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## Genetic Services Policy Project Final Report

### **Appendix B: Analysis of GINA Through the Advocacy Coalition Framework**

The Genetic Information Nondiscrimination Act of 2007 (GINA) would have seemed to be legislation with no impediment to passage in the 110<sup>th</sup> Congress. Previous versions of GINA had passed the Senate by big margins in 2003 (108<sup>th</sup> Congress) and 2005 (109<sup>th</sup> Congress). President Bush had been favorable to passage and had indicated that he would sign the legislation into law.

The House of Representatives passed GINA in February 2007 by a wide margin. The House version of GINA, sponsored by Representative Louise Slaughter (D-NY), had been blocked in previous years by the Republican leadership that controlled the House. Democratic control of the House following the 2006 midterm Congressional election s cleared the way for house passage and – or so it seemed – quick passage in the Senate.

And yet as of the spring of 2008, GINA had not come to a vote in the Senate and there was no apparent prospect of a Senate vote on GINA in the near future. Indeed, there seemed a substantial likelihood that the 110<sup>th</sup> Congress would adjourn without the Senate having taken up this legislation that it had passed twice before by wide margins, and that – this time – the House *had* acted upon. When the 2007 version of GINA had been enacted by the House and sent on to the Senate for consideration it was subjected to a “hold” by Senator Tom Coburn (R-OK), and Coburn’s objections (based on objections to GINA raised by business interests and the U.S. Chamber of Congress) seemed to be irresolvable.

Then, in early April, 2008, there began to be indications that after a year with no visible activity, behind-the-scenes negotiation by a very persistent Senator Ted Kennedy (D-MA) – with the constant support of pro-GINA interests led by the Center for Responsible Genetics and the Genetic Alliance – was leading to a compromise that would move GINA to a vote in the Senate. On April 24<sup>th</sup> the Senate passed a modified version of GINA by a vote of 95-0. On May 1<sup>st</sup> the House passed the Senate version of GINA by a vote of 414-1, and the legislation was signed into law by President’s Bush on May 21, 2008.

Why GINA was floundering in the 110<sup>th</sup> Congress bears examination as a case study of national policy-making, a study of the manner in which interest groups affect policymaking, and a study of the agenda-setting that occurs at the federal policy-making level. In particular, GINA as a case study illustrates the value of Paul Sabatier’s Advocacy Coalition Framework as a shorthand method for understanding the policy process.

#### **An Introduction**

For citizens to have meaningful participation in the US political economy, they must find ways to act and speak collectively. Interest groups represent the freedom to join together with others to make political contributions and demands. These groups must impact the politicians and bureaucrats who serve as our policymakers, within the structure of our governing institutions.

Two concepts have come to describe our governing institutions and the intersecting activities of interest groups: political subsystems and issue networks.

The concept of the political subsystem is recognition that much of our policy-making takes place at levels below the three classical branches of American government, predominately at the administrative level. Surrounding the activities of this administrative state are issue networks, loose structures involving various bureaucrats, interested academics and professionals, and interest group representatives, all with a mutual interest in matters of policy-making within the subsystem.

As agenda-setting raises issues to the level of policy-making probability, these interested parties and interest group representatives form advocacy coalitions to stake claim to influence on the politics and policies at issue. Political and policy entrepreneurs also respond in such agenda-setting moments, to try and stake claims of influence on the policies at issue.

### **The Genetic Information Non-Discrimination Act of 2007**

There has been concern over issues of “genetic privacy” (protection against the misuse of genetic information by employers and health insurers) for over twenty-five years (Hudson, 2007). Some states enacted statutes in the 1970s that prohibited discrimination in health insurance underwriting based upon positive sickle cell and other genetic traits. Interest in these issues increased dramatically when Congress funded the commencement of the Human Genome Project in 1990. The first consideration of federal legislation – the 1990 Human Genome Privacy Act – was directly tied to the beginning of the Project. With the conception of the Human Genome Project, efforts were led by the Center for Responsible Genetics, based in Cambridge, Massachusetts, to get state legislation enacted that would prohibit the use of genetic information to deny healthy individuals insurance or employment. Broad legislation was passed in California, but vetoed by Governor Pete Wilson, who expressed concern for adverse effects on employers providing employee health insurance. Broad state legislation was adopted in Oregon, and went into effect in 1995, but even with regard to that legislation the potential for adverse employment and health insurance actions remained.

