Taking Charge: How to Make a Difference

Shaping Public Policy

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Synopsis

Public policy is an area of increasing study. Of concern in this presentation is the consensus-building feature of policymaking in the United States. The role of government in following the procedures established to achieve consensus and the importance of citizen participation in this open process cannot be underestimated. The five central features of American consensus building are separation of powers, multiple levels of government, citizen participation, policymaker accountability, and individual freedoms. These features frame the efforts of those who shape the public policies that determine the ways laws are made and enforced and public funds are spent.

THE NATURE OF PUBLIC policy is a subject on which attention is being increasingly focused. Policy research centers, graduate study programs, and professional association divisions of policy are proliferating across the country, inside and out of the policy centers of this nation and its States. More and more talent is being directed to questions of policy and the nature of the policy process itself. The policy arena is under increasing scrutiny. Through telescopes and microscopes, those of us who examine the policy world are drawing conclusions about how it works, and when it does not, and how to make it better serve the American people.

I first began to describe this nation's policy process as a government official assigned to attend an international meeting of policymakers, theologians, philosophers, and scientists to explore the ways in which the religious values and cultural ethics of a nation affected the ways in which health policy was made. Amidst representatives of 44 nations, the major world religions, the major schools of philosophy, and medical scientists, my assigned task was to discuss the way health policy was made in the United States. As a policy official for a number of years, conference organizers reasoned that my task would be a simple description of what I did on the job. They were wrong. It was not simple. Getting lost in the complexity of which button to push and which string to pull was easy. Seeking simplicity in the policy process was not.

The assigned title was "Policymaking In America," and the social science perspective of my background provided me with many insights. I read the Declaration of Independence and the Constitution and observed the actions of my contemporaries in government, in associations, and as individuals in a new light. My observations impressed and awed me. I saw a process that I have come passionately to believe in and to promote; one that, in my opinion, truly capitalizes on the great strengths of this nation.

I subtitled the talk "The Process of Building Consensus" and made the presentation in Athens, Greece, in October 1984. The concept I proposed, namely, that public policy was a consensus-building process, framed the discussion of the conference and has been useful to others since then. It provides a framework for understanding public policy for those in the professions called into the health policy fray by virtue of technical, scientific, or administrative credentials and despite relative lack of political science or governance experience. It provides some reassurance to those skeptics who wonder whether government can work at all. To those who have not yet actively participated, it describes how simple and intuitive the process can be. It provides the hope that everyone can make a difference and the encouragement to do so.

Recently, my focus has shifted away from policymakers and toward policyshapers. Even in government I never sensed the omnipotence necessary to have been a policymaker and now, as a part of the policy arena outside of government, I have not seen any individual or group I could call a maker of

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policy. They all seem now to be more accurately called shapers. How do all these shapers work? What is the environment within which they exert such influence on the health of the nation? Who affects them? How do you affect them? In the first part of these remarks I will address the public policy environment and the essential features of the policy process. In the last part of my remarks I will encourage you to become a shaper of policy yourself.

The Policy Environment: American Society

It is obvious, but not at all trite, to say that the policy environment is American society itself. That society is richly heterogeneous. It accommodates a diversity of races, religions, and social groups. Policy matters that affect a society so diverse must reflect the variety of opinions and views that inevitably exist.

In a country of nearly one-quarter billion people who proudly call themselves individualists, it is pragmatic and deeply embedded in law and tradition that public policy is the result of a deliberative process of consensus building. Policy officials seek to provide the public with ample opportunity for comment before, during, and after their deliberations on matters of public concern. It is this process of expression and reexamination of divergent public views that ultimately allows consensus to develop. Consensus building is not only a principal feature of policy making in America—it is its essential strength.

Public deliberation is especially important in health policy. Americans care deeply about public decisions in health care, especially because these decisions relate to their lives with an immediacy that few other policy issues share. For health policy officials to ignore the public's views is to risk the ultimate failure of the policy, to ignore the nature of policy shaping itself, and to violate the public's trust.

It is not only the views of the American people, but the American health care system as well that are pluralistic. The public and private sectors each make contributions—from the levels of basic research to product development, from health care delivery to the financing of health care services. And so, the health policy process in the public and private sectors is frequently interdependent. Complex? I think not. Impossible to influence? I am certain it is not.

In this discussion, however, let's focus on health policy shaping as it concerns decision making regarding those functions that government performs within the domain of public health—namely, making laws, enforcing laws, interpreting laws, and expending public funds.

Policy Environment: American Governance

Since the founding of this nation, certain key features of public policy have merged over time through law and tradition. Each feature plays a critical role in the process of consensus building. These features are

- separation of powers,
- multiple levels of government,
- participation by citizens,
- accountability of policymakers,
- value of individual freedoms.

