



On Dealing with Challenging Priorities

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Abstract

Justifiably there has been a great deal of enthusiasm, hope, and excitement about the idea of identifying genetic mutations and defects that cause diseases and the ability to manufacture medications to treat these medical problems. But, in addition to the progress made in this field, the cost of these medications is so astronomical that, in many cases the costs impoverish families striving to keep their loved ones alive. Our society cannot leave these families behind, but we also have to prioritize our resources and address other social issues such as increasing agricultural productivity in adverse, arid environments, converting dirty water to clean water with purification technology, providing clean energy to relieve poverty, and building sustainable cities and communities. Furthermore, we want responsible consumption and production of food. If the above considerations are not properly addressed, then we shall continue to experience even more human migration to better areas of the world.

Keywords: Cancer, Personalized Medicine, Affordable Medications Environmental Conditions, Human Migrations

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Introduction

Personalized Medicine or Precision Medicine has captured the attention of the medical world and the hopes of millions of patients worldwide. I have previously written and published several articles on this subject.⁽¹⁻⁸⁾ Personalized Medicine is now being promoted and employed in medical centers all over the world and is bringing hope to millions of patients particularly those who have been diagnosed with various forms of cancer, infectious diseases, cardiac problems, hematological maladies, and congenital malformations. As a result of the advances in these fields, we can now identify whether or not a patient has a genetic predisposition to get a particular disease and can recommend effective interventions with better medications. But unfortunately there is a high price for many of the medications. The cost of health care all over the world has increased dramatically.

The high cost of medications is a major factor of this healthcare cost and this is a popular political topic as evidenced by the 2016 presidential election in the United States.⁽⁹⁾ An example and often mentioned medication is imatinib or Gleevec. This drug is used for the treatment of chronic myeloid leukemia and its cost increased after the US Federal Drug Administration (FDA) allowed a new indication for its use. Novartis raised the price of this drug from \$31,930 in 2005 to \$118,000 per year in 2015, even though more doctors and patients were using the medication.⁽¹⁰⁾ In the US sofosbuvir (Sovaldi) lists for a price of \$84,000 for a 12-week treatment, or \$1000 a pill.⁽¹¹⁾ Some health plans refuse to cover this drug for hepatitis C virus infection.⁽¹²⁾ US patients with cystic fibrosis have been denied reimbursement for ivacaftor (Kalydeco) which costs \$311,000.⁽¹³⁾ The cost of pyrimethamine (Daraprim) went from \$13.50 to \$750 per pill after Turing Pharmaceuticals bought the distribution license.⁽¹⁴⁾ Price hikes in Mylan's EpiPen from \$94 to \$609 for a pack of two pens precipitated US Congressional hearings.⁽¹⁵⁾ These high prices are beyond the ability of most individuals, health insurance companies, or even the government to pay for these medications.⁽¹⁶⁾ The cost of the medications is partly determined by price and volume. Government regulation can try to lower the price of these expensive medications or it can try to reduce the usage of medications. Life expectancy has continued to benefit from better health care and the population is now aging. But there are some additional options for taking care of the growing number of patients. New solutions will have to be found to keep the cost of health care from getting completely out of control.⁽¹⁷⁾ Some believe that basic human rights like healthcare and access to essential medications should be equitable and should not be limited by property rights.⁽¹⁸⁾ Still other opinions argue that pharmaceutical companies are for-profit entities. Without patents these companies would not have an incentive to develop the drugs. Pharmaceutical companies must register new drugs, which require clinical studies and safety tests. Usually it takes a company ten years to register a new drug.^(19,20) Estimations of the cost of new drug development range from \$60 million to \$2.6 billion depending on the drug and the trial data.

