Government 103: What Happened to the Great Idea?

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ABBREVIATIONS: HIPAA = Health Insurance Portability and Accountability Act; HR = House of Representatives; PL = public law; WEDI = Workgroup for Electronic Data Exchange

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The *great idea* is the great foundation of the system of self-governing brought to this portion of the North American continent in 1789.

Let us say you had a great idea about how things in health-care could work better. Then you did all the right things. You formed it into a cohesive thought and purpose. You looked up pertinent existing statutes at the appropriate level; municipal, state or federal. You determined how your idea could fit in and you took a shot at writing draft language. You found a sympathetic legislator at the appropriate level and secured their support. You had the legislation filed and assisted it through the legislative process. You made compromises to appease objectors and applauded your success when the bill became law.

At this point you realize that several challenging steps remain. Regulations implementing the new statute need to be written. The new law has to fit itself into the existing pantheon of other great ideas. Other laws in the same area will follow. The landscape upon which your idea was founded will change. Why are you getting that cold, clammy feeling? Here is a look at how some previous legislation fared.

PL 100-175 (HR 1451, SIGNED November 29, 1987) OLDER AMERICANS ACT AMENDMENTS OF 1987
This legislation reauthorized the Older Americans Act of 1965 through 1991. While the Older Americans Act has been reauthorized several times since, this established (Title III) state and area agencies on aging and a new authority for in-home services for the elderly. Generally thought to be a very productive idea, it did not come under direct assault once in place, but it has been weakened several times by funding authorization limitations. This is an example of an interest group, elderly Americans, thinking they had a good next step, found a path for it to happen, did the work to get to the goal and saw some of what they won lost due to the work of others with a different agenda.

PL 100-360 (HR 2470, SIGNED July 1, 1988) MEDICARE CATASTROPHIC COVERAGE ACT OF 1988
Almost universally thought to be a good idea at the original signing, this law expanded Medicare coverage of inpatient hospital care while limiting beneficiary out-of-pocket expenses for hospital and physician care. It also expanded skilled nursing facilities benefits to 150 days and allowed spouses of Medicaid nursing home patients to retain higher levels of income and assets for their living expenses. Then over time, this became a bad idea because elders and most working people paying into the Medicare system faced higher fees. In the end, the law was gutted in 1989 as part of tax-cutting initiatives. Good ideas do not always cost money, but they often do. Whenever this is the case (and in a dose-related way, the extent to which it is the case), the proponents need to be especially vigilant after the fact. Vigilance must extend to an appropriations committee that is likely not to have been the committee that argued the merits. In this case, the effect lasted just over a year; less if you consider that without the appropriations step it was never truly implemented even though it was passed.

PL 100-203 (HR 3545, SIGNED December 22, 1987) OMNIBUS BUDGET AND RECONCILIATION ACT OF 1987

This act increased the Title IV hospital payment rate applicable under Medicare for fiscal years 1988 and 1989. It specified allowable increases for physician services and decreased the payment for certain overpriced surgical procedures. "OBRA"s are a common venue for ideas that have narrow scope or not quite enough political horsepower to find their way through the committee structure on their own. It is often thought that getting an appropriation incorporated into one of these consolidated bills enhances the appropriation's chance of passage. Indeed the bill may have only gotten there through the direct intervention of a friendly member of Congress. Once attaining this status however, the next miracle occurs when the idea emerges unscathed from the committee process, minimally changed by legislators or their staffers. Unless your legislator was on the committee of relevant jurisdiction, there could be little you could do to influence the immediate future of your idea at this point.

PL 108-173 (HR 1, SIGNED December 8, 2003) MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERIZATION ACT OF 2003 (HASTERT BILL)

Quite well known in the political arena and in the popular press, this bill makes it possible for senior citizens to potentially save 10% to 25% off the cost of most medicines through a Medicare-approved drug discount card beginning in 2004. Arguments floated at the time suggested that the typical senior spends $1,285 annually on their medicines. The sponsors expected that the card could save seniors as much as $300 annually.

This bill has the opposite status of the Omnibus Budget and Reconciliation Act of 1987. The prescription benefit is part of the national debate and each party has specified landmarks for responsible outcome. Changes in language are scrutinized intensely on a national stage.

Proponents of any direction in which the idea is pushed are sure to respond. There is a downside to such celebrity status: no matter what your ability to respond, your idea could be caught up in a tidal wave of arguments created by either side that have little to do with its merits. The up side is that when such so prominent an idea is established it is likely to be followed up by all interested parties, ensuring fidelity in enforcement. Even though one side lost in the legislative arena, it could still use the issue in the political arena, especially if the winning side didn't follow through in its promise.