As scientific research continued throughout the 1990s leading to the completion (in 2001) of the mapping of the genome, debate continued over concerns that the ultimate predictive medical advances to be gained by the Human Genome Project would pale by comparison to the negative impacts of the use of genetic information by employers and health insurance underwriters. Some commentators pointed out that state legislation regarding health insurance underwriting would not apply to self-insured employers because of the preemption provisions of the federal ERISA statutes, and that protection under the Americans with Disabilities Act is incomplete (absent “subterfuge,” selective insurance underwriting is not prohibited discrimination).

After the collapse of the Clinton health reform efforts in 1993, and the shift to Republican control of the House of Representatives in the 1994 election, the 1995/1996 congressional term saw the introduction of new health (and genetic) privacy legislation. Four pieces of legislation introduced that session addressed issues of genetic privacy and discrimination, and the issue was addressed during committee hearings on the Health Insurance Reform Act of 1995, introduced by Senator Nancy Kassebaum (R-KS).

This last development is significant, because the Health Insurance Reform Act of 1995 was a major component of what became the Kassebaum-Kennedy Health Insurance Reform Act of 1996, ultimately adopted as the Health Insurance Portability and Accountability Act of 1996 (HIPAA). While the major purposes of HIPAA were to “reform” the small group and individual health insurance markets nationwide, this effort mostly has been unsuccessful in that policy-making sense. The most far-reaching effects of HIPAA have come from Title IV of the Act, which established the regulatory procedure and authority for the Department of Health and Human Services to adopt what became The Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”) *if* Congress did not adopt medical privacy legislation within three years of HIPAA’s enactment on August 21, 1996.

Congress did not do so, and so during the Clinton administration, HHS proposed a Privacy Rule and released it for public comment on November 1999. The Department received over 52,000 public comments and adopted a final rule published (effective) December 28, 2000. In March 2002, under the Bush administration, HHS proposed and released for comment modifications and a proposed, new “final” Privacy Rule, and received over 11,000 public comments. The new version of the Privacy Rule was published August 14, 2002, and became the Privacy Rule effective for regulatory purposes.

In its report on the Health Insurance Reform Act of 1995 (the original Kassebaum bill) the Senate Committee on Labor and Human Resources clearly noted that for policy reasons, “health status” and “medical history” covered by the act should be read broadly to include genetic information. As such, the rule-making process that led to the Privacy Rule could have – in classic subsystem operation – resolved many of the concerns regarding genetic privacy. Ultimately, this did not happen. The Privacy Rule as adopted, after an extensive comment process, excludes a group health plan with less than 50 participants administered solely by an employer, but more importantly it excludes from protected health information “employment records that a covered entity maintains in its capacity as an employer.”

While the rules could have been drafted to address broader health insurance and employment privacy and discrimination concerns, they ultimately were not. This circumstance led directly to the introduction by Representative Slaughter (D-NY) and Senator Snowe (R-ME) of the Genetic Information Non-Discrimination Acts of 2003, 2005 and 2007. Further analysis of these events demonstrates how advocacy coalitions attempted to work within the political subsystem on both sides of the issue to influence the ultimate policy outcomes in the HIPAA Privacy Rule, and how in the aftermath, genetic privacy advocates have found policy entrepreneurs to serve as their allies in an attempt to resolve these issues at the macro-policy level.

### **GINA and the Politics of the Policy-Making Process**

In April of 2007, immediately following House passage, Senator Kennedy issued a report on the Genetic Information Nondiscrimination Act of 2007 as Chairman of the Senate Committee on Health, Education, Labor and Pensions (the HELP Committee). This extensive report tracked the origins and history of this legislation from the early 1990s forward.

