In his 2015 State of the Union address, President Barack Obama announced the precision medicine initiative, which is described as “a bold new research effort to revolutionize how we improve health and treat disease.” The foundation of this effort is our increasing ability in biomedical research to obtain and integrate individual patient information from genomics, proteomics, metabolomics, environment, lifestyle, diet, etc. (See sidebar.) The goal of acquiring and integrating all this information is to personalize treatments and care plans, hence provide more effective health care to every patient. 

The goal of more precise and personal health care is indeed laudable, but not exactly new. The January announcement strikes very similar tones to the announcement in September 2007, by Michael Leavitt, then Secretary of the Department of Health and Human Services, about the federal government’s bold, new initiative in personalized health care. In fact, much of the underlying concept of integrating all these elements of biology, lifestyle and informatics into a more systematized and individualized health care is easily traced back to the announcements claiming the completion of the Human Genome Project [HGP] in 2003, and to the development of systems medicine by Leroy Hood and his group at the Institute for Systems Biology, founded in 2000. From this timeline, one can readily conclude that the announcement regarding precision medicine is just the latest stage in the development of a more individualized approach to health care, grounded in advances in genetics and genomics, which has been underway for at least the past two decades. Hence, in addressing the issues of precision medicine, one can address the entire development of this more individualized approach to health care.

Simultaneous with this development in medicine has been a growing awareness of the momentous ethical and social ramifications that could occur, some intended and some unintended, as part of this technological development. Recognizing this potential for ethical, legal and social disruption, designers of the HGP made the Ethical, Legal and Social Implications Research Program [ELSI] an integral part of the overall project in 1990. The conclusion of the HGP in the early 2000s did not diminish the need for the ELSI program. In fact, a quick review of the literature related to ELSI issues in genomic medicine demonstrates how this area of research has continued to grow and develop in its own complexity parallel to the development of the reach and complexity of systems medicine. This challenge of adequately addressing the ELSI arena within systems medicine continues to be highlighted by researchers and ethicists alike, as can be seen in this quotation by FR. KEVIN FITZGERALD, SJ, PhD, PhD.

**OMICS-RELATED DEFINITIONS**

**Systems biology**: Biological research focusing on the systematic study of complex interactions in biological systems using integration models. The ultimate aim is to understand whole systems, e.g. complex cellular pathways, by studying the effect of altered external factors on the genome, transcriptome, proteome and metabolome simultaneously.

**Genomics**: The study of the structure, function and expression of all the genes in an organism.

**Transcriptomics**: The study of the mRNA within a cell or organism.

**Proteomics**: The large-scale study of proteins, including their structure and function, within a cell/system/organism. A name coined as an analogy with the genome.

**Metabolomics**: The study of global metabolite profiles in a system (cell, tissue or organism) under a given set of conditions.
from the text, *Genomic and Personalized Medicine* (2nd edition), in the chapter “Systems Biology and Systems Medicine,” with Leroy Hood as one of the co-authors. (Note: “P4 medicine” is another term for “systems medicine.”)

The challenge in bringing P4 medicine to patients and consumers is two-fold: first, inventing the strategies and technologies that will enable P4 medicine and second, dealing with the impact of P4 medicine on society — including key ethical, social, legal, regulatory, and economic issues. Managing the societal problems will pose the most significant challenges. Strategic partnerships of a variety of types will be necessary to bring P4 medicine to patients.

It is of great relevance when leaders in the research arena recognize and proclaim that the societal ramifications of a developing biotechnology are in fact of greater challenge than the scientific and technical issues. Hence, it seems quite prudent to accept their invitation to join the group of strategic partnerships they wish to create so that Catholic health care can engage with them, and others, in developing solutions to the societal challenges of precision medicine. But, what exactly is it that Catholic health care can bring to these partnerships that will help produce a better outcome for all involved?

