



Here's To Your Health! Leadership and Advocacy for Health Professionals

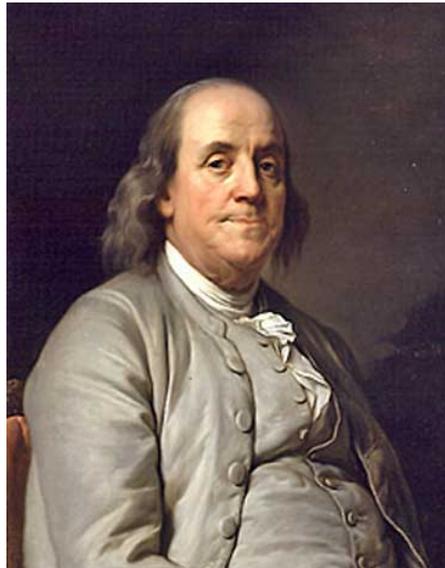
William C. Kling, JD
Clinical Assistant Professor
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School of Public Health

“Courage is the human virtue that counts most— courage to act on limited knowledge and insufficient evidence. That’s all any of us have.”

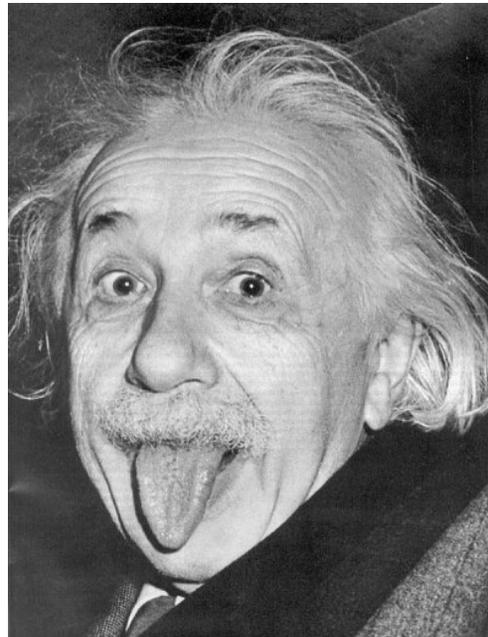
--*Robert Frost*



“All human situations have their inconveniences. We feel those of the present but neither see nor feel those of the future; and hence we often make troublesome changes without amendment, and frequently for the worse.”
--*Benjamin Franklin*



“A problem cannot be solved with the same
consciousness that created it.”
--*Albert Einstein*





World Health Organization

- “Health ethics has been an integral part of the activities of many units and departments at WHO for many years and is addressed not only within the Department of Ethics, Equity, Trade and Human Rights (IER/ETH) but throughout the organization. ETH works collaboratively with staff from all departments and the regional offices to identify, design, and carry out projects addressing the ethics of health care, public health, and biomedical science.” *WHO Ethics and Health Department of Ethics, Equity, Trade and Human Rights World Health Organization WHO/IER/ETH*



Australian Model

- “The *National Health and Medical Research Council Act 1992* specifies that NHMRC will issue advice and guidelines on ethics and related issues in the fields of health and human and animal research.”
Australian Medical Health and Research Council



President Obama's Story

When my grandmother got very ill during the campaign, she got cancer; it was determined to be terminal. And about two or three weeks after her diagnosis she fell, broke her hip. It was determined that she might have had a mild stroke, which is what had precipitated the fall. So now she's in the hospital, and the doctor says, Look, you've got about — maybe you have three months, maybe you have six months, maybe you have nine months to live. Because of the weakness of your heart, if you have an operation on your hip there are certain risks that — you know, your heart can't take it. On the other hand, if you just sit there with your hip like this, you're just going to waste away and your quality of life will be terrible. And she elected to get the hip replacement and was fine for about two weeks after the hip replacement, and then suddenly just — you know, things fell apart

President Obama's Story (con't)

- . I don't know how much that hip replacement cost. I would have paid out of pocket for that hip replacement just because she's my grandmother. Whether, sort of in the aggregate, society making those decisions to give my grandmother, or everybody else's aging grandparents or parents, a hip replacement when they're terminally ill is a sustainable model, is a very difficult question. If somebody told me that my grandmother couldn't have a hip replacement and she had to lie there in misery in the waning days of her life — that would be pretty upsetting.. I think that there is going to have to be a conversation that is guided by doctors, scientists, ethicists. And then there is going to have to be a very difficult democratic conversation that takes place. It is very difficult to imagine the country making those decisions just through the normal political channels. And that's part of why you have to have some independent group that can give you guidance. It's not determinative, but I think has to be able to give you some guidance. And that's part of what I suspect you'll see emerging out of the various health care conversations that are taking place on the Hill right now. NYT 05/03/09