The report identified the purpose of GINA as:

The purpose of this legislation is to protect individuals from discrimination in health insurance and employment on the basis of genetic information. Establishing these protections will allay concerns about the potential for discrimination and encourage individuals to participate in genetic research and to take advantage of genetic testing, new technologies, and new therapies. The legislation will provide substantive protections to those individuals who may suffer from actual genetic discrimination now and in the future. These steps are essential to fulfilling the promise of the human genome project.

As to health insurance, GINA would prohibit discrimination in health insurance in employer-sponsored group plans, health insurers in the group and individual policy markets, Medigap and state and local (non-Federal) government health plans. GINA would increase existing (ERISA) protections and supplement other protections to restrict the use of genetic information obtained by insurers in processing reimbursement. GINA would further prohibit insurers from requiring genetic testing and would restrict the use of genetic information in insurance underwriting.

As to employment GINA prohibits the use of genetic information in employment decisions by employers, unions, employment agencies and training programs. If an employer obtains genetic information it shall be considered confidential and treated by the employer as such.

These protections, the Kennedy Report notes, are about perception as much as reality; there is no real documentation of discrimination in insurance or employment, rather the “expressed belief” is documented in a series of surveys that insurers and employers *will* discriminate if they gain possession of genetic information. Some legal protections currently exist, but there are gaps in federal legislation and in the availability of existing state protections.

The HELP Committee of the Senate has been conducting hearings on genetic nondiscrimination since 1995. In 1996, as part of the passage of HIPAA the Senate prohibited discrimination against any individual enrolled in a group health plan because of health status, including health status based on genetic information.

HIPAA did not directly address medical privacy; the legislation provided that HHS must issue regulations on comprehensive medical privacy if Congress did not pass comprehensive medical privacy legislation by August 21, 1999. Congress did not do so, although the Senate HELP Committee continued to hold hearings on genetic discrimination in health insurance and employment. After the adoption of the HIPAA Medical Privacy regulations by HHS, the HELP Committee and the Senate as a whole have considered genetic nondiscrimination legislation which is broader in application than the HHS regulations, as noted in earlier discussion of the Genetic Information Nondiscrimination Act of 2007.

### **Policy-Making Theory**

Several academics (Salisbury (1992); Berry (1997); Browne (1998)) have observed that the activities of interest groups, and their impact on federal policy-making, began to shift significantly in the 1980s. Correspondingly, the actions of members of Congress and of the administrative bureaucracy have shifted significantly as well. Coalitions are much more

important than prior to the 1980s. In illustrating modern policy-making, the Advocacy Coalition Framework (ACF) is a very productive tool.

Over twenty years ago, political theorist Terry Moe posed what he viewed as a central question in American political analysis: how do you construct a proper theory of political organization and structural choice in the context of political uncertainty? As he noted, the problems are many and the task is complex. Most critically, we must attempt to explain policy change and learning through examination of the reality of political organization and structural choices (Moe, 1980).

Also twenty years ago, Paul Sabatier first described the theoretical structure he labeled the Advocacy Coalition Framework (ACF). There have been other theories of the policy process proposed and developed over the same twenty year period; policy theorizing of this type has blossomed. But through the evolution of thinking about the ACF, Sabatier and others – most notably Sabatier’s partner Hank Jenkins-Smith – have developed one analytical tool to use in answering Moe’s central questions (Sabatier, 1993; Sabatier and Jenkins-Smith, 1993; Sabatier, 1999; Sabatier and Jenkins-Smith, 1999).

### **Policy Change in the ACF**

Sabatier has a central purpose of his own in developing a theory of the policy process: “The process of policymaking includes the manner in which problems get conceptualized and brought to government for solution; governmental institutions formulate alternatives and select policy solutions; and those solutions get implemented, evaluated and revised ... Given the staggering complexity of the policy process, the analyst *must* find some way of simplifying the situation in order to have any chance of understanding it.” And so, he argues, we have a need for theories of the policy process – ways of simplifying the manner in which we look at the process of policy-making in order to better understand it.

