

Understanding Policy Outcomes on the Frontiers of Science as a Power Maintenance Problem

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Abstract

U.S. science policy outcomes are often best understood as solutions to a power problem—not a policy problem. Policy will maintain the power of current subsystems by extending current government programs to cover the new science. Policy will also continue to support the regulated interests at the expense of public interest. True policy innovation will come only if the new science changes elite beliefs or causes disaster—something rare but possible in science policy. This paper examines five U.S. policy areas (patents, reproductive medicine, food safety, human subject research, and criminal prosecution) to demonstrate the reality of power maintenance in policy reactions to new science and the rarity of disaster and changes in belief systems. Gene patenting, assisted reproductive technology, genetically modified foods, gene therapy and forensic DNA regulations maintain current power structures and do not adequately address substantive policy problems.

Understanding Policy Outcomes on the Frontiers of Science as a Power Maintenance Problem

Public policy is notoriously long on politics and short on effective problem solving of the sort firms and citizens might welcome. Scholars of public policy have used a variety of theories to account for policy outcomes, explaining the deficiency as a product of institutional rules and procedures, group theory, elite preferences, and most recently the sub-structure of advocacy coalition politics. In short, the theories predict that policy outcomes will be politically optimal, not necessarily analytically optimal. Why doesn't politics produce analytically optimal results? The answer is deceptively simple. The goal of policy analysis is to solve a substantive problem. The goal of policymaking is to maintain power. Analytical solutions will rarely perfectly overlap with political goals because the maintenance of power requires the maintenance of current political structures within a political system, and it is precisely these existing institutions and programs that fall short of fully effective policies.

Policy Analysis v. Policymaking. As understood by political science, policy *analysis* is a rational method of generating policy solutions typified by a step-by-step formulaic process (Bardach 2009, Dunn 2006). Steps in the process begin with problem definition (e.g. too little patient protection in assisted reproductive technology). Once the problem is defined, analysts gather evidence (data on current patient protection measures), construct alternatives (professional self-regulation, government oversight and inspection, etc.), select criteria for choosing among alternatives (patient health and welfare, efficiency), project the outcome of each alternative (reduced access to services, more successful births, etc.), confront the trade-offs (compliance costs versus patient safety), and make a policy recommendation (stricter penalties for non-compliance). Policy analysis can also include implementation and evaluation of policy outcomes (Cochran et al. 2006). The goal of policy analysis is to find effective solutions to policy problems.

Policy analysis is specifically concerned with rigorous analysis of the causes and consequences of public policies, with an emphasis on explanation for the purpose of articulating alternative solutions (Dye 2008). By contrast, *policymaking* is a much broader process where the focus changes from a policy problem to a power problem. Policymakers are foremost concerned with maintaining or gaining power, and policy outcomes are power relationships, not clinical problem-solving. A variety of policy models recognize the centrality of power relationships in policy outcomes. Institutional models consider the way organizational structure and procedure influence outcomes (Meyer and Rowan 1977, 2006; DeMaggio and Powell 1991; Hall and Taylor 1996; Scott 2001).

Elite Models focus on the role of powerful elites to shape policy outcomes (Dye and Ziegler 2003). Pluralist models (Truman 1951) examine the way group interactions, and the relative power of those groups determine policy outcomes. Advocacy Coalitions (Sabatier 1991) examine sub-structures within policy areas to explain policy outcomes as a function of the coalition power and structure. In terms of policy outcomes, optimal choices will vary with the actor. To the analyst, an optimal outcome will best solve the problem given discrete constraints of the problem environment. To the policymaker, the optimal outcome will maintain power given the constraints of the political environment. In the policy process, policymakers are closer to the actual decision than analysts, and we would therefore predict that policy is much more likely to resemble policymaker goals. In short, policy will maintain the power of the ruling elites and institutions.

Why must this be in conflict with what will be effective? It does not logically follow that power-maintenance policy must be ineffective policy. However, it is empirically true that political problems arise in a political environment where the problem is perceived *precisely* because current approaches are not working. However, those current approaches are the product of current power relationships commonly described as stable political subsystems of advocacy coalitions (Sabatier 1991). Advocacy coalition analysis focuses on the interactions of actors from different institutions—interest groups, legislative offices and staff, agencies and bureaus, etc.—who follow and seek to influence governmental decisions in a policy area (Sabatier 1991). The Advocacy Coalition Framework (ACF) tells us “The core (basic attributes) of a governmental program is unlikely to be significantly revised as long as the subsystem advocacy coalition that instituted the program remains in power” (Sabatier and Jenkins-Smith 1993, 34). In short the focus is on the power structure in the policy subsystem.

