



## Presidential Address:

### *The War of Regulation (1767–1977)*

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PLEASE ACCEPT MY SINCERE gratitude for the great honor you have granted me to serve as your President during this year. While many of you are more deserving of this honor than I, there can be no one among you who is more enthusiastic about holding this high office and no one who is more reluctant to leave it! I keep wondering if in some way I can be recycled.

Presidential addresses presented to this association have frequently described works of men and historic events that have been a part of the rich heritage of the South. In this tradition I want to talk to you today about the War of the Regulation—firstly, a war that was waged from 1767 to 1771 by American colonial citizens against their government and which the colonists lost. Secondly, I want to discuss with you a War of the Regulation which the American government is waging in 1977 against its citizens and which the citizens are in grave danger of losing.

Let me begin by directing your attention to colonial North Carolina during the latter half of the eighteenth century. More specifically, let us look at the county of Orange near the center of the Royal Province with the town of Hillsborough, founded in 1754, as its county seat.

At that time the colonial settlers, largely of English origin, were concentrated along the eastern seaboard. The seat of the Royal Provincial government was the eastern town of New Bern, founded by Swiss colonists in 1710 and selected by British Governor William Tryon in 1766 to be the site of his palatial residence. Orange County, named after the Dutch Prince of

Orange who became King William III of England, was frontier country, settled largely by German and Scotch-Irish colonists. The latter designation was given to those descendants of lowland Scots and "borderers" who had originally emigrated from Scotland to the Ulster plantations of Northern Ireland in the seventeenth century and whose families subsequently emigrated to the American colonies by the hundreds in the early eighteenth century—some historians say to escape the long sermons of their own Presbyterian ministers. At best these emigré Scots had little enthusiasm for English rule.

During the decade just before the Revolutionary War, there was a great deal of restless discontent among the colonists in what was then called the "back country" in North Carolina. The principal causes were the inept colonial policies of the British crown, the tyrannical measures of Royal Governor Tryon and the corrupt governmental administration of Edmund Fanning, Tryon's representative in Hillsborough.

Fanning was a native of New York and a Yale graduate who came to Hillsborough in 1762. He soon became Register of Deeds of Orange County and, subsequently, Justice of the Peace and Governor Tryon's factotum in the frontier capitol. His corrupt practices and harsh measures enraged the colonists. Embezzlement of tax money by the 11 sheriffs on Fanning's staff was further cause for outrage. In a widespread movement to rebel against the corrupt county governments in 1767 the colonists in Orange and surrounding

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counties organized themselves into a group known as the Regulators.

At its beginning the Regulators' movement was enveloped in secrecy with the objective of establishing good local government. Efforts to obtain justice in local county courts failed consistently. When the Regulators appealed for justice to the Assembly at New Bern, Governor Tryon had the Assembly dissolved. By 1770 the spirit of the Regulation was widely aroused and local officials in many counties were openly accused of dishonesty, extortion and bribery by the Regulators. In September, 1770 in Hillsborough 150 Regulators took over Judge Richard Henderson's courtroom, pulled Edmund Fanning from behind the judge's bench and gave him a public whipping. For two days there was rioting and destruction of much governmental property and court records. The violence caused a special session of the Assembly to be convened in New Bern that began at once to draw up reform measures in line with the demands of the Regulators, providing for honest dealing by the sheriffs, attorneys and court officers and specifying their fees. However, when rumor reached the Assembly that the Regulators were going to march on New Bern, the reform measures were replaced by punitive legislation. The Attorney General was instructed to prosecute charges of riot in any superior court in the province. All who avoided the summons of the court for 60 days were to be declared outlaws and were to be shot on sight by the militia.

The Regulators were quick to retaliate. They announced that they would pay no more taxes, that no more court sessions were to be held and that Edmund Fanning and any other officials or attorneys who came among them were to be killed.

Governor Tryon ordered a superior court session to be held in Hillsborough in March, 1771. To quell anticipated riots, Tryon raised a force of militia in the eastern counties by offering a bounty of 40 shillings per man and began the long march to Hillsborough with over 1000 men. Tryon's men were well armed and had plenty of ammunition. They encamped outside Hillsborough in May, 1771 and were joined by an Orange County militia company headed by Fanning. This raised Tryon's numbers to about 1450 men. This well armed force met an ill-equipped, poorly organized band of about 2000 Regulators at Great Alamance creek in Orange County on May 16, 1771 and after a two hour battle Tryon's force gave the Regulators a crushing defeat. Tryon's losses were nine men killed and 61 wounded. The Regulators lost nine men killed and over 200 wounded.