Since the original 1988 article in which Sabatier proposed the ACF, he and Jenkins-Smith have continued to develop this “theoretical lens on public policy,” revising it every “six years or so (1993, 1999, 2006).” The ACF views the central element of policy analysis to be the examination of “policy change,” the evolution of policy-making over time. This encompasses the “formulation, implementation and reformulation of policies through the process of “policy-oriented learning. “

The locus is actors in the policy subsystem, dealing with a policy issue over a period of a decade or more. These policy actors form the advocacy coalitions that are at the center of the framework. Each coalition has a central, shared belief system, a “set of basic values, causal assumptions, and problem perceptions”, and each coalition, based upon this shared belief system, shows a “degree of coordinated activity over time.”

The primary task is to “identify the conditions under which a productive analytical debate between members of *different* advocacy coalitions is likely to occur.” This examination focuses upon three variables: 1) the level of conflict over an issue 2) the “analytical tractability” of the issue and 3) the nature of the subsystem itself.

Recognition of the stability of core belief systems and the centrality of these belief systems to policy actors is also a critical element of the ACF.

### **Policy Subsystems and the ACF**

The ACF focuses analysis first on the institutional setting for action: the policy subsystem. Focusing on this setting helps explain changes in beliefs and policies among actors, as well as the manner in which actions are “shaped and constrained” by larger governing systems in which political subsystems are placed.

A useful way of looking at governing systems is in terms of macro-policy or “high politics” systems, below which are policy or micro-policy subsystems. Major decisions that may change the political power structure in a major policy area are macro-policy decisions which the ACF has labeled external system events. These decisions often result from an inability to resolve policy issues at a lower level.

Micro-policy systems are “relatively hidden” policy systems where government policies of limited public interest, often in areas of technical complexity, arise. At this level are networks of policy actors and decentralized power structures. Communications are informal, but frequent among subsystem actors, which include interest group representatives, government officials and their staff, bureau and agency personnel, non-governmental policy specialists, and interested media members.

These policy subsystems are a form of “functional representation,” and policies of regulation or redistribution that can be resolved without resort to new macro-political legislation are addressed at this level. It is at this level that interest group conflict – through the actions of advocacy coalitions – most frequently manifests itself. A subsystem can be “dominant,” that is controlled by a small number of actors with significant influence and control over policy outcomes, with stable relations among policy actors. Alternatively a subsystem can be “competitive,” with coalitions in constant competition for control.

Recent work by political scientists of the historical institutionalism school is consistent with this aspect of the methodology of the ACF. Kathleen Thelen (1992) and Margaret Weir (1992) have argued respectively that “institutions evolve (with) shifts in the political coalitions on which they rest to inspire or compel changes – sometimes abrupt and discontinuous but more often incremental and cumulative,” and that historical attention is needed to “the organizational substructure of politics, particularly to processes of issue definition and coalition building among nonelite actors.”

These observations are particularly apt given Moe’s work on political uncertainty and structural choice. The most significant issue, Moe would argue, is “not simply to get the policies and structures (an interest group) wants in the current period, but also to design them in such a way that they have the capacity to survive and prosper in an uncertain political future.”

### **The Organizational Politics of Actors, Interest Groups and Coalitions**

Actors within policy subsystems often have multiple functions, operating as actors with political expertise and beliefs, as representatives of interest groups or other identifiable organizations

operating within the subsystem and acting as advocacy coalition members. In these capacities actors seek to influence policy, to avoid political uncertainty – or at least to cope with it – and to influence structural choices. All of these functions are influenced, in ACF theory, by each actor’s belief systems, and by the organizational and interest group dynamics that are tied to the formation of advocacy coalitions.

In the American system of politics, collective opposition to change is easiest to organize and advance. Action to effectuate change is much more problematic; it requires agreement on purpose, goals and tactics. As each of these elements becomes more specifically focused, more energy and resources have to be expended in agreement on a common purpose and a course of collective action. For instance, contrast the concerted efforts in opposition to the Clinton administration’s 1993 attempts at health reform (see Chapter 5 of Theda Skocpol’s *Boomerang: Health Care Reform and the Turn Against Government* (1997)) with the several decades of effort by earlier reformers that led finally to the 1965 adoption of Medicare (see Chapters 1-5 of Theodore Marmor’s *The Politics of Medicare* (2000)).