Biopolicy. So what does this mean for policymaking on the frontiers of science, where firms, citizens & policymakers find themselves in uncharted public policy territory? Let us narrow our question to the frontiers of genetic science and call it biopolicy. The frontiers of genetic science, and the commerce opportunities associated with that science, present a variety of policy problems and solutions. Patenting of genes and living organisms, Assisted Reproductive Technology (ART), Genetically Modified Foods and Organisms (GMOs), Gene Therapy, and DNA fingerprints are all recent policy problems presented by contemporary developments in genetic science that have generated substantive policy problems. These particular examples touch a variety of political and business environments and can be used as case studies for their “frontier” quality (presenting something new), for their institutional variation (private and public sector, legislative/executive/judicial activity), and for the variety of values and constituencies.

As will be illustrated below, these diverse biopolicy frontiers have much more in common as policy outcomes. In fact, each of them follows the exact trajectory anticipated by the Analysis/Policymaker divide. Rather than innovative policies rationally designed to solve the problems presented by new genetic science, policy outcomes are politically optimal and are best understood in terms of the political subsystem of each frontier. One might expect new problems to generate new solutions, or at the least generate a significant evolution of policy. However, the surprise finding is that policy making on the frontier does not create new political subsystems—rather it is folded into existing politics and government programs for the purpose of power maintenance. The problem is that these existing programs do not effectively address the problems raised by the frontiers of genetic science. Given the prominence of power maintenance and the rarity of innovative policy, I present four expectations for policymaking on the frontiers of science. First, biopolicy will maintain power of current subsystems by using existing government programs to implement the policy. Second, it will maintain more power to the “regulated” than to the public, as the coalitions most threatened by the policy will be the most likely to use pinpoint resources in the fight. These twin expectations will act as stabilizing forces in the biopolicy environment.

However, biopolicy also possesses unique destabilizing capacity, one of which has the potential to change the policy environment, and one of which does not. By creating new knowledge about how the world works, biopolicy presents the potential for value conflict. Elite belief systems are central to advocacy coalition activity (Sabatier 1991). As will be explained below, biopolicy uniquely challenges deep core belief systems, possibly breaking down consensus and allowing for new coalitions and new government programs.

There is the expectation that knowledge from the frontiers of science can change or at least significantly challenge deep core elite beliefs, thereby changing the direction of elite/advocacy coalition behavior. Thus, a third expectation is that biopolitics may destabilize existing coalitions, eventually resulting in innovative policy.

Fourth, disaster alone will not precipitate innovative policy approaches. The science of genetics also introduces uncertainty and the risk of safety, health and environment through hazards and possibilities for natural or social disaster. Yet, disaster will not be enough to change government programs alone. Rather, the disaster must change social or economic conditions, change system-wide governing coalitions, or produce a policy output from another system (Sabatier and Jenkins-Smith 1993, 34). If the disaster does not accomplish this, it will not significantly change the policy.

Maintaining the Balance of Power

As noted above, we would expect biopolitics to serve the interests of policymakers and maintain current power structures. We would not expect biopolitics to effectively solve policy problems if those solutions would change the balance of power. As will be demonstrated, each and every new development in this study was framed as just another version of a conventionally regulated area, an approach which minimized regulatory change and kept political power from shifting away from stakeholders. For each case study it is possible to map the general policy area in terms of who has the power prior to the policy challenge presented by genetic science. Table 1 presents a before-and-after look at each policy power environment.

Table 1 The Balance of Power and Biopolitics challenges

Policy Area	Policy Support for	New Science	New Policy?	Policy Winner
Patents	Inventors/producers	Genetics	Minimal	Inventors/producers
Reproductive Medicine	Medical Practitioners/labs	IVF, ART	None	Medical Practitioners/labs
Food	Food producers/mfg.	GMOs	None	Food producers/mfg.
Human Subject Research	Researchers/Pharm.	Gene Therapy	Minimal	Researchers/Pharm
Criminal Prosecution Evidence	Law enforcement	Forensic DNA	None	Law enforcement

According to Sabatier and Jenkins-Smith (1993) policy battles will at the most concern only secondary aspects of elite belief systems—namely minor program modifications that do not significantly affect the overall balance of power. These primarily take the form of instrumental adjustments, such as minor rule changes, and informational searches, such as reporting requirements. This is quite evident for each case study.