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At the present time, the US government does not control reimbursement but relies on the free market to determine the cost of the medications. In the US, drug prices are the highest in the world and a cancer diagnosis can be a major cause of bankruptcy.⁽²¹⁾ The US government does give an incentive to pharmaceutical companies to develop orphan drugs and tropical disease drugs. After a pharmaceutical company releases the patent on one of these drugs, the company is awarded a voucher which permits the expedited review of a new drug which then accelerates the regulatory process by several months and can increase the income for that company up to \$300 million.⁽²²⁾ Some moralists feel that the medical society should pursue new therapies for everyone; whereas, others feel that money spent for diseases that affect very few people should be used for research that affects a larger population.⁽²³⁾ Regulations for orphan drugs can be effective, but should include price-ceilings so that tax payers do not pay for the R&D costs and then pay again for the reimbursement of the drugs. There are several ways to effect price reduction for pharmaceuticals and they are all based on one of the following options: (1) Shifting from expensive to cheap drugs, (2) Shifting costs to the patients and insurers, (3) Reducing the drug prices, and (4) Reducing total drug uses.⁽²⁴⁾ The FDA does have regulations for accepting biosimilars if the manufacturer has shown that the biosimilar drug has the same effect and safety as the originator. But some doctors and patients are skeptical of using biosimilars when they can use originator drugs. Although there are several price control mechanisms, a popular one is value-based pricing which includes the health and socio-economic benefits of a drug. Using this method, the price of the drug would be proportionate to the quality of life or the number of years saved by the drug or the shrinkage of the tumor.⁽²⁵⁾ Drug prices are negotiated between governments and companies based on a reference price which includes cost-effectiveness or budget impact, but in the US, Medicare is not allowed to negotiate for drug prices.⁽²⁶⁾ The present situation threatens to disrupt the compromise between affordable access to healthcare for everyone and the protection of inventions to incentivize innovation.⁽²⁷⁾

On May 5, 2018, in Boston, Massachusetts, Professor Tony Ryan OBE, Director of Grantham Centre for Sustainable Futures outlined his efforts in conjunction with the University of Sheffield to save planet earth.⁽²⁸⁾ He stressed that our population is growing at a rapid rate and our consumption of planetary resources is accelerating. He described how their philosophy has three goals: we must be environmentally, economically, and socially sustainable. Presently the Grantham Centre is doing research on renewable energy systems, crop protection, water purification and the recycling of waste. Their overall goal is to demonstrate how sustainable options impact industries, processes, the environment and society.

One of the goals has to be the worldwide attainment of zero hunger. Already in Oman, Professor Ryan and his group are developing a modular "microcosm farm" solution with Sohar University. They hope to develop an innovative approach to increasing agricultural productivity in adverse, arid environments. Since they do not have much rain there, they are developing solar-desalinating water and they are using polyurethane foam to make their own soil with the help of a greenhouse to cool things down. All of the above will produce high value horticulture crops.

Water shortage is a world-wide problem and the Grantham Center is working to convert dirty water to clean water with effective purification technology. One of their other projects is to develop a low cost, portable and solar-powered pump to improve income, food and energy security in developing countries. Clean energy is a step toward relieving poverty and a way to burn less of the fuel that

is detrimental to good health. Clean electricity can be provided in the form of a microgrid which scholars at the Grantham Center are researching. These scholars are also trying to harness the power of photosynthesis to power the world. They are also studying the energy-capturing mechanisms in plants and algae. They seek to create efficient photovoltaic devices which can convert energy into an electrical current. And they are examining the impact of mining on migration in Peru.

An interesting issue which they are exploring is what factors keep cities and communities sustainable? For example, cities are responsible for 80% of the global energy consumption and are necessary for business and economic growth. "Urban Metabolism" needs to be considered when planning a foundation for urban planning and environmental policy making. Increasing temperatures due to greenhouse gas emissions have an adverse impact on food production. Rice is extremely sensitive to heat stress and the rice crop would be damaged with increased temperatures.

Others are also concerned about the growing population predictions and wonder if there will be enough food for the projected 10 billion people on earth. What will everyone eat? Presently more than half of the calories we eat come from plants such as rice, wheat, and corn. The growth and production of these items have already reached maximum growth in one third of the world. We need a way to feed everyone without degrading the environment and this is a great social problem. In an effort to increase the supply of food, farmers have increased their use of chemical fertilizers, insecticides, fungicides, and herbicides and improved their irrigation practices and technologies. They have purchased machines to cultivate and harvest their crops. But as time passed some of the world economies improved and for example, the demand for pork and soybeans grew. Forested lands were converted to farms all of which increased Brazil's greenhouse-gas emissions. And much of the chemicals and insecticides have polluted the fresh water resources and some of the fertilizers have contaminated the oceans.⁽²⁹⁾ Researchers have identified beneficial microbes that help plants grow and have edited plant genomes to improve them. A relatively new company named Indigo Ag was founded by David Perry who is the CEO. Their scientists have identified microbes that confer resistance to drought. They are developing techniques which will reduce the need for fertilizers and pesticides. They are coating seeds with these microbes which should reduce the need for irrigation and enhance the ability to extract nutrients from the soil. Jonathan Shaw cites research from "Arnoldia", the journal from the Arnold Arboretum which describes fungal networks, not roots, which are the principal ways in which plants extract nutrients from the soil. Indigo Ag was started to take advantage of the mutualisms among plants and their endophytic inplant microbial partners.⁽³⁰⁾