As the ACF has evolved, there have been attempts to address these collective action problems. According to ACF theory, collective action is enhanced by sharing the expense of a common effort to effectuate change (the “transaction costs”), and a common enemy tends to create allies. Policy change is much easier to resist or deflect than to accomplish. Regulation is more easily effected than re-distribution, and “self-contained” regulation (such as legislation of prohibition) is more easily effectuated than regulation by bureaucratic activity over time. A certain amount of political uncertainty can be removed through “self-contained” regulation, as it tends to set into place what might be called “political property rights.”

### **The Input of Policy Entrepreneurs**

Policy Entrepreneurs (PEs) are policy actors that propel political and policy changes. They transform existing coalitions and add new dimensions to policy debates in the effort to effect policy change. In many instances this function will be served members of Congress who decide to take on “national” issues, issues with a scope that extends well beyond the interests of their immediate constituency. In national policy-making it is not necessary to be in Congress to serve as a policy entrepreneur, but members of Congress are uniquely positioned to take on these tasks.

These efforts are critical in defining ideas and moving them through the policy process, looking for opportunities to effect positive policy change and seizing these opportunities when presented. PEs “frame” an issue to move it to the proper level of attention in policy-making institutions together with the interest groups that they mobilize or with which they ally. They interject “new dimensions of evaluation” into otherwise conservative policy institutions through what Schattschneider (1960) first labeled “conflict expansion.”

For conflict to “expand” to the level necessary for policy change to occur, “new definitions” of policy problems and solutions must be interjected into the policy process. New interests will be activated to participate in the policy process as the conflict over the need for policy change “expands.” In cases where subsystem control of an issue serves to inhibit policy change, PEs redefine the issue to de-stabilize subsystem control. Redefinition serves the purpose of reframing issues in familiar terms and values such as “privacy” or “nondiscriminatory” or “equitable.”

The ACF focuses much of its attention at subsystem levels of policy-making in order to provide an analytical framework that can view policy change as a product of a process that occurs over as much as a decade or more. At the same time, the ACF recognizes that policy change happens for a reason, not for its own sake. Either the activities occurring within a political subsystem gradually reflect a recognition that policies need to be changed or at least adjusted (policy learning), some significant “shock” external to the subsystem literally forces change to occur, a shock “internal” to the subsystem precipitates change through the disruption of control by a dominant coalition, or the actors within a subsystem negotiate change.

One other circumstance can cause policy change to take place: the inability of subsystem actors to effect necessary changes leads policy entrepreneurs to seek change at another level of policy-making.

When we examine the case of the Genetic Information Non-Discrimination Act, we will see an example of a perceived need for change that advocacy coalitions could not resolve at the policy subsystem (in this case administrative agency) level. This being the case, the contest over policy change has moved to Congress, in part because change has been effectuated in no other way.

### **The ACF and Interest-Group Theory**

Consideration of policy-making is helped by an understanding of two additional concepts: interest-group theory and agenda-setting. Questions have been raised about the “assumption” implicit in the ACF that collective action by members of an advocacy coalition is a given. Interest – group theory will help resolve these collective action concerns, and also help provide a link to an understanding of the nature of agenda-setting.

A connection has been formed between the study of interest groups and the ACF in the work of Andrew McFarland. McFarland’s work on the political process theory of interest groups in a pluralist system has been developed over almost forty years (1969 to present), finding its most thorough exposition in his 2004 book *Neopluralism, the Evolution of Political Process Theory*. As noted in *Neopluralism*, while a great deal of work has been done in the study of interest groups, the classic focus has been on why individuals join groups and how groups maintain an organizational structure. McFarland notes that Baumgartner and Leetch, in their 1998 book *Basic Interests: the Importance of Groups in Politics and Political Science*, argued that more theoretical work should be directed to the study of the “role of interest groups in the policy process.”