Tryon took 15 Regulators prisoner. One of these, James Few, was immediately hanged on the battle-

field and subsequently 12 others were judged guilty of treason; six of these were hanged and six were later pardoned by King George III.

On the day after the battle of Alamance, Tryon proclaimed pardon for all those suspected Regulators who would take an oath of allegiance to the crown, excepting the captured and those whom he outlawed. In the end about six thousand men took the oath. Some 1500 people, however, left the Royal Province of North Carolina and emigrated westward.

The Regulation movement in North Carolina failed in 1771 to eliminate corruption in local colonial government but it showed that the frontier counties were rebellious against a form of government in which the people could not hold officials accountable for their conduct in office. In this historic vignette we can clearly recognize the spirit, shared by a majority in all colonies, which subsequently led to the American Revolution against the British crown and to the adoption of a constitution for the United States based on government by and for the people who are governed.

From this historic springboard, let me invite you to take a quantum leap in time from the War of the Regulation in the eighteenth century to our current situation in 1977. More specifically, let us look at the relations between today's huge federal government and one segment of those who are governed, the medical and scientific community.

In my view of the scene today, I am persuaded that the War of the Regulation has been resumed, but the lines of battle have been redrawn and the role of the contestants strangely reversed!

The Regulators in the war that is waged today no longer wear the white hats with which we adorn our pioneer ancestors; rather in our current imagery a vast army of the federal establishment with a predilection to wear black hats represents the Regulators of 1977. To carry this conceit further, the malevolent spirit of British Governor Tryon that harassed North Carolina colonists over 200 years ago seems to have surfaced in the late Twentieth Century to harass physicians, surgeons and hospitals in the power structure of our own federal government—the great medical regulator of today!

Our federal government first entered the regulatory field in 1887 with the creation of the Interstate Commerce Commission (ICC) which was organized to crack down on the railroad barons of that day. In 1920 Congress authorized the ICC to set both minimal and maximal rates for railroads. Some observers view this as the beginning of the unfair practices of federal regulatory agencies in stifling competition and protection of the business which they regulate.

Forty-five years ago President Franklin Roosevelt

invoked the massive power of the federal government for social action and economic control. With the multiple programs of the "new deal" came the socialistic ideas of the primacy and benevolence of big, centralized government and its role in the solutions of the nation's problems. Since Roosevelt's time these concepts, bordering on national socialism, have been upheld by the liberal establishment in Congress, in the federal bureaucracy, and by the liberal media of our country. These socialistic trends flourished under Presidents Kennedy and Johnson, and with the flowering of multiple, costly federal programs came a flood of federal agencies established by Congress to administer and regulate them. The most massive expansion has occurred in the fields of health, welfare and environmental control. Over the last decade the government's alphabet soup has had OSHA, EPA, CPSC, ERDA, FEC, FEA and EEOC added to ICC, FDA, FCC, FPC, CAB, SEC and FTC.

During the 1970's, state governments and private industries, including the health care industry which may be the most heavily regulated of all industries, have become deluged by the ceaseless flow of complex, arbitrary, unnecessary, unclear and frequently unrealistic rules and regulations imposed by the federal government. The General Services Administration calculates that government forms alone cost the private sector 20 billion dollars annually and the government another 20 billion dollars to read them.

Phillips and Sprague in a report to the American Hospital Association consider that the proliferation of regulations, especially for hospitals, has reached a critical mass with bureaucratic inertia too heavy to control. The proliferation of health care legislation during the 1970's has been accompanied by complex and highly integrated sets of social and economic regulation. In addition, the methods for enforcing regulations have increased and include institutional licensure and accreditation, franchising, stipulations on loans and grants, interest subsidy, institutional tax exemptions, personnel licensure and certification, drug and device licensure, private drug evaluation and listing, professional liability, fines, administrative orders and public disclosure.

As Phillips and Sprague point out, "regulations can be classified by their purpose: economic regulation of prices, rates or fees to affect conditions in the market and social regulation of services and practices to affect conditions regarding individual rights and public health and welfare." However, the overlapping of regulatory activity by multiple federal agencies and their separate, often disparate and even paradoxical standards and rules have created a nightmare for the health care industry and particularly for hospitals.