Dr. Jeremy Grantham, CBE, in his address to the Sheffield in America reunion in Boston May 5, 2018, talked about how the planet is experiencing the first human induced mass extinction, which will affect our economies and our way of life. He described studies which show that pollinating insects in parts of Europe have disappeared and that other studies show that the sperm counts in men in certain areas have diminished. Recently the news in the US is that the birth rate has dropped significantly, which means there may not be enough people to support our entitlement programs such as Social Security in years from now.⁽³¹⁾ Studies have not yet been publicized examining whether the drop in the birth rate is in any way due to the diminished sperm count in American men due to the environment. But history has demonstrated that humans will hopefully leave an area for a better area in which to live if the environment prohibits the growth of food and does not provide clean air and clean water.

In his book "Who We are and How We Got Here", Dr. David Reich at Harvard University goes to great lengths to explain the migratory history of mankind and how this affects one's genetic make-up and composition. (32) He demonstrates in genetic detail just how the early humans moved from Africa to Asia and Europe in large part looking for food. The hunter-gatherers and later the farmers moved to Europe and to England because of farming techniques and their quest for a better life. According to Reich farming began twelve thousand years ago in southeastern Turkey and Syria where they began domesticating most of the plants and animals West Eurasians depend on today. This included wheat, barley, rye, peas, cows, pigs, and sheep. Around nine thousand years ago, farming spread west to Greece and spread east to Pakistan. In Europe, farming spread to Spain and to Germany until it reached Scandinavia and the British Isles. Farmers from the area that is now Israel and Jordan spread to what is now Ethiopia and farmers migrated from what is now Iran and spread to India. History shows us just how important environmental issues are and how they influence the geographical and political scene even today. Partly because of politics and due to the inability of humans to earn a living and support their families in safety, we are witnessing massive human migration today. It is true that the politics and war in Syria is responsible for much of the migration to Europe. But the migration from Africa to Italy and Spain is mostly due to famine and the environmental issues. The soil in parts of Africa does not permit the growth of vegetables and fruits. Similarly, we are witnessing the migration of humans from Central and South America to the United States. Some of this migration is due to safety issues resulting from drug cartels and the failure of socialism in Venezuela, but some is due to the fact that people are seeking a better life in which they will have clean air, clean water, and a safe environment in which to live and bring up a family.

The responsibility falls upon those of us who realize that there are significant problems to be solved. We need to prioritize the issues discussed and deal with them. It may be that since a great deal of the research is done in universities today, that we should divert some of the resources scheduled for research for pharmacogenomics to research for the environmental issues. There is probably not enough funding in the whole world to satisfy the environmental issues for so many people resulting from the explosion in the population particularly in Africa. But we see that some issues influence other issues and we see human beings risking their lives to get to Europe and the United States for food, water, safety, and a better life.