Patenting of Living Organisms and Genes. U.S. patent policy has essentially maintained its core support for inventions and exclusive licensing rights for those inventions meeting the standard statutory criteria—novel, useful and non-obvious. When modern science made it possible to isolate genetic material or create non-naturally occurring living organisms, US patent policy supported these endeavors with continued patent support. U.S. patenting policy is primarily set by the United States Patent and Trademark Office (USPTO) and federal courts interpreting federal patent law. Under federal law, “Whoever invents or discovers any new or useful process, machine, manufacture or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this Title” (35 USC §§101). Patented material must be “novel, useful, and nonobvious” (Andrews 2010).

The novel rule requires that the invention cannot be publically described for more than a year in, for example, a scientific journal. The non-obvious rule requires that professionals in the field do not consider the invention a trivial advance. The useful rule requires the patent applicant to provide a specific and substantial utility of the invention. Prior to 2001, the USPTO had allowed plant patents on agricultural crops (e.g. 1930 Plant Patent Act and the 1970 Plant Variety Protection Act) and the US Supreme Court had upheld the patenting of living organisms (a bacteria) in a landmark court case *Diamond v. Chakrabarty* 447 U.S. 303 (1980). Exclusive ownership and licensing rights for genetic material was first allowed in agricultural plant patents in the 1930s, where seed companies wanted exclusive rights to the sale and use of their hybridized, conventionally developed seed. Companies owned these living organisms and could control their dissemination. It was illegal for a farmer to save some of the seed for next year's planting. The political power struggle in agricultural patent wars continues into the modern day (See Halweil 1998 for a reference to "Bio-serfdom" in world agriculture), and the policy continues to serve producer/inventors more than the consumer/users.

In the late 1990s, the gene fragment applications created a new policy frontier for the Patent office and for the Courts. Prior living organism patents were used for synthetically created bacteria for cleaning up oil spills or curing cheese—a marketing environment similar to farming, where manufacturers sell a product to another manufacturer to use. Gene fragment patents, however, are largely used by researchers and medical testing labs. The USPTO issued patents for gene fragments (called expressed sequence tags) prompting opposing researchers to call for stiffer patent guidelines. For example the manufacturers of the BRAC-II test for a breast cancer gene had the power to license use of the common lab test through their patent rights (Shute 2007). The introduction of an obstruction to research added a new voice to the coalition against patenting. Detractors argued that exclusive patent rights will discourage research through a variety of mechanisms such as patent stacking, costs of royalty compliance, secrecy in primary research and discovery, and lack of publication (US Dept of Energy 2010).

However, the USPTO responded in 1999 by requiring stiffer guidelines on the "specific use" of a patented gene and with final guidelines in 2001 requiring more "usefulness" and a "specific and substantial utility that is credible" (US Department of Energy 2010). This did not significantly alter the overall support for the patenting of genes (Andrews et al. 2010). The specific use requirement simply kept genetic explorers from staking a claim on a piece of the code without knowing what it was for, but it did not prohibit the overall ownership and licensing rights for discovered genetic material. The policy outcome, thus, effectively preserved the balance of power in favor of advocacy coalitions supporting inventor-rights and rewards for research and development. It also failed to adequately address the research concerns inherent in patenting the gene sequences themselves. The politics of patenting pits researchers against researchers, with all manner of scientific professionals and corporations seeking to benefit from exclusive rights and licensing fees for the use of patented genetic sequences. The law has specifically pitted researchers at public institutions (who do not have the resources to find and pay licensing requirements) against profit-driven research and development arms of corporations who hold patents. This is politics as usual for the USPTO and its advocacy coalition framework: Patent holders v. Researchers and producers who need patented material. License holders have consistently used federal patents to charge researchers, labs, or (in the old days) farmers and other producers for the use of their patented products.

Assisted Reproductive Technology. The practice of assisted reproduction includes the collection and preparation of gametes (sperm and ova donation), fertilization (including in vitro fertilization), transfer of human embryos to the uterus, and pregnancy procedures (including multiple gestations, treatments, fetal reductions, etc.), and the disposition of unused embryos (President's Council on Bioethics 2004, *hereinafter* PCB). Each of these practices, procedures and treatments has generated political pressure for regulation, due to concerns of morality, health and safety. However, current direct regulation is quite limited. The dominant regulatory model for assisted reproductive technology (*hereinafter* ART) is consistent with regulation of medical practice generally, for which the model is professional self-regulation. Regulation of the practice of medicine is undertaken at the state-level with requirements for informed consent, licensure, registration with the Drug Enforcement Administration (for prescribing controlled substances), hospital credentialing, board certification, facility licensure (excluding doctor's offices), malpractice insurance coverage, and disciplinary procedures by state licensing boards (PCB 2004). While the American Society of Reproductive Medicine offers additional certification for ART clinics, the process is entirely voluntary and non-compliance has no penalties.