Undoubtedly, the most complex, confusing and rapidly changing group of regulations involving hospitals has to do with codes and standards associated with design, construction and maintenance of facilities. In the past, the regulation of hospital construction through national standards implemented at state level to ensure the safety of patients has always been an accepted responsibility shared by government and hospitals. However, in the last decade Congress has acted to incorporate these standards into the bodies of legislation having to do with patient care and complicated by formulas for reimbursement of services.

The standards and codes are changed in an almost ceaseless fashion. In one recent year according to Phillips and Sprague, there were 4800 pages of changes in the total National Fire Protection Association (NFPA) standards, 600 pages in Building Officials and Administrators Code and 500 in the Uniform Building Code.

Leonard Cronkhite, President of Boston Children's Hospital, commenting on the plight of hospitals in his Chairman's Address to the Association of American Medical Colleges said last year, "I doubt that any one of us could, even with unlimited funds, comply with this bureaucratic lunacy short of hiring a permanent construction crew to renovate on a year round basis." Cronkhite also made the sage observation that the enormous bureaucratic structure of the federal government in terms of its growth rate and invasiveness has many of the characteristics of a malignancy.

The major objectives behind the massive intrusion of the federal government into the regulation of health care institutions and medical practice have had to do ostensibly with public safety and with control of the costs of medical care. There can be no quarrel with the soundness of these objectives. They are and have been long supported by the private sector. However, as so pleasantly stated by HEW Secretary Califano to the AMA Convention last summer, it is the federal government's view that the health care industry has not only failed to contain costs of medical and hospital care, but has been largely responsible for the recent inflationary rises in costs. According to Califano not only is health care spending eating up an ever larger portion of the gross national product, but it is his prediction that by 1980 total health expenditures in the United States will double and, if unchecked, total hospital costs could reach 220 billion dollars by 1985.

However, Secretary Califano testified before Congress in November, 1977 that HEW loses more than \$2 billion per year in fraud, over-payments and other bureaucratic snafus. Losses were said to result from massive over-payments to ineligible recipients, from fraudulent claims by clients, from abuse by doctors,

pharmacists and other health care providers and from failure to collect more than \$600 million from third party insurers. This testimony prompted a Chicago Tribune editorial on November 10 which is most pertinent, "It is difficult—perhaps impossible—to eliminate all waste and fraudulent loss when bureaucrats run such large scale programs as Medicaid. But that annual \$2 billion waste in one program alone should flash an oversized red light at government officials and legislators pushing national health insurance plans. Until HEW proves to Congress it can run Medicaid without losses amounting to seven percent of total spending, it would be foolish, and intolerably expensive, to expand such services."

The federal establishment appears to presume that within the medical and scientific community there are large numbers of ignorant evil-doers, chiefly surgeons, who will, if not watched closely, violate the civil rights of their patients, steadfastly refuse to provide them with primary care, mental health, and preventive medicine, treat them with drugs which cause cancer in federal rats, fail to obtain a second opinion, and without informed consent submit them to unnecessary surgery for which a fraudulent claim is made against Medicare for a fee of over \$100,000.

These erroneous presumptions, ridiculous in the extreme, have apparently been responsible for the increased rigidity of the Food and Drug Administration, HEW's restrictions on clinical investigation, the informed consent controversy, the concept of mandatory second opinions for elective surgery, altered commitment procedures for the mentally ill and retrospective audits of all aspects of medical care in hospitals as measured by federally approved norms. Containment of costs of the Medicare and Medicaid programs is the true objective of the Professional Standards Review Organization, although the government insists that enhancement of the quality of medical care is the aim of PSRO.

The War of the Regulation against our profession and our hospitals has been enthusiastically supported and applauded with Naderesque zeal by the liberal media who respect and love us dearly, about as much as does Secretary Califano.

Why is this War of the Regulation being waged against us by our federal establishment at a time when the United States of America has a superb pluralistic health care delivery system based on free enterprise in the private sector with voluntary self-regulation—a system that is outstandingly superior to that of any other country in the world today?