For twenty years, McFarland has argued that the best way to understand the role of interest groups in the public policy process is through the application of the theory of triadic power. Under this theory – adapted from the work of James Q. Wilson (1973) – the government policy process takes place in specific policy areas. Economic producers (P) organize to lobby for rents in their area of economic production. Countervailing interests (CV) organize to compete with and oppose the interests of P. Administrative agencies with greater or lesser autonomy (AA) control much of the policy process in each area of production, and the unit formed by these three interests creates a “power triad” in the area of production.

McFarland's theoretical work has evolved from and expanded on the concept of triadic power, which is still at the core of his work; added to this are the concepts of routine politics and high politics, and the idea that the focus of the policy subsystem "cycles" from one to the other. Routine politics is the normal, day-to-day decision-making and administration within a policy area. High politics is the political process of policy or administrative structural change.

McFarland's concept of interest-group cycles is adapted from Schlesinger's thinking in *The Cycles of American History* (1986). McFarland's basic argument is that the actions of interest groups, in addressing specific issue areas, go through cyclical phases. In periods of routine politics producer groups are commonly in control, leading to periods of excessive control and leading to popular discontent. This is followed by a transition period during which countervailing power groups coalesce, followed by a period of high politics in a reform cycle. During reform cycles countervailing power groups and autonomous government agencies respond with corrective policy-making, after which another transition phase occurs in which matters recede from the public agenda, producers maintain their constant efforts for control and another era of producer dominance follows before the cycle revolves again.

In *Neopluralism*, McFarland brings his study of interest group participation in the policy process to fruition. In doing so, he finds the ACF to be the most useful theory for purposes of studying how interest groups participate in, and influence, the policy process. Political process theory, McFarland argues, should address three questions. Who has the power here? How is policy made in this area? What are the activities of interest groups in this area? The answers, he argues, are best arrived at by recognizing the power of an analysis using the triadic concepts, agenda-setting as seen through the interest-group cycle theory, and the tools of the ACF.

In applying the ACF to interest groups, McFarland first observes that the ACF acknowledges the utility of Hugh Hecho's (1978) concept of issue networks which McFarland refocuses as "policy networks." A policy network is an ad hoc communication network of interest group participants, bureaucrats, public officials, academics and interested media members interested in a common set of policy areas. Secondly, from within a policy network, and remaining relatively stable over a long term, are advocacy coalitions. These operate to influence the processes within policy subsystems. The common beliefs that hold advocacy coalitions together are not only material interests as Sabatier and Jenkins-Smith had noted (and McFarland reinforces), but extend to core social and political values as well.

### **Agenda-Setting, Interest Groups and the ACF**

Interest-group cycles theory is a theory of political agendas. One of the driving forces in agenda-setting as it affects interest groups is the impact of political cycles on the content and timing of policy agendas. John Kingdon's influential theories of agenda-setting utilize a policy network concept as well, labeling these networks "policy communities." In Kingdon's work (1995), the existence and activities of these policy communities becomes critical to problem recognition, problem definition, the generation of policy proposals, and the selection of policy alternatives. The ultimate question becomes, is there a problem that needs a solution?

Conceptually, McFarland notes, this is consistent with ACF theory. The evolution of the perspectives of members of a policy network or community is, Kingdom recognizes, one of three

major contributors to the setting of governmental policy-making agendas, along with significant, or triggering” public events that accelerate problem recognition, and the effects of political events and processes.

Some policy communities, Kingdon observes, are close knit and some are more fragmented. A close-knit policy community shares a commonality of outlook, orientation, vision; a fragmented community tends to be relatively unstable and lack a shared sense of structure. Close-knit policy communities have a greater impact on the policy agenda, and fragmented communities less so. But surrounding each “area of policy concern” (Kingdon’s description) – the policy subsystem, where policy problems emerge and are matched with alternative policy solutions – such a community exists. And in turn, as problems emerge and rise higher on the public agenda, the impact of the interested policy community on resulting policy outcomes becomes more significant.

Kingdon poses a straightforward question: How does the list of potential alternatives for public policy choices get narrowed to the ones that actually receive serious consideration? There are, he says, two classes of answers: alternatives come to life and evolve in what he calls the “policy stream” (again, analogous to the policy subsystem), and it is policy specialists that work within a particular “policy area” (again, a subsystem) that are engaged in the narrowing process.