Context

- Passion drives policy
 - Experience drives passion
 - Personal story
-



A Smorgasbord of Ethical Issues

- Beginning of Life
- End of Life
- Patient Safety
- Quality of Care
- Vaccines
- Human Genome
- Cloning
- Reproductive Rights
- Hospital not-for-profit status
- Trips to Hawaii



Framework for Public Policymaking

- Navigating the Policymaking Infrastructure
- Collecting, Analyzing and Assimilating Relevant Information (evidence and research based)
- Identifying Policy Paramours
- Strategic Delivery of policy proposal



Important Premises about Process

- Most policymaking is incremental
- Most policymaking is reactive
- Policymakers choose committees/issues based on particular interests
- Policy process is driven by money influence/voter impact parity



High Level Venues for Health Professionals

- Hospitals/Clinics
 - JCAHO
- American Medical Association
 - Medical Ethics
 - Institute on Ethics Pop Up– Prolia Advertisement
- Universities (Including Hospitals)
 - IRB
 - NIH Ethics Standards
 - Belmont Report



Mapping Assets and Liabilities

- Determination of Community Assets and Liabilities
 - Political environment
 - Business environment
 - Community-based environment
 - Grass Roots environment



Leadership Model

- Identify subjective/objective inputs and outputs
- Overlay internal/external hierarchies
- Determine resource allocation
 - Human
 - Physical
 - Fiscal
 - Program



A quick review of Policy Infrastructure

- **Governmental**
 - Venues
 - Local
 - Regional
 - State
 - Federal
 - Legislative
 - Elected officials
 - Staff
 - Executive
 - CEO (President, Governor, etc.)
 - Administrative Agencies



A quick review of Policy Infrastructure

- Non-Governmental (a.k.a. stakeholders)
 - Business and industry
 - Unions
 - Professional associations
 - Interest-based/constituency-based organizations
 - Media
 - Philanthropy
 - Universities



Context for our Conversation

HUMAN SUBJECTS



NON-GOVERNMENTAL RESPONSE



Hospitals/Health Care Systems

- Joint Commission
 - The Board of Commissioners is The Joint Commission's governing body, providing policy leadership and oversight. Board members govern The Joint Commission with a dedication to its mission to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.



Joint Commission Officers

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JACHO Leadership Standards

- “Healthcare is value-laden for patients, families, practitioners, and provider organizations. Consequently, it is common for the values of individuals or groups to come into conflict. It is not so much that the values themselves conflict, but that the available choices of actions (or behaviors) are unable to fully achieve both values at once



JACHO Leadership Standards

- “For example, activities designed to achieve universal access to care may not also achieve the goal of financial sustainability for the hospital. Resolving this “conflict”—or at least “uncertainty”—is an ethical challenge, not just a business or a clinical decision. Healthcare workers and administrators face these uncertainties daily, and often could benefit from assistance that can help them resolve the uncertainties.



JACHO Leadership Standards

- “The “process” that provides this assistance is, most commonly, an ethics committee, but can also be an ethics consultant or consultation service. Whatever the process, it needs to be readily accessible to staff, physicians and other licensed independent practitioners, and managers. The governing body and its members should also have access to the process—they often face decisions that, at their core, involve competition among values.



JACHO Leadership Standards

- “As stated in the discussion of Standard LD.02.02.01 in Chapter 4 of this white paper, while governing body decisions are often driven by values, the decision should be as fully informed as possible by *evidence.*”



JACHO LEADERSHIP STANDARDS

- Standard LD 01.03.01
 - The Governing body is ultimately accountable for the safety and quality of care, treatment and services.
- Standard LD 01.07.01
 - The governing body, senior managers, and leaders of the organizational medical staff have the knowledge needed for their roles in the hospital, or they seek guidance to fulfill their roles



JACHO Leadership Standards

- LD.02.01.01
 - The mission, vision, and goals of the hospital support the safety and quality of care, treatment, and services.
- LD.02.02.01
 - The governing body, senior managers and leaders of the organized medical staff address any conflict of interest involving leaders that affect or could affect the safety or quality of care, treatment or services



Governmental Response



Belmont Report

- “The Belmont Report attempts to summarize the basic ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the course of its deliberations. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees.”



HHS Office of OHRP

- “The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.”