ASRM provides ethical and practice guidelines that are advisory in nature. Additional federal oversight is provided for marketed products (drugs, devices or biologics regulated by the FDA) and labs (regulated by the Centers for Medicare and Medicaid Services) and primarily applies to manufacturers, not clinicians (PCB 2004).

The FDA is specifically forbidden from regulating the practice of medicine, and has rightly included reproductive medicine in this limit on its authority. The President's Commission on Bioethics notes recent FDA enroads into ART regulation for only two narrow areas—human cloning and gene-transfer technologies. As the PCB notes, "As a general rule, clinicians can, without FDA oversight, employ novel and untested interventions on patients in the course of treatment, provided the articles involved have been previously approved for their originally intended purpose" (PCB 2004, 12). The report also notes that lab regulation does not apply to assisted reproduction laboratories, but rather only the semen or blood analysis within such laboratories—and only if they are not undertaken as an adjunct to ART services. Under the pertinent act (the Clinical Laboratory Improvement Amendments of 1988, CLIA), labs must meet quality assurance, personnel, record keeping, and inspection requirements. Current advocacy coalitions have pitted medical practitioners and their professional societies, as well as the relevant federal agencies, against the politically weaker patient's and consumer protection groups. As the President's Commission concluded, the current regulatory atmosphere is largely left to professional self-regulation and malpractice liability torts, and this places power squarely in the professional societies and medical practitioners (as well as medical malpractice insurance companies). Assisted reproductive technology has presented significant territory for additional regulation, yet no new regulations have been forthcoming. Concerns about embryo research, patient safety, gamete commerce, and pre-conception genetic manipulation have produced significant political coalitions, particularly from the conservative and family-values groups. However, only the barest of changes have been made.

Some states require insurance to cover ART services and federal embryo research dollars have been restricted, but for the large part, ART doctors, Medical licensing boards and the American Society for Reproductive Medicine remain firmly in charge of reproductive medicine, as is the model for the general practice of medicine. No new laws or regulations, federal or state, significantly give political power to the politically weaker coalitions. The policy outcome remains as it was, with medicine regulating itself, preserving the balance of power to ART technology manufacturers, medical doctors, and professional societies. The winning coalition is also supported by broader liberal concerns for freedom of research and reproductive rights, which are also preserved under the current self-regulation model.

Genetically Modified Foods. Genetically modified organisms (GMOs) entered the food supply during the recombinant DNA development of food staples (primarily GM corn and GM soybeans) and more recently animal cloning of livestock. GMOs use DNA fragments from other organisms (or more recently synthetic DNA) to produce desired traits in agricultural food (e.g. naturally occurring pesticides in Bt Corn or glyphosate herbicide resistance in Round Up Ready Soybeans). Animal cloning duplicates prize livestock for breeding and production. Federal oversight by the Food and Drug Administration currently treats genetic modification and cloning as no different from traditional hybridization and animal breeding, requiring little additional testing or oversight (Thompson 2000, Bren 2007). Corporations and producers can choose to undergo voluntary compliance measures, but the FDA does not require additional testing, as it has determined genetic modification and cloning do not meet the statutory requirement of a "food additive"—for which additional safety testing is required. GM production is also regulated under the U.S. Environmental Protection Agency (EPA) in the case of insecticides (Bt Corn) and under the US Department of Agriculture (USDA), which oversees field production. GM foods and cloned animals are currently marketed without special labeling requirements for consumers, except in the case of known allergens.

The politics of GM foods and cloned animals has pitted producers (farmers and agribusiness corporations), the FDA, USDA, and even the US Environmental Protection Agency, against consumer and environmental groups, such as the Union of Concerned Scientists. As might be expected, agencies and legislative oversight committees support these current producer-friendly regulatory schemes (See for example, Thompson 2000, Bren 2007), and even the President, Secretary of State, and the US Trade Representative have defended these practices in international trade disputes (see for example Lionel 1999, Tidmarsh and Torello 2010). Genetically modified food policy has likewise preserved existing programs and power structures.

First, the US Food and Drug Administration (FDA) has preserved its primary role as regulator. Second, companies won a significant battle when the FDA concluded that genetic modification did not constitute an “additive,” thus shielding it from the more extensive testing requirements (Thompson 2000).

The FDA also released cloned beef for general consumption, with the similar finding that cloning did not automatically subject product to additional regulatory oversight. Unlike a European model, where food is regulated differently based on the manufacturing process (e.g. conventional v. genetically modified), the FDA uses a product-based model—where all “products” (e.g. corn or beef) are treated the same, regardless of process. The farthest the FDA would go was to offer “voluntary” testing programs for GM foods to those companies willing to participate. Most companies choose to participate for marketing purposes, and the process has not prevented the significant sale and manufacture of GM food products. The FDA’s primary enforcement tool is voluntary recall and additional fines for after-the-fact problems, both relatively business-friendly in practice. For all practical purposes, GM food products have no new regulation. As one can see, the balance of power has remained quite stable for food manufacturers, with only minor encumbrances for allergens, such as genetic material from nuts.