In attempting to answer this question, let us agree initially that codes, standards and regulations are

clearly necessary in the health care field. Traditionally, these have been developed and administered by state and local governments in collaboration with voluntary agencies of the private sector such as the Joint Commission on Accreditation of Hospitals. However, the recent study of regulation made by the Hospital Association of New York State identified a total of 164 different agencies with some jurisdiction over hospitals in New York State: 96 at state level, 40 at federal, 18 city-county and ten voluntary agencies. The study indicated that the majority of these regulatory bodies are concerned with bureaucratic matters having little to do with patient care but much to do with administrative, financial and informational services. This overgrown regulatory system in New York has become a costly, counterproductive burden which increases the cost of health care. Clearly, the zeal for over-regulation has become rampant at the state level.

The high command in the War of the Regulation today, however, is the enormous federal bureaucracy. As Leonard Cronkhite has observed, this is a "loose federation of single purpose agencies, bureaus, commissions, and boards so highly compartmentalized as to be unmanageable. Each agency pursues its single purpose zealously without regard for any possible aggregate national purpose—bureaucracy has much more autonomy than any other branch of government. Using the loose mandate from Congress that the various secretaries shall promulgate regulations to implement a given law, the regulations themselves become, in effect, the law."

Although on legal grounds only state governments, not agencies of the federal government can regulate health care markets directly, the federal government does in fact regulate those markets through the exercise of its power of the purse. In providing grants to states the federal government characteristically places regulatory requirements on them. The strictness of requirements depends on a mixture of congressional and federal bureaucratic objectives.

John T. Dunlop, former Secretary of Labor, thinks that a major reason for the attraction of regulatory legislation in recent years has been the belief that regulation is a speedy, simple and cheap procedure. "Perhaps, too," he says, "because the majority of congressmen are lawyers, and not business executives, labor leaders, economists or labor mediators, they are apt to think of social and economic problems in legal terms. For these and other reasons, when a problem acquires national concern . . . the natural reaction has been to create a new regulatory agency to deal with it."

Two years ago, Theodore Cooper pointed out the

stark fact that the tremendous increase in governmental expenditures in the health field greatly increases the ability—"some would say the obligation—of the federal government to impose its will on every segment of the health establishment. . . . It is a small jump from the provision of money to the imposition of control. As we have seen all too often once that jump is made, it is virtually never reversed."

Former Secretary for Health, Charles C. Edwards, argues that our present health care system with its rising, inflated costs is headed for certain financial collapse with the inevitable result of total federal takeover and control of all medical services and facilities. His suggestion is that a strong centralized National Health Authority be established to create national regulations on an aggregate rather than a piecemeal basis for the entire health care industry. Edwards stipulates that this is a mandatory step, if the chaotic alternative is to be avoided, before initiation of national health insurance which he strongly favors. Without such regulation he believes that the adoption of national health insurance would hasten rather than prevent the collapse of the system.

Perhaps another major cause of the massive governmental regulatory attack on the health care industry that might be considered by paranoid surgeons and other observers of the current national scene is the possibility of a diabolical plot by evil bureaucrats aimed at the destruction of the voluntary, free-enterprise portion of our pluralistic American system of health care and its replacement by a totalitarian socialistic system of governmental control. The George Orwell concept of "double think" as used in his terrifying book *1984* may be implicated in the overwhelming likelihood that overregulation of the health care industry under the rubric of cost containment will most certainly have the diametrically opposite effect and actually increase the costs of health care. *1984* may be closer than we think!

That these thoughts may be something more than paranoid surgical delusions is signalled by the activities of the federal health care planners during the last few years. There are ten health policies listed in Section 1802 of the National Health Planning and Resources Development Act. They are to be used by the National Council on Health Planning and Development and the Secretary of HEW in formulating national health goals and by Health Systems Agencies and State Health Planning and Development Agencies in developing and carrying out their plans and programs. Since these priorities on health policies were introduced into Congress in 1973 they are in no way new. They are linked to the three overall purposes of Public Law 93-641

which are: equal access to health care, improved quality of care and cost constraint.