Separation of powers. The writers of the Constitution were deeply concerned with limiting the authority of government. Arising from concerns over what is described in the Declaration of Independence as the tyranny of a monarchy ruling its colonies from a great distance without concern for the good of the colonies, the founders of this nation created a type of union and governance which sought to prevent the tyranny of a central government and preserve individual freedom. What developed subsequently, through conscious design and by tradition, was the establishment of three independent branches of national government which were, by design, compelled to cooperate with each other—the objective being the restraint of power of any one branch.

The Legislative Branch (U.S. Congress) enacts laws, appropriates Federal money, and monitors the implementation of its laws by the Executive Branch. The Executive Branch (the President and his Cabinet) executes laws and expends funds. The Judicial Branch (the Supreme Court and lower Federal courts) interprets the laws in case review situations.

This separation of powers allows for a balance of the powers and encourages cooperation and accommodation. It encourages conflict as well; and when those inevitable conflicts arise, negotiations, bargaining, and compromise are the tools of resolution—the tools of consensus building.

Consensus building in legislation. The process of passage or defeat of a particular legislative proposal illustrates the interactions between branches of Government and the public. Bills are introduced by Members of Congress when sufficient public consensus raises the issue to that level of visibility. Thereafter, comment is solicited through public interest groups, professional organizations, and the public, as each presents its views on the proposed legislation, addressing the legislation from the perspective of its responsibilities, authorities, rights, and values. When disagreement emerges, as it inevitably does in a pluralistic society, consensus-building compromise is sought both during and after the hearings, and both in the halls of the Congress and elsewhere throughout the nation.

Through this process of negotiation and consensus building, the proposed legislation is modified. Since consensus is never achieved quickly, more hearings are held, more subtle disagreements are expressed, and there are even greater attempts at consensus. This is an essential feature of policymaking—namely, consensus building through an iterative process of hearings and deliberations in which views are expressed, examined, refined, reexpressed, and modified in order to permit some form of agreement well before the bill is in its final form for a vote by Members of Congress. In many cases, the complexities of the issues and the divergence of opinion prevent adequate consensus development, and so a bill rarely reaches the final stage of passage. In the small number of cases when a bill is successfully transformed into law, the average duration of debate in the Congress is 2 years. Debate among the people of the nation, however, may last for decades.

Case study: Legalization of heroin. The case of the bill to legalize heroin for the treatment of pain in terminal illness is representative of an attempt and failure at consensus. A consumer group known as the Committee for the Treatment of Intractable Pain brought the pain of dying cancer patients to the attention of the American public and the Congress after 10 years of painstaking effort. Consensus building was attempted through the hearing process and media appeals, but little consensus emerged either on the extent of the problem or on the nature of the appropriate solution. Some professional medical groups negated or minimized the view that large numbers of dying cancer patients were suffering needlessly; others, such as the U.S. Department of Health and Human Services and the American Medical Association, acknowledged the presence of the problem but sought to solve it by educating health professionals in the proper use of already existing pharamaceuticals. In a tactical error, the consumer group forced a vote in Congress in the absence of a consensus, and the bill was defeated.

Consensus building in administration. These principles apply to the Executive Branch agencies as they actively administer and enforce legislation through regulations, rules, and related activities. Internal public arena debates, hearings, public comment, and consensus are required. After a bill is passed and signed into law the appropriate Federal Agency develops an implementation plan that specifies how the requirements of the law will be administered. In that plan, the staff requirements, delegations of authority, grants programs, budget requirements, and regulations needed are detailed. Assignments are made to various staff offices and operating programs and the management of the Agency monitors progress towards the completion of the implementation plan. Rules specifying the nature of public involvement in the consensus-building activities of the Cabinet departments are specified in the Administrative Procedures Act.

Case study: alpha-fetoprotein testing. The Medical Device Amendments of the Food, Drug, and Cosmetic Act give the Food and Drug Administration (FDA) authority to regulate the marketing of medical devices, including certain diagnostic test kits. Based on evidence suggesting that neural tube defects in a fetus could be detected during pregnancy by measuring a certain protein in maternal serum, a test kit was developed and submitted to the FDA for premarketing approval. FDA initially sought to regulate the marketing of the kit by restricting its use to situations in which defined protocols were used and specialized personnel were available to conduct and interpret the test results. The Agency was concerned that false positive tests would lead to abortions.