HEALTH INSURANCE PORTABILTY AND ACCOUNTABILITY ACT (HIPAA), [ALSO KNOWN AS THE KENNEDY-KASSEBAUM ACT]

In the early 1990s, the Bush administration called a group of healthcare industry leaders together to discuss how healthcare administrative costs could be reduced. This group concluded that this could best be done by increasing the use of electronic data interchange within the industry. This advisory group later organized as the Workgroup for Electronic Data Interchange (WEDI), which was initially co-chaired by the Presidents of the Blue Cross and Blue Shield Association and the Health Insurance Association of America, which represents commercial insurers.

WEDI conducted a number of studies and eventually recommended Federal legislation to ensure a consistent set of standards that could be used across all states. Many of WEDI's recommendations were included in the Clinton Health Plan, which failed to pass, and similar provisions were included in other draft legislation. They were eventually included in the House version of HIPAA under the sponsorship of Congressman Hobson (R-OH), and survived a House/Senate conference thanks partly to extensive industry support.

HIPAA was finally signed into law on August 21, 1996 (PL 104-191). HIPAA officially amends the Internal Revenue Service Code of 1986. Title I protects health insurance coverage for workers and their families when they change or lose their jobs. Title II includes a section, Administrative Simplification, requiring improved efficiency in healthcare delivery by standardizing electronic data interchange, and protecting confidentiality and security of health data through setting and enforcing standards. From these humble beginnings a major effector of daily policies and procedures now exists with thousands of pages of regulations. This is an example of legislation that had its roots in seemingly unrelated thinking, going through various false starts. It then became a bill and eventually law for different reasons still. In the regulatory phase, this idea has morphed into something that few of its original conceivers could have imagined.

There are reasons for such development, many of which are germane to the field of clinical laboratory science. One of these would be the rapid development of technology. In this case, think of how much computer technology has changed in the 15 years since the beginnings of the Bush administration. Imagine how much of a patient's medical and personal information is now vulnerable to hackers who could easily cut through a 1990 firewall. In the end, the security aspects of the original idea have been emphasized over its initial importance.

THE HOSPITAL SURVEY AND CONSTRUCTION (HILL-BURTON) ACT, ENACTED August 13, 1946

Better known by its principal bipartisan co-sponsors, Senators Harold Burton (R-OH) and Lister Hill (D-AL), the Hill-Burton Act launched a nationwide hospital-building program, designed to provide the necessary number of staffed hospital beds per 1,000 people throughout the land—regardless of race, color, creed, gender, or ability to pay. It was an unprecedented move in the history of the United States.

Prior to 1946, the US hospital system had evolved with great disparities in facilities and accessibility. On the eve of World War II, of 3,076 counties in the United States, 1,282 had no hospital for community use and hundreds of the existing 1,794 community hospitals were substandard. There were local concentrations of malnutrition and disease.

What seemed obvious to a consensus of policy makers as of the end of the war was the need to wage a peacetime war against disease, and to provide care wherever it was needed to any of the population, then numbering 148 million. Why not build infrastructure? Why not beat back tuberculosis, which was still taking a terrible toll, and poliomyelitis, and other diseases? Plus, the baby boom was at hand. Why couldn't women look forward to giving birth in modern hospitals?

In his 1944 State of the Union address, President Roosevelt spoke of an "economic bill of rights", including the right to adequate medical care and the "opportunity to achieve and enjoy good health". In his January 6, 1945 State of the Union address (the last he was to give; he died in April of that year), the president again spoke of the right to "good medical care". Virtually everyone agreed with the President and indeed his sentiment constituted the idea upon which the greatest single expansion of the US healthcare system would take place.

Our field benefited tremendously from this in that clinical laboratories were part of the building infrastructure. These laboratories increasingly contained the consequences of scientific research that went on during WW II. Eventually scientific procedures and instrumentation were developed that led to the great awakening of clinical laboratories in the 1960s and 1970s—our greatest single growth period.

So how can there be a downside to Hill-Burton? Well, all that growth led to expanded use by physicians of our services and perhaps even to a bit of dependency upon it. This led to its own issues related to quality, cost, and eventually to direct federal legislation for the previously little-noticed clinical laboratory industry.