HHS OHRP

- **International Compilation of Human Research Protections 2011 Edition** *Compiled By:* Office for Human Research Protections U.S. Department of Health and Human Services
- Over 1,000 laws, regulations, and guidelines that govern human subjects research in 101 countries, as well as the standards from a number of international and regional organizations. This Compilation was developed for IRBs/Research Ethics Committees, researchers, sponsors, and others who are involved in international research. Its purpose is to help these groups familiarize themselves with the laws, regulations, and guidelines where the research will be conducted, to assure these standards are followed appropriately.



International Compilation of Human Research Protections 2011 Edition

- General, i.e., applicable to most or all types of human subjects research
- Drugs and Devices (Also see the World Health Organization website: http://www.who.int/medical_devices/policies/en/)
- Privacy/Data Protection (Also see the Privacy Laws and Business website: <http://www.privacylaws.com/>)
- Human Biological Materials
- Genetic (Also see the HumGen International database at <http://www.humgen.umontreal.ca/int/>)
- Embryos, Stem Cells, and Cloning
- Key Organizations – include those groups that issue regulations or guidelines, or serve in a national oversight role for human subjects research.
- Legislation – includes statutes, statutory instruments, and legislative decrees, as well as constitutional provisions that relate to human subject protections.
- Regulations – refer to instruments that are created and issued under the name of governmental administrative bodies.
- Guidelines – pertain to non-binding instruments.



NIH Mission

- NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

NIH Office of Extramural Research, Research Involving Human Subjects

- **NIH Releases New Program Announcements (PA's) on Bioethics Research**

NIH published three new PA's on "Ethical Issues Related to Biomedical, Social, and Behavioral Research": [PA-11-180](#) (R01), [PA-11-181](#) (R03), and [PA-11-182](#) (R21). The new PAs replace the "Research on Ethical Issues in Human Subjects Research" PA's that expire on May 8, 2011 (PA-06-367, PA-06-368, and PA-07-277).



Congressional Approach

- Policy Paramours
 - Senator Ted Kennedy
 - Representative Earl Blumenauer
- Specific Initiatives
 - HR 1589, Personalize Your Care Act of 2011
 - (Referred to Committee April 25, 2011)



Rep. Blumenauer, HR 1589

- “Advances in healthcare have led to increasingly complex health care decisions and more treatment options than we have ever before had the benefit--or the burden--of choosing between. Both Democrats and Republicans agree that individuals should be fully involved in decisions related to their own health care and should be able to make informed decisions about that care reflecting their values and their needs. We also agree that when people have expressed their wishes, particularly in a formal and legally binding manner, those wishes should be known and respected.
- While there is widespread agreement regarding these principles, too often this is not the reality. Most adults have not completed an advance directive; if documents are completed, they are not regularly revisited and can be difficult to locate. Because these issues are difficult to discuss, surrogates often feel ill-prepared to interpret their loved ones' written wishes.”

Rep. Earl Blumenauer





Rep. Earl Blumenauer

- Elected to the US House of Representatives in 1996, Mr. Blumenauer has created a unique role as Congress' chief spokesperson for Livable Communities: places where people are safe, healthy and economically secure. From 1996 to 2007, he served on the Transportation and Infrastructure Committee, where he was a strong advocate for federal policies that address transportation alternatives, provide housing choices, support sustainable economies and improve the environment. He was a member of the Foreign Affairs Committee from 2001 to 2007 and vice-chair of the the Select Committee on Energy Independence and Global Warming from 2007 to 2010. He is currently a member of the Ways and Means Committee and the Budget Committee.
- Congressman Blumenauer's academic training includes undergraduate and law degrees from Lewis and Clark College in Portland.



Potential Stakeholders

- [AcademyHealth](#) [American Association for the History of Medicine](#)
[American College of Healthcare Executives Code of Ethics](#)
[American College of Physicians Center for Ethics and Professionalism](#) [American College of Surgeons Ethics Page](#)
[American Medical Association](#)
[American Medical Association Institute for Ethics](#)
[American Philosophical Association](#)
[American Society for Bioethics and Humanities](#)
[American Society for Law, Medicine, and Ethics](#)
[American Society for Reproductive Medicine Ethics Page](#)
[Center for Studying Health System Change](#)
[Department of Clinical Bioethics \(NIH\)](#)
[Department of Health and Human Services](#)
[National Cancer Institute](#)
[National Conference of State Legislatures](#)
[National Endowment for the Humanities](#)
[National Institute of Health's Bioethics Resource Site](#)
[National Medical Association Presidents Council on Bioethics](#)
[U.S. Department of Health and Human Services](#)
[U.S. Food and Drug Administration](#)
[Veterans Health Administration National Center for Ethics in Health Care](#)



Conclusion

- Timely issues
- Incremental change
- Individuals can have an impact
- Balance between non-governmental and governmental
- **DRIVEN BY PASSION**