Gene Therapy. Gene therapy is still experimental in the United States. Gene therapy, while somewhat modified, remains largely under the umbrella of human subject research, over seen in a moderate, yet predictable, regulatory fashion by the National Institutes of Health (which regulates government funded research) and the Food and Drug Administration (which regulates private research when it involves investigational new drugs). In general, these agencies review research protocols and approve the use of investigational therapies. Researchers and supporting institutions are bound by their own research protocol design, and severe penalties are forthcoming if a researcher is found to have departed from the approved protocol. There are no inspections or oversight during most trials, and paper trails are maintained in the event of a problem. At that point, the agencies become involved in investigation. Adverse events during trials are not triggers in and of themselves, rather a departure from approved protocols or highly publicized severely adverse events can mobilize additional oversight.

As novel medicine, gene therapy protocols were subjected to some additional protocol work, mostly for safe handling of genetic material and virus vectors, but the process did not change the balance of power for researchers or potential manufacturers. As human subject research, gene therapy is currently regulated as an investigational new drug and is subject to FDA “investigational new drug application” requirements (Food and Drug Administration 1984, 1993). If publically funded by the National Institutes for Health (NIH) it is also subject to the Recombinant DNA Advisory Committee “Points to Consider” approval process as well as institutional level review board approval (US Department of Health and Human Services 1985). Each of these regulatory bodies requires extensive documentation of prior animal work and detailed research protocols. They also require the reporting of adverse events (see for example FDA regulation 21 C.F.R. § 312.32). The FDA will not publish adverse events and will protect them as trade secrets. (NIH, by contrast, publishes adverse events.) The secrecy of adverse event reporting is designed to encourage corporations to report human subject complications, including deaths. In terms of enforcement, the FDA has the authority to fine and criminally punish (subject to criminal prosecution by the US Department of Justice) researchers who violate INDA requirements and fail to follow approved research protocols. The NIH can withdraw funding from individuals and institutions supporting research in violation of its requirements.

These requirements apply to all pharmaceutical human subject research and all NIH funded projects, and are not unique to gene therapy. Following the high profile death of Jesse Gelsinger in 1998, the FDA suspended all gene therapy trials (Andrews and Mehlman, 2010). The fine print of agency notification letters reveals the fault to lie with researcher failure to follow protocol—a business as usual enforcement tool (CBER 2008). Suspensions were short-lived and a new monitoring plan only added additional reporting and paperwork—not any real enforcement change. In 2000 the FDA announced a new Gene Therapy Trial Monitoring Plan (FDA 2000), effectively resuming gene therapy trials. The policy was updated with a joint FDA and NIH adverse event reporting system in 2004 (Andrews et al. 2010). The politics of gene therapy remains largely research-and-development friendly with both the NIH and the FDA trying to find ways to accommodate researchers, and the balance of power has been retained in favor of manufacturers and research interests.

DNA Fingerprinting. In 1988, Virginia and the Federal Bureau of Investigation obtained legal sanction from the courts to use DNA fingerprinting analysis in a criminal trial (Harris 2008). DNA fingerprinting is part of a larger body of criminal law regulating the introduction of forensic evidence more generally. Forensic evidence is generally taken for granted as admissible in criminal proceedings. All manner of evidence is routinely admitted and left to the jury for the question of its persuasive “weight” in their decision.

This policy area was prosecutor friendly and largely supportive of law enforcement efforts. Police were limited only by the exclusionary rule requiring the Constitutional seizure of evidence. State legislatures largely codified the admissibility of most forms of forensic evidence, leaving case-by-case challenges to individual trial circumstances. These state laws make forensic evidence automatically admissible unless some legal reason unique to the case and determined by the judge to prevent admittance. DNA fingerprinting is subject to common law policy for the admissibility of novel scientific evidence, which could vary from jurisdiction to jurisdiction. Most states and the federal government used a “general acceptance test” where new scientific evidence had to be “generally accepted in the relevant scientific community” U.S. v. Frye (1923) in conjunction with a relevancy standard. In 1993, the US Supreme Court ruled that federal courts could also admit experimental evidence if it had used the scientific method, had been subjected to peer review or had known rates of error (Bander 1997). States and state courts varied in their acceptance of DNA fingerprinting evidence in criminal trials, and the FBI pushed for a National Research Council report touting the validity and reliability of forensic DNA. In 1992, the NRC issued a report fundamentally supporting DNA forensic science, but questioning the statistical use of the probability rule to calculate the possibility of a random match (National Research Council 1992). While some jurisdictions used the report to decide in favor of DNA admissibility, other jurisdictions balked. The FBI redoubled its efforts and in 1996 the NRC issued a second report signaling that the statistical concerns had been overblown and that DNA evidence was reliable and valid for criminal identification.