Kingdon describes three agenda-setting and alternative-selection processes through which policy-making will occur: “the inexorable march of problems pressing on the system,” “the gradual accumulation of knowledge and perspectives among the specialists in a given policy area,” and “political processes.” The second of these processes would originate in a policy subsystem. Policy-making through the other two processes would originate at the levels earlier described as macro-political. At all three levels McFarland’s cycles of excess and reform, routine and high politics, will occur.

When Congress is involved in the policy-making process some additional agenda-setting elements will apply as well, including some elemental agenda differences in the Senate and the House. These will become relevant to the analysis in due course.

### **Agenda-Setting in the U.S. Senate**

One of the early, pre-eminent observers of interest groups was Jack Walker (See “The Origin and Maintenance of Interest Groups in America,” *American Political Science Review* 77: 390-406 (1983). In his 1977 article, “Setting the Agenda in the U.S. Senate: A Theory of Problem Selection” he addressed the significant restrictions on the opportunities for members of the US Senate to move individual agenda interests. These opportunities are restricted by a variety of factors:

The Senate's capacity to shape its own agenda is increasing, but members are still able to exercise little discretion over the scheduling of items for debate. Much of the business transacted by the Senate is either mandated by the Constitution or required for the maintenance of the vast federal establishment. Each year a budget must be assembled, innumerable amendments made to existing statutes, and presidential appointees confirmed or rejected. In addition, the daily schedules of

individual Senators are jammed with activities – subcommittee hearings, talks with constituents, lobbyists or reporters, roll calls on the Senate floor, consultations with staff members – that originate with other people and are virtually unavoidable. Little time and energy remain for reflection or the promotion of new legislative departures (Walker, 2007).

In addition, Walker points to what he labels “sporadically recurring problems” – issues that must be addressed because of prior legislation (typically reauthorization items) or administrative oversight. The Senate, Walker observes, tends to respond even more than the House to the exigencies of the moment, leaving little opportunity to address the type of priority that GINA represents: establishment of broad policy statement, particularly in the absence of a perceived crisis. Walker has posited three “features or conditions,” the presence of which would tend to significantly increase the probability of a legislative item successfully appearing on the Senate’s discretionary agenda: actual (not theoretical) impact on large numbers of people, convincing evidence that a serious problem will be addressed (again, actual not theoretical) and an easily understood solution exists, has been identified and is being adopted.

If all three of these desirable characteristics are clearly present, the likelihood increases significantly that the matter will get space on the Senate’s agenda, though this is by no means guaranteed. Matters not meeting all of the observed elements have virtually no chance. Senator Kennedy’s report, discussed earlier, virtually establishes the failure of GINA to meet Walker’s observed agenda-setting standards: the problem that GINA was designed to address was prospective and theoretical, not representative of a clear and present necessity.

### **Looking at GINA with a Theoretical Lens**

The Council for Responsible Genetics is a genetic professionals group formed 25 years ago to “foster public debate about the social, ethical and environmental implications of genetic technologies.” As such, it is an advocacy coalition with a set of beliefs generally consistent with efforts to “work through the media and concerned citizens to distribute accurate information and represent the public interest on emerging issues in biotechnology.”

A major player within the Council for Responsible Genetics, and in seeking passage of GINA, was the Genetic Alliance. In describing itself, the Genetic Alliance says that it is “a coalition of more than 600 advocacy organizations serving 25 million people affected by 1000 conditions.” The existence of the Genetic Alliance is premised on the legitimacy of the coalition perspectives discussed thus far. Founded 20 years ago, the Genetic Alliance was intended to facilitate the formal linkage of what has grown to over 600 organizations, each of which constitutes an interest group dedicated to building the capacity of these organizations to address issues of concern to “the genetics community.”

Many of the advocacy organizations that had joined the Genetic Alliance had been formed to link together people with a personal interest in defined genetic diseases that - while devastating in their effects on sufferers – impact very limited portions of the US population. By themselves these groups had limited resources and found it virtually impossible to impact broad public policies. But 20 years ago the organizers of the Genetic Alliance could see the potential for

significant developments in genetic research, and the attendant emergence of a wide array of policy issues that would be of significance to each of these smaller advocacy groups.