The publication of the proposed rule raised additional issues. Physician groups viewed the requirements of the Agency as an intrusion into the patient-physician relationship. Physicians also argued that, even if in the absence of the defined protocols and specialized staff they neglected to provide the test to a woman who later gave birth to a child with neural tube defects, they could not be held immune from malpractice liabilities. Manufacturers argued that the requirements imposed unreasonable and unjustified restrictions and set a dangerous precedent. Antiabortion groups feared the abortion consequences of positive test results and a number of

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groups opposed the medical cost inflation impact of the requirements. Public health advocates knew the testing was being done in "home brew" laboratories with results of questionable quality and encouraged the marketing of the more reliable kit then under FDA review. The discussion among the various parties and between the agencies of the government spanned many years and two Administrations. Finally, in 1983, after 4 years of delay, the test kit was approved for marketing without the proposed protocol requirements.

Multiple levels of government. Authority in this nation is not only divided among branches of government, but among different levels of government—Federal, State, and local. The U.S. Constitution designates responsibilities to the national government and gives all other functions to the States. Each of the 50 States of the United States, in turn, has its own constitution, which similarly describes the specific duties and obligations of its respective government. Finally, many cities, counties, and smaller public subdivisions have sets of rules. Individually and collectively, these constitutions serve as the written codes on how and by whom public matters are decided.

These constitutions build complex interrelationships between the different branches and levels of government (Federal, State, and local). As a result, the requirement of consensus building among policymakers is not restricted to the incorporation of the general public's views; policymakers must also build consensus within and between the multiple layers of government in order to effect change.

Within the domain of public health, there has been a historical separation of State and Federal responsibilities, although there are some areas of overlap. The State governments traditionally have been responsible for the delivery of public health programs, including the licensing of health professionals, enactment of laws for regulating the health insurance industry, care of the mentally ill, and the shared financing of health care for the poor. The Federal Government's responsibilities have been in biomedical research and training; food and drug safety; allocation of health professionals in, and delivery of services to, medically underserved areas; and financing of health care for the aged and disabled.

Case study: compulsory immunization. A good example of how State and Federal agencies can perform complementary roles is found in the evolution of the widespread and compulsory use of vaccines of the United States. This was not an easy task in the mid-1900s. Questions surrounded the right of the State to require an individual to accept medical invasion of his or her person for the common good. Furthermore, there were scientific, legal, and ethical concerns about the safety of the vaccines. In fact, as late as the mid-1930s, 4 States had laws prohibiting compulsory vaccination; 28 States had no vaccination laws; 6 States provided for local option; and 10 States had compulsory vaccination laws.

Beginning in 1955, the Federal Government, working within constitutional tradition, orchestrated a national campaign to convince States of the value of requiring vaccination of children before school entrance. This was done largely through the Federal initiative of educating the public about the importance of vaccination and by providing financial assistance to help States and local communities buy and administer the Salk poliomyelitis vaccine. Later in the 1960s, a more comprehensive program of Federal assistance was developed, addressing the whole range of vaccination needs, including funding and the assignment by the Federal Government of individuals to the State agency that administers the program. Today, every State has laws denying school entrance to children who are not immunized against several diseases: diphtheria, measles, mumps, pertussis, poliomyelitis, rubella, and tetanus. The result has been very high national immunization rates. In the 1981-82 school year, for example, the immunization rates for children at school entry were more than 95 percent for measles, rubella, polio, and DPT (diphtheria, pertussis, and tetanus), and more than 90 percent for mumps.

Participation by citizens. The most fundamental form of citizen participation in policymaking is in the selection of policy shapers: the President, the Members of Congress, and the State and local officials. But participation does not stop there. It is encouraged not only in the selection of policymakers, but also throughout their tenure. This happens in a

variety of ways, but especially through correspondence, testimony at public hearings, and personal contacts, especially during visits to home districts.

We encourage participation in the affairs of government by calling it a right and making it one of our most fundamental of responsibilities. Children are taught in the earliest school years about national affairs and the participatory process of governance; children are encouraged to practice participatory skills in student government organizations; and communities routinely recognize citizens with exemplary records of participation in policy and programs.

We encourage the citizen participation of individuals and also of groups. Organizations whose memberships are structured along professional and interest boundaries serve their memberships by acting as representatives of those collective interests before the Congress and the Administration. Within the area of public health alone, for example, there are hundreds of professional organizations representing many different groups of health professionals and interests. This participation is important—even vital.

Case study: orphan drugs. The Federal Government had recognized since the early 1970s that some drugs were orphans, that is, they were of such limited commercial value that no drug manufacturer could afford the investment necessary to research and develop them through the Food and Drug Administration's approval stages. The Department of Health and Human Services made some efforts to resolve the problem and gave some thought as to how best to provide a home for those orphans. It was only after the assertive, tireless, and persistent efforts of patients with rare diseases, their families, and their physicians had been effective that concrete action took place. Led by Abbey Meyers, a homemaker from Connecticut, the groups organized and the Government heard of the plight of those suffering with rare diseases. Using the limited resources available to them, members of these groups walked the halls of Congress and, despite the Administration's objections, secured the passage of the legislation. Grants, programs, coordination offices, recognition awards, and a study commission have resulted from their work. They have established the legitimacy of their claim to research resources. Most important, they have succeeded in meeting their initial goal, as proved by the large numbers of orphan drugs that are becoming available.