While DNA was initially subjected to judicial policymaking, state legislatures were quick to add statutes likewise supporting its admissibility. Beginning in 1992 state legislatures began statutorily admitting DNA evidence, essentially removing the policy decision from their state supreme courts. DNA evidence was largely viewed as yet another kind of fingerprint evidence—a unique identifier to aid in the crime solving process. This politically friendly characterization meant business as usual for law enforcement. Courts used established vetting processes and prosecutors were largely successful in gaining approval (Harris 2008). The politics of DNA fingerprinting pitted the much stronger law enforcement and crime lab coalition against a much weaker defendant-rights coalition (Harris 2008). With federal support, state attorneys general and prosecutor organizations supported both judicial and legislative approval of forensic DNA evidence. Thus, DNA fingerprint evidence did not significantly alter the larger forensic evidence balance of power. Even the use of post-conviction DNA and other forms of forensic evidence continues to favor law enforcement, with prisoners facing multiple legal barriers to obtaining additional sampling.

In general, biopolicy is largely public policy by the usual means. Policy issues from the frontiers of science are folded into existing regulatory programs, maintaining the balance of power among competing coalitions. As seen above, each and every new development was framed as just another version of a conventionally regulated area—patents, medicine, food, human subject research, and forensic evidence. Those controlling the conventional policy area remained in control of the frontier area by subsuming the science/technology under existing programs and categories. This is not necessarily a bad approach. In fact it is an efficient use of scarce political resources until true parameters of problems are known. However, it is problematic when health, safety or social problems presented by the new science are not adequately addressed by conventional policy programs. When political realities prevent innovative policy development, sub-optimal policy approaches can result.

More Power to the Regulated

As is well known in the study of politics, the regulated will maintain significant control over government regulation in a pluralistic, fragmented system such as the United States. As both classical “iron-triangle” politics and the new sub-system politics recognize, coalition strength is partially a product of concentration—and private interests will be much more concentrated than public interests. Iron triangle politics recognizes a closed system where legislative oversight committees, executive administrative agencies and regulated interests work together to produce policy and regulation.

Sub-system politics expands this view to admit other interested parties such as journalists, other government officials, and broader coalitions, but the new view still concedes that concentrated, organized power will drive the policy. A careful reading of the policy outcomes above reveals a continued maintenance of power to the regulated. Patents clearly remain friendly to inventors and licensors. There have been blanket bans only on the patenting of human beings (PCB 2004). Otherwise, any invention meeting the criteria can be patented. Professional societies and medical practitioners significantly control assisted reproductive medicine, with almost no additional oversight of patient or gamete care.

Food producers and manufacturers are free to use GM foods and animal clones with minimum restrictions, and consumers are must rely on voluntary labeling. Gene therapy researchers can write their own regulation essentially in the form of a research protocol, with only the usual informed consent procedures to protect patients. And, forensic DNA evidence is largely taken for granted in criminal prosecutions—maintaining the power of law enforcement in criminal prosecutions. Many crime labs are government-owned and assumed clients of police work. Furthermore, even power brokered deals will produce programs where the regulated give up some power in exchange for relatively friendly policy environments. All agencies must allow some activity, and as such, the clients are given what they need, because the nation needs them. In other words, inventions, food, medicine, medical research, and criminal prosecution are all essential functions in a successful nation. Biopolicy on the side of these essential functions is likely to find itself inherently supported by government. The forces producing frontier knowledge are almost always forces pursuing societal values. Patents are valuable to inventors because someone will find them useful and seek a license to use or manufacture them. Food, medical assistance with child-bearing, therapeutic research, and criminal prosecution are highly valued by society. Thus, it should come as no surprise that winning coalitions supportive of frontier science can be found in biopolicy. Very few outright bans and societal points of rejection exist in genetic science—largely due to its contribution to basic human values.

Elite Beliefs and Human Genetics

Biopolicy may uniquely challenges elite belief systems, and has the potential to weaken conventional coalitions overtime. This serves only to destabilize coalitions, but not necessarily to change the direction of a program. For each case study, it is possible to delineate threatened core beliefs and destabilizing coalitions which may lead to new policy over time (See Table 2).