The Genetic Alliance openly avows “leveraging the voices of its members in formal communication with governmental officials and agencies” and the “application of organizational network theory” in advancing the interests of its member advocacy organizations. The Genetic Alliance is literally an advocacy coalition as defined by Sabatier, organized around a central, shared belief system. The Alliance has enumerated this shared belief system, in its mission statement, its statement of its central philosophy and consistently in its position statements over the course of its history.

Both of these coalitions joined in an open fight against what they labeled “genetic discrimination.” What is “genetic discrimination” as these coalitions have defined it in this policy dialogue? An employer’s use of genetic information to make hiring and firing decisions would be genetic discrimination. An insurance company’s denial of coverage based on genetic test results would be genetic discrimination. These coalitions centered themselves around a belief that genetic information must not be used to discriminate in insurance underwriting or in employment decisions.

GINA was the subject of discussion and public dialogue among many of the small groups and the researchers which were first concerned about genetic discrimination, and the establishment of genetic privacy, in the late 1980s and early 1990s. In classic fashion issue networks emerged surrounding the genetic research that was being done at the time, as it began to show promise and receive public funding. Through the development of policies by the Equal Employment Opportunity Commission (EEOC) under the Americans with Disabilities Act, the enactment of HIPAA, the medical privacy Final Rules under HIPAA and the debates over GINA 2003, 2005, and 2007, advocacy coalitions have operated within classic issue networks centered on genetic issues.

### **The Continuing Call to Arms**

The ACF is a model that supports, and conforms to, much of the best work on interest group theory, in that its primary focus is on the coalition-building that is most influential at the administrative level. Moreover, as a model of the policy process, the ACF emphasizes the difficulty of influencing policy-making at the Congressional level by any means, including coalition-building. As long observed by political observers, coalition-building can best marshal forces at the Congressional level to create opposition to the adoption of new policies.

The interest groups that had set passage of GINA as a priority had to continue to try and influence Congress in a positive way. But as interest group theorists and application of the ACF demonstrate, the task at hand was a daunting one. Robert Salisbury and Jeffrey Berry, in contemporaneous articles in 1989 and 1990 both observed that the sub-governments and iron triangles that political scientists had observed from after World War II until the mid-1970s had begun to disappear in the early 1980s, replaced by the issue networks discussed earlier. And both observed, as Salisbury put it, that the result was a substantial increase in interest group activity in Washington with less, not more, impact on Congressional policy-making. And as William P. Browne documented in the early 1990s, a further result has been that members of Congress have

reverted, if you will, to being most concerned about constituent issues and not broad policy issues that don't sell "back home."

These were the impediments that the proponents of GINA faced. Attempts to gain passage of the type of broad, general policy-making that GINA represented are daunting, even if the nature of the policies in question would seem to be lacking in controversy.

### **How GINA Came to Pass into Law – and What We Can Learn**

The proponents of legislation that would create a national policy of genetic privacy and prohibit genetic discrimination mounted what turned out to be an almost two-decade effort to accomplish this end. First, those that had similar interests in the passage of such legislation began public dialogue about the issue in classic issue networks. There was opposition over the years from business and insurance interests, though not in a consistently organized fashion due to the lack of any apparent agenda-setting event that would catalyze an effort to make genetic discrimination issues emergent.

Still, citizens groups concerned about a myriad of possible genetic-based medical advances aligned with researchers concerned with the need for research volunteers who were not inhibited by issues of genetic discrimination to argue for protective legislation. The arguments were first centered at the political subsystem level of administrative agencies (EEOC, HHS), and then moved to the level of Congressional macro-politics as the proponents gained more and more converts, eventually reaching to members of Congress.

This is the policy change that Sabatier and McFarland have theorized about in arguing the merits of the ACF as a method for analyzing the evolution of public policy. An examination of the long development of the policy momentum that led to the passage of GINA in the 110<sup>th</sup> Congress would seem to bear out the legitimacy of the ACF.

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