References

- (1) Kushner J, "The Ethics of Personalized Medicine", *Personalized Medicine Universe*, 3:42-45, 2014
- (2) Kushner J "Ethics of Personalized Medicine Revisited." *J Precision Med Public Health* 1:e2017
- (3) Kushner J "On the neuronal connectivity of our thoughts into actions." *Personalized Medicine* 5:44-46, 2016
- (4) Kushner J, Kinter C "The Influence of Chemistry on Personalized Medicine" *Curr Trends Biomedical Eng& Biosci* 6(3), 2017
- (5) Kushner J, Buchanan, J.L. "Employing Mathematical Models to Understand Personalized Medicine." *EC Microbiology* 12.4 : 196-201, 2017
- (6) Kushner J "Employing Blockchain Technology to Understand Personalized Medicine" 2018, *Medicine Updates*, www.kushneropinions.WordPress.com, Feb, 2018 and www.Lupinepublishers.com/oajbealpdf/
- (7) Kushner J, "World Class Genomic Medical Center in India; Association with Division of Medical Genomics George Washington University Medical Center", *Journal of Precision Medicine and Public Health*, 2017
- (8) Kushner, J, "Gliomas and Genomics", *Personalized Medicine Universe* 4, 79-80, 2015
- (9) Parker-Lue S, Santoro M, Koski G. "The Ethics and Economics of Pricing". *Annu Rev Pharmacol Toxicol* 2015;55:191-206
- (10) Kushnick HL. "Pricing Cancer Drugs: When Does Pricing Become Profiteering?" *AMA J Ethics* 2015 Aug;17(8):750-3. <http://doi.org/10.1001/journalofethics.2015.17.8.nlit1-1508> PMID:2627080874
- (11) Radhakrishnan P. Commentary: "Making middle income countries pay full price for drugs is a big mistake." *BMJ* 2015; 351:h3757 <https://doi.org/10.1136/bmj.h3757> PMID:26163479).
- (12) Wilensky G. "A New Focus on Prescription Drug Spending." *JAMA* 2015 Aug 4;314(5) 440-1
- (13) "The Editorial Board, Runaway Drug Prices". *The New York Times* 2015 May 5
- (14) Farrell S. "Clinton's promise on treatment prices hits pharma shares". *The Guardian* 2015 Sept 22).
- (15) Walker J, Winslow R, Steele A., "Mylan to Offer Generic EpiPen." *Wall Street Journal* 2016 Aug 30
- (16) Wirtz VJ, Hogerzeil HV, Gray AL, Bigdeli M, de Joncheere CP, Ewen MA, et al. "Essential medicines for universal health coverage". *The Lancet* 2016 Nov 7;389(10067):403-76
- (17) Kaiser U, Mendez SJ, Ronde T, Ullrich H. "Regulation of pharmaceutical prices: evidence from a reference price reform in Denmark". *J Health Econ* 2014 Jul;36:174-87. <https://doi.org/10.1016/j.jealeco.2014.04.003> PMID 24879578).
- (18) Ooms G, Forman L, Williams OD, Hill PS. "Could international compulsory licensing reconcile tiered pricing of pharmaceuticals with the right to health?" *BMC Int Health Hum Rights* 2014;14:37. <https://doi.org/10.1186/s12914-014-0037-7> PMID:25518744
- (19) Ingram R. "A Not-So-Transparent Attempt to Cap Drug Prices." *The Wall Street Journal* 2015 Jul 19
- (20) Miller G. "Is pharma running out of brainy ideas?" *Science* 2010 Jul 30; 329(5991):502-4
- (21) Mailankody S, Prasad V. "Implications of Proposed Medicare Reforms to Counteract High Cancer Drug Prices." *JAMA* 2016 Jul 19;316(3):271-2
- (22) Ridley DB, Regnier SA. "The Commercial Market For Priority Review Vouchers." *Health Aff (Millwood)* 2016 May 1; 35(5):776-83 .
- (23) Hyry HI, Cox TM, Roos JC." Saving orphan drug legislations: misconceptions and clarifications." *Expert Rev Pharmacoecon Outcomes Res* 2016;16(1):111-7.
- (24) Acosta A, Ciapponi A, Aaserud M, Vietto V, Austvoll-Dahlgren A, Kusters JP, et al. "Pharmaceutical Policies: Effects of Pricing, Other Pricing, and Purchasing Policies". *Cochrane Database Syst Rev* 2014; 10:dCD005979
- (25) Brooks E, Geyer R. "Can a Medical Need Clause Help Manage the Growing Costs of Prescription Drugs in the EU?" *Health Econ Policy Law* 2015 Sep 3;1-14
- (26) Alpern JD, Song J, Stauffer WM. "Essential Medicines in the United States—Why Access is Diminishing" *N Engl J Med* 2016 May 19; 374(20):1904-7
- (27) Marshall Allen, "Why Your Health Insurer Doesn't Care About Your Big Bills", <https://www.propublica.org/article/>
- (28) "The Story So Far". Grantham Centre for Sustainable Futures. www.grantham.sheffield.ac.uk/ and <https://www.youtube.com/watch?v=QnRY3L35KeM.>
- (29) Jonathan Shaw, "A New Green Revolution", *Harvard Magazine*, March 2018
- (30) <https://www.indigoag.com>

(31) Adamy J, WSJ, May 17, 2018 and Carl J, Fox News, @jeremycarl4, "Here's Why It Matters That Americans Are Having Fewer Children Than Ever Before". May 19, 2018.

(32) Reich, D., "Who We Are and How We Got Here: Ancient DNA and The New Science of the Human Past"., March 22, 2018 .