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA '88)

PL 100-578 (OCTOBER, 1988); REPLACED SECTION 353 OF THE PHSA 42 CFR 405-494

This bill amends the Clinical Laboratory Improvement Act of 1967, the most sweeping law ever to affect clinical laboratory science. CLIA '67 was an attempt to regulate laboratory costs, then considered responsible for an increase in costs in the healthcare infrastructure that had blossomed after WW II. The return of veterans and the subsequent invigoration of the US economy put a strain on the healthcare system. In 1946, Congress passed the Hill-Burton Act that provided construction dollars to expand existing hospitals and create new ones—some across the street from one another. The Metcalf-McCloskey Act in New York had similar effect on the beginnings of health planning. Tens of millions of babies were born in these new facilities and many laboratory tests were performed. The technology of WW II and this new growth conspired to create a wave of scientific innovation in our field and a growth spurt of test menu development began to propel us toward the 27,000 tests we now have. Both quality and quantity issues eventually came up and by 1967 Congress was seriously trying to deal with each. Unfortunately, elements within our practice field foiled the best efforts of the lawmakers and the regulators such that by 1988 they were ready to try again.

One key element of this new effort was that all clinical laboratories were to be mandated by the will of the Secretary of Health and Human Services. This was quite new in scope and tone for us and got a lot of people to pay attention that continues to this day.

Language of CLIA '88:

> *The executive branch shall issue standards necessary to assure consistent performance by laboratories of accurate and reliable laboratory examinations and procedures. The standards shall require quality assurance and quality control procedures and policies, hiring of proper personnel, proficiency testing, and other matters as determined by the Secretary of HHS.*
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> *First regulations: 55 FR 20896-20959, May 21, 1990. All clinical laboratories in the United States and its territories that examine human specimens must meet performance requirements based on test complexity and risk factors related to erroneous test results.*

The law was intended to be mandatory and comprehensive.

Does CLIA '88 affect my laboratory?
Yes. No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary of Health and Human Services.

These provisions require that the following laboratories or entities that perform test procedures or examinations also meet federal requirements.

- Accredited laboratories
- Non accredited laboratories
- Federal hospital laboratories
- Independent laboratories
- Physician office laboratories
- Laboratories in critical care facilities, including operating rooms
- Laboratories in skilled nursing facilities, end-stage renal disease facilities, intermediate care facilities, including intermediate care facilities for the mentally retarded
- Laboratories associated with tissue banks and tissue repositories
- Laboratories in ambulatory surgical centers and rural health clinics
- College of American Pathologists accredited and New York State licensed laboratories
- Low volume exempt laboratories
- Industrial laboratories
- City, county, and state laboratories
- Laboratories associated with federal clinics
- Laboratories located in Planned Parenthood clinics
- Laboratories located in health maintenance organizations (HMO)
- Drug screening laboratories
- Mobile laboratories
- Any other facility or entity including pharmacies and health fairs that perform quantitative, qualitative, or screening test procedures or examinations on materials derived from the human body

And as if this weren't clear enough, the Omnibus Budget and Reconciliation Act of 1989 (OBRA 1989, PL 101-239) added compliance regulations for all Medicare laboratories. The act established personnel qualifications, test complexity definitions and quality issues clarified by Congress and subsequently reinforced by regulators. CLIA '88 and OBRA '89 send the message that clinical laboratories should perform tests on patients at the highest level of quality at the lowest possible cost and with the greatest possible patient access.

We seemingly hadn't gotten this point from the 1965 Medicare legislation, from CLIA '67 or from subsequent federal encouragement. What happened next illustrates the need for vigilance. Physicians with in-office clinical laboratories and owners of independent clinical reference laboratories who had missed the opportunity to influence the legislation attempted to soften the first set of regulations. They did this by deluging the regulatory agency charged with writing the rules. The agency received the largest number of letters they had ever received on a single topic. By comparison, we clinical laboratory professionals wrote very few letters in support of the regulations. The results affect us today. Contention between the forces advocating for relaxing the rules and those advocating for protecting the patient public by strengthening the rules (ASCLS and others) continues to this day, with the patient public and their medical welfare in the balance.

SUMMARY

A similar analysis relates to bloodborne pathogens legislation, clinical laboratory reimbursement regulations, and Title VII support for health professions education. What ultimately happens to a great idea depends on our nurture and protection, meanwhile the efforts of others may subjugate its purpose. Failure to nurture the idea means it may have a previously undreamed-of effect.

This commentary on the consequences of political action supports hard work, action, and vigilance. The framers intended that the system be energized, not paralyzed by multiple checks, balances, controls and remedies. George III wasn't big on any of these in the 18th century, so they now exist for the protection of us all. That they may seem obtuse is but one more reason for a vibrant participatory body politic, players on all sides who care to take the time to know the issues and our current boundaries. ASCLS has understood this, has taken up the gauntlet and has advocated for our field and its effect on patients in need of clinical laboratory tests for longer and with more success that any entity in US history. What part can you play in the knowing and the doing?