Table 2 Elite Beliefs and Coalition Destabilization

<u>Policy Area</u>	<u>Traditional Coalitions</u>	<u>Threatened Beliefs (Sabatier 1993)</u>	<u>Destabilizing Conflict</u>
Patents	Researchers and Mfg.	Ownership of nature?	Researcher v. Researcher Manufacturer v. Manufacturer
Human Subject Research (Gene Therapy)	Researchers and Disease Advocacy (patients)	Manipulation of nature? Freedom of scientific inquiry Pursuit of health	Researcher v. Patient
Medical Practice (Reproductive Technologies)	Doctor and Patient	Manipulation of nature? Reproductive Freedom Professional Decision-making	Women v. Women Doctor v. Doctor
Food Safety (GMO's)	Farmers and Food Processors	Dominion over nature—manipulation	Farmer v. Farmer Processor v. Processor
Forensic Science (DNA)	Forensic Scientists and Law Enforcement	Nature of Man Security	Scientists v. Law Enforcement

In the case of patent policy, researchers and manufacturers were generally quite supportive of patents. However, the patenting of genes and genetic material has been controversial among researchers and manufactures for quite some time, as patent stacking can interfere with primary research and development (Andrews and Mehlman, 2010).

Core beliefs about ownership and property, as well as the appropriate role of government in the regulation of market activity, have been challenged within these coalitions. The more general value of the freedom of scientific inquiry has also been challenged among researchers.

Even beliefs about critical social groups switched from consumers to other researchers and manufacturers. This interaction of biopolicy with elite core beliefs has somewhat destabilized those coalitions supporting USPTO patent policy and genetic programs in particular. Core beliefs about whether humans should own a DNA sequence has also been challenged—how far should dominion over nature proceed? In the case of human subject research, scientists, disease advocacy groups, and manufacturers formed a strong coalition in support of aggressive marketing and testing of new products. Support for “fast-track” FDA approval is good example of this coalition and its program support. However, gene therapy presented a challenge to core beliefs about the manipulation of nature, pursuit of health, and freedom of scientific inquiry. Scientists challenged scientists as unsure if gene therapy should be used on humans in the near future. Disease advocacy groups had to support patients, but also research subjects. This generated a different programming approach for gene therapy, with plenty of skepticism among usually supportive groups.

In the case of medical practice, doctor and patient were generally united against insurance companies and government interference with the practice of medicine. However, assisted reproductive medicine, particularly aggressive infertility practices, has split doctors and has split patients. Manipulation of nature and reproductive freedom have created value and belief divides among normally unified groups. For instance, family values groups may not agree with manipulating creation, however, several faiths embrace family and the ability to bear children, thus dividing citizens within those groups on the proper regulation of ART. ART also challenges women’s rights groups who push for insurance coverage, yet simultaneously push for bans on sex-selection techniques. Likewise, patient and doctor groups who traditionally do or do not trust expert, professional decision-making are questioning the professional self-regulation and malpractice liability model in fertility medicine. One key challenge has been the identification of critical social populations—is it the rights and freedoms of the mother, or is it the health and safety of the child? This destabilization of coalitions has somewhat eroded general support for self-regulation, at least with regard to ART.

In the case of food safety, farmer and processor, as well as seed and chemical manufacturers, were fairly united in favor of better growing products (seeds, fertilizers, chemicals) and they typically stood in firm resistance to additional government oversight. However, genetically modified organisms and cloned livestock split farmers into three groups: conventional, GMO, and organic. Beliefs about the manipulation of nature and values such as nutrition and health were somewhat challenged. The definition of good food and the image of a wholesome farm product was quite changed. Food safety somewhat differs from the other case studies in that the dominant coalition is still quite firmly agribusiness and those farmers and food processors aligned with agribusiness. Hence, we see FDA policy as usual, and very little destabilization of the dominant coalition. In the case of forensic evidence, public policy has overwhelmingly favored a coalition of law enforcement and law & order politics. However, forensic DNA has presented a very strong challenge to the politics of justice. If justice has meant punishing the guilty and freeing the innocent, DNA can be a tool of defense lawyers and accused persons. Debates about the use of DNA evidence have made other types of evidence vulnerable to legal challenges, even fingerprint evidence.

Values about security, privacy, and knowledge have also been challenged, with many supporters of law and order politics also skeptical of DNA databanks for anyone other than convicted felons. Beliefs about the critical social population have turned from victims to average citizens or even to the falsely accused (who free themselves with DNA evidence). As with food safety, these belief challenges have not been enough to destabilize the dominant coalitions, but there is some evidence of erosion. Faith in forensic evidence is waning on some fronts, and forensic scientists are increasingly employed by defendants, though still quite rare.