There are two unique contributions that I believe Catholic health care can bring to this partnership. They are fundamental to the Catholic medical tradition but also can enhance the broader public deliberation for achieving the desired societal and individual benefits of precision medicine. The first contribution may seem obvious: the history and experience of Catholic health ministry in bringing the best care possible to each and all. Catholic health care has an extensive repository of engaging multiple communities, with divergent cultures, in widely varied environments, both within the U.S. and globally. Hence, the Catholic health care tradition can share an enormous number of cases and approaches (both successful and unsuccessful) that have tried to engage communities and individuals with new technologies and treatments in a manner that includes caring for the values and goals of the communities and individuals as a crucial part of instituting a new treatment option.

Though there may be aspects and technologies within precision medicine that have never been seen before by patients, there have been medical advances in the past that also brought revolutionary changes to societal concepts and values. One need only look back at the breakthroughs in organ and tissue transplantation (e.g., heart and face) to see how dealing with social issues of relationships and identity becomes as essential to the successful incorporation of these medical advances as dealing with technical issues such as organ reperfusion and rejection. Multiple examples from Catholic institutions of dealing with these delicate issues in ways that are sensitive to a broad range of cultures and circumstances, while still preserving the fundamental value of care for each and all, could be an invaluable contribution to the challenges that will come from precision medicine.

The second contribution Catholic health care can bring to the development of precision medicine is a bit less obvious due to the relative newness of the problem that is now becoming more apparent as genomic research and technology are being applied more broadly. The problem is that this broad application of genomic medicine has begun to reveal quite unexpected conditions within human nature that can challenge traditional concepts of human health. One brief example will help explicate this issue.

In the late 1980s, a diabetologist from the Institute of Endocrinology, Metabolism and Reproduction in Quito, Ecuador, Jaime Guevara-Aguirre, discovered a group of people in a village in Ecuador who all shared a metabolic condition called Laron syndrome. The genetic basis for this condition is a mutation in the growth hormone gene.
receptor, which results in the individuals with this mutation having extremely short stature, in addition to other physiological differences from average human beings. Two of those other differences are almost total resistance to malignant cancers and to type 2 diabetes. Interestingly, in the “News and Analysis” article in Science magazine that announced this finding, another researcher, not connected to this research project, was asked if researchers should now look into applying this mutation to the rest of us who do not share it, or its apparent benefits. The researcher replied, “Manipulating this in a healthy person as prevention is a very delicate issue and very complicated.”

While I certainly agree that any thought of trying to apply this mutation to others who do not have it is indeed delicate and complicated, I am not as certain about this researcher’s categorization of those of us without the mutation as “healthy,” implying that those with Laron syndrome are in contrast “diseased.” After all, two of the biggest challenges of global health in the 21st century are thought to be cancer and type 2 diabetes. So, who among us are truly the healthy ones? In addition, should we be looking to “cure” people with Laron syndrome, or their children, so they can grow to taller heights yet face the higher risks of getting cancer and type 2 diabetes? As more and more people in the world get their entire genomes sequenced, and we find that everyone has multiple genetic “mutations” that result in some physiological difference as compared to most other people, who will decide what is to be treated and what range of physiological characteristics will be considered healthy, normal or desirable?

As medical and ethical experts confront this genomic quandary, they will need to bring some kind of value framework or world view that they hope will keep them, and all people, from sinking into a medical morass of conflicting concepts and information. Whichever framework one brings, it will have to withstand both the crucible of the public square as well as the instability of the current biomedical research landscape. It is a scenario that the Catholic medical moral tradition is well suited to enter.

One need not accept the fundamental beliefs of the Catholic Church to recognize and respect the reasoning that has gone into 2,000 years of Catholic deliberation and reflection — as well as its integration of earlier Judaic and Greek insight and thought.

Any ethical framework engaging the challenges of precision medicine will have to demonstrate consistency, coherence, comprehensive-ness, clarity, and relevance to every community impacted by these developments in research and treatment. Catholic medical moral reasoning can stand alongside any ethical framework currently employed in the ELSI arena and the public square. After all, it has 2,000 years of its own development and history in health care to use to explain the development of its current practices and policies and its hopes for future engagements and contributions. To not bring these assets of the Catholic tradition to the U.S. and global health care arena, with all its promise and challenges, would be truly to fail in pursuing the very goal of care for each and all that is central to Catholic health care.

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NOTES
2. “The Precision Medicine Initiative.”