAL INTEGRATIVE SYSTEM

Before entering upon the considerations of the medicine, health and care resources, roots and development trends, and into their manifold particularities and needs, a general interest may lead people to want to know more about the new excogitation related to the health sector and the medical knowledge as presented in this research entitled: *“Empowering the Structural Reform in the Health Sector: An Innovative, Synergistic and Business Masterminded Approach”*. The coming after ideas represents an introduction into the spirit of the doctoral research and an assertion making the dreams, the objectives and purposes, more comprehensible.

The activities run in the field of medical and health sector are considered historically, as the most originative in their becoming development and approach of the simplest habits of the humankind. The mere free inhalation of the air of which constituents sustain the life’s vitality, the proper exposure to the stimulating agency of light upon the surface are essential to the preservation of all beings’ health and shouldn’t undergo impaired, by the insufficiency of all the natural preservatives, by an insensible return to the natural conditions of living and by the denial of the need for a natural, authentic and respectful behavior of *Natural Law* at individual level in aim for a good societal functioning.

Health and Education are the most essential parts of the societal system because they are responsible with preserving and transmitting to the generations to come, the legacy we receive from our ancestors providing them with the right information allowing them not only to survive but also to evolve. Hence the topic of the present research springs from the core state-of-the-art of the Health and Care systems and develops around its connections with the other elements of Medical Science, Socio-Economics and Business fundamentals. The subject is more than essential, especially nowadays; it is on the top fields, worldwide, for the acute necessity of scientific research development and implementation and the managerial assessment and innovative changes requisite.

The evolutionary study of the Health and Care Management naturally motivates the identification and presentation of sometimes sophisticated Medical, Economic, Mathematical models, as a solid contribution to the study of the so-called European Health Management. It starts with the idea that while health care represents the *“large number of services rendered to individuals or communities”* (WHO, 2013) by the agents of health services or professionals *“for the purpose of*

promoting, restoring and maintaining health” (WHO, 2013)¹, the taking up of all the goods and services designed for “*prevention, promotion and rehabilitation interventions*” includes the medical care (WHO, 2013)².

According to the WHO global strategy (2007) as emerged in the Organization’s annual reports (WHO)³, countries and governments affiliated to United Nations bodies are strongly recommended to integrate “*the concept of Health*” in their national Constitution as “a universal right” and dispose, at central and local administration levels, adequate policies and management to distinguish and discern, to accept and incorporate, in their national budget, the necessary conditions related to inhabitants’ Good Health. The right to a good health is part of the principles of humanism for citizens of every country that also draws the governments’ obligation to assure “*their citizens’ fundamental rights to food, shelter and health*” (WHO, 2013)⁴. Therefore, the human right to health may be achieved differently, in different parts of the world, in different political regimes. In conformity with each country’s own specific justice values, law system, ethics and morality code, the access to health is the result of a negotiation process between the one government and its citizens. The process is also sustained by different international bodies, agencies, other governments, or nongovernmental organizations and various religious bodies (for example: *Amnesty International*, HIV/AIDS societies, *Red, Yellow or Blue Crosses*, and *Save the Children* and many others), acting in the health sector and representing the rights for different categories of people.

This multilevel collaboration and partnerships provide the right international dimension to the activity of the various actors involved, which entitles them to seed and implement the international designed health objectives in a faster and better, simpler and cheaper, transparently and profitably manner.

In this respect, the goals are oriented are to: a) sustain the global security and avoid all sorts of disaster and pandemics; b) encourage the social justice to reinforce the social value and humans’ rights; c) empower the patients to create a participatory, proactive, aware and committed behavior, for sustaining both the universal rights and the care in using the public money; d) develop a new generation of partnerships to make prevention fundamental, long life integrated and profitable medical education. It is true that efforts scarcely touch the good finality of their suitable purposes; often they are disproportioned and not quite adequately visible with the wish to do well; inasmuch, that the great and continual effort of social energy is directed to supply and sustain the organic structure of central and local authorities, The recurrence of perturbations, instead of an adaptive changing process, are frequent enough to continuously damage the development of good ideas and the

¹ World Health Organization - WHO, (2013), *Research for Universal Health Coverage: 2013 World Health Report*, ISBN: 9789241564595.

² World Health Organization - WHO, (2013), *Research for Universal Health Coverage: 2013 World Health Report*, ISBN: 9789241564595.

³ World Health Organization, (2007), *Everybody business: strengthening health systems to improve health outcomes: WHO’s framework for action*, ISBN 978 92 4 159607 7.

⁴ World Health Organization - WHO, (2013), *Research for Universal Health Coverage: 2013 World Health Report*, ISBN: 9789241564595.

implementation of decisions. The administrative and managerial disturbances cause dysfunctions within the entire system with unimaginable consequences for the future. Often the damage is even worse when manipulative activities are considered and they jeopardize the system as a whole.

In a highly dynamic society, dominated by multilevel distributive channeled structures, a complicated and complex logistics of protocols, treatments and drugs, of medical devices and therapies, of producers and distributors, merchandisers and managers, medical and administrative units, central, local and collateral nongovernmental establishments, staffs, patients, agencies and authorities, all react upon the vigor of the *bona fide* management⁵ and cautionary governing⁶ of health. Any languidness, inactivity, disorder, inadequate exposure affects not only the whole logistics but also each systemic component that result into economic and financial exhaustion, loss of profits, efficiency deprivation, development of turbulences. A recovery state will require more resources (time, funds, and energy). A total recovery may not be complete, if the proper timing and opportunities are disregarded or lost.

The governments may have their own vision and strategies about how to apply the health principles and achieve their related duties, but the implementation of the health principles is meant to happen openly, at different rhythms and intensities, depending on the stage of socio-economic development, political regime, culture, traditions, customs specific to each country. There are governments and authorities that reject the idea of health and care financed through taxpayer funds⁷, while other intentions concern the increase of the state contribution at about one-fifth of GDP⁸. Some figures remained only on the paper.

The classical European standards occur with the study of the role of central and local administrations, in parallel with the general attributions of the non-governmental charity and religious bodies, is also considered challenging, when issues are related to: a) the private insurers and their competition against the public national health insurance system (Canada), b) the public effort and costs in comparison with the individual responsibility (Australia and New Zealand).

More and more scientific studies depict higher concerns: (Murray & Lopez, 1996 a&b),^{9,10} for defining the “*evidence-based health policies*” (Dobrow, 2004)¹¹ to strengthen the global health as a core component of the world sustainable development. Important efforts are done to:

✓ determine countries to adhere to the international ware data to develop comparable and solid analysis basis in all healthcare sectors,

⁵ undertaken in good faith.

⁶ preventing governance.

⁷ In USA: Pennsylvania, Texas, Mississippi and Florida.

⁸ The USA agreed with an annual increase up to 6.2% through 2018 (16.2% GDP₂₀₀₇ to 20.3% GDP₂₀₁₈).

⁹ C.J.L. Murray & AD Lopez, (1996a), Evidence-based health policy: Lessons from the Global Burden of Disease Study, *Science*, 274 (5288), pp. 740-743.

¹⁰ C.J.L. Murray & A.D. Lopez, (1996b), World Health Organization Geneva, *The global burden of a Disease: a comprehensive assessment of mortality and disability from diseases, injuries, and risk factors in 1990 and projected to 2020: summary*.

¹¹ Marc J. Dobrow, (2004), Evidence-based health policy: context and utilization, *Social Sciences & Medicine*, Vol. 58(1), Jan., pp. 207-217, Elsevier.