Genetics and policymaking on the frontiers of science can cause within-group conflict and necessitate the restructuring of coalitions in a policy area. For instance, gay rights groups may find themselves splintered on their position with regard to the study of genetics and homosexuality.

Reproductive rights groups may also find a lack of consensus on prenatal testing policy and prenatal practices. When deep core beliefs are challenged, it can precipitate a shift in near core beliefs: suddenly government regulation is or is not warranted; suddenly public input is not as desirable as expert input, etc. While human genetics and policymaking on the frontiers of science challenges the belief systems of elites in unusual ways, it does not change predictions about coalition learning and perturbation. Core (basic attributes) of a government program is unlikely to be significantly revised as long as the subsystem advocacy coalition that instituted the program remains in power (Sabatier 1991).

This is most clearly understood when common-sense observations would suggest otherwise. For example, in the area of regulation of assisted reproductive technologies (ART), the current model is professional self-regulation with very little state or federal oversight. Federal policies reach only to information collection and the approval of medical devices or techniques in ART. This is supported by the dominant coalition of practitioners and professional societies—most notably the Association for Reproductive Medicine. ART policy is currently located in the larger practice of medicine where professional self-regulation and litigation are the primary policy tools. In spite of numerous infertility consumer groups and even a Presidential Commission's report calling for more structured regulation, the practice of assisted reproductive medicine remains largely unregulated (President's Council on Bioethics). Patenting of genetically modified organisms and of genes is likewise still continuing apace despite widespread recognition of the added costs to both basic research and clinical practice.

Disaster Plus

Core (basic attributes) of a governmental action program is also unlikely to be changed in the absence of significant perturbations external to the subsystem. According to Sabatier and Jenkins (1993), disaster alone will not be enough to alter coalition policy outcomes. Rather, the disaster must change social or economic conditions, change system-wide governing coalitions, or produce a policy output from another system. Only these events will alter existing balances of power in coalition frameworks supporting conventional policy programs. Of our case studies, only gene therapy has come close to a “disaster” and that was significantly absorbed by the current program. The death of human subject Jesse Gelsinger is widely recognized as a catalyst for change in NIH and FDA approval processes (Andrews 2010). However, as noted above, these actual changes were only minimal additions to policy as usual. After a short term ban on gene therapy research, the FDA has again given the green light to researchers with only informational additions for policy (namely a gene therapy research database). As noted by Sabatier and Jenkins, this is exactly the kind of insignificant policy change anticipated by the advocacy coalition framework.

Assisted reproductive medicine was considered quite taboo until the opposite of a disaster, Baby Louise (the first test-tube baby), was introduced to the world (Bonnicksen 1989). After that, mainstream policy embraced ART as medicine as usual (PCB 2004). This observations occasions the introduction of a new hypothesis: the diversion of disaster, or the opposite of disaster, will strengthen dominant coalitions and entrench policy even further. This is certainly the case for GMO policy—GM foods are becoming foods as usual. The lack of real disaster from the Starlink episode, has strengthened the dominant coalition and kept food policy quite “normal” with only voluntary labeling and the usual recall process to protect and inform consumers. Forensic DNA has likewise been folded into crime control policy, and has actually strengthened public support for DNA databanks and other aggressive law enforcement use of novel scientific evidence. The ability to solve more crimes “with the click of a mouse” has only given law enforcement more political power for additional funding of forensic science (see for example the 2006 Presidents DNA Initiative at www.dna.gov). Patent policy is likewise in the category of a non-disaster that strengthened the dominant coalition. The patenting of living organisms in Chakrabarty did not end life as we know it. Similarly, research and development continues even with gene patents. These every day successes tend to weaken any political handwringing and nay-saying precisely because of the reasons given by Sabatier—no change in economic or social conditions, no policy output from another system, and no change in system-wide governing coalitions.

Conclusion

In general, policymaking on the frontiers of science is politics as usual. It is consistently folded into existing policy programs to preserve the power of dominant sub-system advocacy coalitions. It consistently retains as much power as possible to the regulated.

However, it has the potential to destabilize elite belief systems and has shown some power to weaken dominant coalitions. Even so, most elites will resolve the conflict without changing sides or politics. Finally, policymaking on the frontiers of science can be quickly normalized and accepted by the *lack* of immediate disaster. So what does this imply for the analysis/policymaking divide? Those who rationally approach the practical and empirical nuances presented by policymaking on the frontiers of science will not win out over the politics of programs and policies already in place. Evidence in favor of radical policy departure will be no match for the politics already in motion. Biopolicy in and of itself will not generate the new government programs or coalitions that might be expected.

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