Accountability of policymakers. Accountability is the *sine qua non* of each branch and level of government. The Executive Branch has internal controls and is accountable to the Congress. The Congress, too, has its internal controls and is accountable to its public constituents. The Supreme Court and the whole of the Judiciary, while the least accountable, are not immune from public scrutiny and action, as recent impeachments and the scrutiny of new nominees have shown.

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An example of how accountability can succeed in causing modification of existing law occurred in the implementation of the End-Stage Renal Disease Program. Public accountability procedures brought to light the incentives in the law that encouraged more expensive forms of treatment for those who might be treated just as effectively but more cheaply at home. Consequently, the law was modified to allow for reimbursement of kidney dialysis procedures at home.

Value of individual freedom. The right to personal liberty is guaranteed in the First Amendment to the U.S. Constitution. It is this right that protects the expression of diverse views among participants in the process of consensus building that shapes policy.

Societal problems ensue when personal liberty conflicts with the consensus of the whole. When the rights or liberties of one group are sought, restrictions for others sometimes result. It is generally accepted that some individual liberties should be traded for the good of the whole, but even so, we Americans view even government protections as tyranny when they are absolute. And so, we allow individual exemptions, usually based on religious or conscientious belief, when the individual is compelled to obey a law which intrudes on individual freedom. We see this in public health: the individual is compelled to receive immunizations for the good of the public but the individual is protected from the tyranny of that intrusion if immunization violates his religious beliefs.

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Public Policy: Science, Art, and Sport

So much for the theory of public policy. Let us turn now to the science, art, and sport of public policy. To participate in public policy at all, as an individual citizen or as a group of citizens such as in professional associations, requires an agenda and the practical skills to address that agenda with policy shapers, program decisionmakers, and the public-at-large.

The agenda proceeds from the self-interest of the individual or group, which regardless of the nature of the agenda, is necessary to the process of producing the best in self-governance which we Americans try so hard to achieve and work so fiercely to protect.

The skills to address that agenda are numerous, but they are essentially four:

First, presence. Decisions in the public policy arena are being made every day across this nation and in its Capitol. They are being made whether or not you or your interest is there: To be absent is to abdicate your rights and your responsibilities as well.

Second, accessibility. Public policy can move as slowly as a turtle in molasses or it can race with the wind. When policy officials need information, advice, and your views, your accessibility is critical.

Third, constructive and realistic suggestions. Problems are many and the need for suggestions which address solutions constructively is great. Simply identifying problems, which groups are sometimes wont to do, or continually criticizing actions does not advance the search for consensus. Further, realize that a central role of government is allocating resources, that there are demands competing with those you want and need, and that you will not always win—either the battles or the wars.

Fourth, credibility. As you place yourself in the public policy arena as a participant, your knowledge and integrity must not be in question. As a participant in policy, whether as a public official or not, you are subject to the scrutiny of the public and will be held accountable for misadventures and violations of the public's trust.

But enough of the high road. There is a low road as well: you must know the formal workings of the committees and agencies you seek to influence. You must know their structures, budgets, objectives, authorities, and staff. You must participate in the meetings, discussions, hearings, and correspondences. You must also know their informal workings. You must know who the decision makers are and where best a given decision should be made. You must go out of your way to supply data, present your case (and others, too), and be scrupulously honest. You must invest in the long term, even with short-term political appointees, and above all you must recognize the etiquette of human relations and the importance of communication.

With that high road and low road now—hit the road. Participate. The future demands that you do. The process expects that you will.

The consensus building process of public policy in general and of health policy in particular reflects traditions in this nation. It allows for participation of citizens and demands accountability of policy shapers—that is, all of us. In the context of a pluralistic society which accounts for individual freedoms, each—the citizen and policy shaper—has responsibility to participate and to "play fair" and by the rules of the process as they have come to be so well-defined and ingrained in our national style. To do less as a professional is to abdicate not only our responsibilities, but our rights. To do less as a policy shaper is to abdicate not only your only responsibilities, but to violate the public trust and stewardship of the governance of which we are so much a part.

When I came to Washington as a political appointee, a wise person told me, "Coming to Washington will open your eyes—and staying there will close them."

Unless you bring your perspectives into this policy shaping town and actively and substantively participate, then the eyes of many will close to the needs of all, and the nation will not have what it expects and deserves.