Priority 1 addresses the need to provide primary health care to the underserved. Priority 2 is concerned with multi-institutional systems for coordinating or consolidating health services and Priority 7 with the development of appropriate levels of care within geographical areas. Priority 3 calls for the development of medical group practices and other organized systems of health care (this is the concern of the Health Maintenance Organization Act of 1973). Priority 4 calls for the training and increased utilization of physician assistants and especially nurse clinicians. Priority 5 encourages the development of multi-institutional arrangements for shared support services. Priority 6 calls for promotion of activities to achieve improvements in the quality of health services such as needs identified by the activities of PSROs. Priority 8 concerns itself with prevention of disease, with nutrition and the environment. Priority 9 calls for uniform cost accounting, reimbursement procedure and utilization reporting. Priority 10 asks for the development of more effective health education and promotion.

At first glance these policies seem quite benevolent, but their progressive implementation by the federal government has generated a proliferation of regulations and bureaucracy that suggest strongly a movement toward total governmental control of health care. The Kennedy-Corman bill, if passed by Congress, would promptly establish national socialistic control of health care in the USA, but, happily, there appears to be little Congressional support for it.

Currently, the Carter administration is urging Congress to pass the Hospital Cost Containment Act of 1977 as a necessary prelude to the administration's anticipated proposal for national health insurance. The various bills in the Congressional hopper which propose national health insurance represent to paranoid surgeons merely additional invitations for more massive inflationary governmental expenditures in health care, huge increases in the federal bureaucracy, and major escalation of the War of the Regulation which will lead us further down the skids to socialized medicine.

What can we do about these terrifying implications of the current phase of the War of the Regulation?

Since lawyers produce most of the bureaucratic regulations, the initial response of a paranoid surgeon might echo Shakespeare's character Dick the Butcher in *King Henry VI, Part 2*, who said, "The first thing we do, let's kill all the lawyers."

On more mature reflection, however, that solution, no matter how attractive it may be to some of you, is not practical—lawyers greatly outnumber us and,

furthermore, they have made a law against Dick the Butcher's suggestion.

A second solution to this War of the Regulation that might come to the mind of a paranoid southern surgeon is to march to the banks of the Potomac and lay siege to the Department of HEW. Again, this solution is not practical. The bureaucrats also greatly outnumber us and I am sure that a siege would be against HEW's regulations. Besides, when southerners marched up in that area some years ago, they ran into a lot of hostility, especially in the vicinity of a place named Gettysburg.

In a more serious vein, we should be aware of and commend the activities of the American Hospital Association in its approach to the problems of bureaucratic over-regulation. The AHA has in recent years pressed to obtain adequate representation on code and standard writing bodies which affect hospitals and AHA member institutions are now said to have the opportunity to take responsive action with regard to both current and proposed health care standards. The AHA has started a research and data collection program to assess safety hazards and thus to identify the need for standards before one is actually developed.

Several states have initiated action more directly related to the federal regulatory process. For example, Kentucky has amended its regulatory statutes to prohibit conflicting federal and state standards and unnecessary and duplicative inspections by federal, state and local agencies. Clearly, more state action is needed.

At the federal level, the Administrative Rulemaking Reform Act (S-3297) aims to improve the production of regulations by federal agencies by increasing the opportunities for public participation, by congressional review of agency rules and by expanding judicial review.

It is to be hoped that these measures will help, but a paranoid surgeon must be very skeptical of their effectiveness. In the current War of the Regulation the federal establishment seems to be dedicated to bringing about total governmental control of health care in the United States and I greatly fear we are losing the war.

As has been emphasized in recent addresses by Director Rollins Hanlon and President Frank Stinchfield of the American College of Surgeons, surgery and surgeons are under attack by the federal establishment as part of the battle plan in this war. To paraphrase Rollins Hanlon, the insidious, mindless notion that surgical therapy, much of which is alleged to be unnecessary, is the major cause of rising health care costs must be exposed as the absurd fallacy that it is. Hanlon urges all surgeons to set the facts concerning proposed operations and other treatments lucidly and fully in front of patients so that they may participate intelligently with full information in the decision to proceed or not with a recommended course of treatment, especially elective surgical operation.

Frank Stinchfield has issued a clarion call to surgeons in all specialties to unite in the common cause of firmly opposing the attack on surgery currently being made by the federal establishment and the media.

Let all Fellows of the Southern Surgical Association respond to the leadership of our great College of Surgeons with vigorous support of the College and its programs! Let us carry factual information to our patients and address every available audience to countermand malicious propaganda! Let us form with the College a unified front against this War of the Regulation and this creeping socialism that would undermine freedom in our country and destroy the high quality of American surgery!