Physicians and scientists are privileged members of contemporary society. They are trusted authorities who are obligated to provide expertise without the influence of self-interest. Coupled to this obligation, they have historically been given the privilege of managing their own affairs. In recent years, however, increasingly stringent policies and mandates developed with the best of intentions by a wide range of regulatory bodies have challenged the autonomy of physicians and scientists. In this editorial, I will explore the forces underlying these changes and consider their consequences for society and for the practice of medicine and biomedical research.

Physicians and scientists hold what the sociologist Max Weber defines as charismatic authority\(^1\) in matters related to their disciplines. According to his construct, charismatic authority is one of three forms of legitimate influence in society, the other two being rational authority (ie, that governed by laws and rules) and traditional authority (ie, that related to cultural norms). Authoritative “charisma,” according to Weber, refers to “specifically exceptional…qualities…not accessible to” other members of society. Physicians possess a unique, complex body of knowledge that can directly affect the physical and emotional well-being of individuals. Similarly, scientists possess a complex body of knowledge that can have broad-reaching effects on the lives of individuals. Science and the rational determinism of the scientific method have become fundamental tenets of modern society and in large measure govern social acceptance of the authority of physicians and scientists. Yet this essential authority can be compromised by aberrant behaviors that exploit the privileges vested in these professions to the disadvantage of members of society. To guard against these events, physicians and scientists have historically governed their disciplines by oversight and intervention.

As practitioners of privileged professions, physicians and scientists have historically had autonomy in the management of their own affairs. Professional autonomy refers to the socially sanctioned ability of the profession to oversee its members’ obligations and behaviors. In medicine, professional organizations and societies are responsible for enforcing regulatory statutes and policing physician behavior. In scientific research, professional organizations play less of a direct role in overseeing the conduct of scientists; the scientific method is believed to speak for itself, ultimately root- ing out those observations that are invalid and those scientists whose work is suspect.

In the United Kingdom, recent changes in policy have greatly weakened the self-regulatory authority of the medical profession, substituting greater governmental (rational) authority in its place. Widespread public anger at a growing number of professional scandals catalyzed this transition. These sentinel events included assaults on female patients by two psychiatrists, a gynecologist, and a general practitioner; the murders of elderly patients over many years by a notorious general practitioner; the potentially avoidable deaths of children at the hands of two incompetent surgeons; and the unauthorized autopsies of children by a pathologist who also retained many of their organs.\(^2\) This understandable societal outcry occurred in the context of a confluence of contemporaneous forces that included a shift in social attitudes toward the profession, an increase in accountability standards, and the growth of managerial intervention as an accepted societal response to serious public concerns.\(^4\) In many respects, this loss of self-regulation is viewed as a consequence of the profession’s abdication of its responsibilities to oversee its members and to weed out those whose performance is substandard or, worse, frankly threatening to the public. Loss of self-regulation may, however, also be a consequence of the natural evolution of a hierarchical guild to a level position in an open, informed society.

Similar changes are occurring in the scientific community. Notwithstanding the general view by society of the importance, value, and validity of the scientific process, science has had limited, if not uncertain, influence on social values and national policy.\(^5\) For reasons ranging from scientific illiteracy to natural conflicts between science and religion, rational determinism is only one of several voices at the policy table and rarely the most influential, as illustrated by issues ranging from global warming to stem cell research. The growing concerns about the safety and privacy of human

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1. Thomas B. Reed, 1886, speech
2. Louis Brandeis, 1928, dissenting opinion, *Olmstead v United States*

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*The opinions expressed in this editorial are not necessarily those of the American Heart Association.*

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research subjects, the health and welfare of research staff, and the care and appropriate handling of experimental animals, and the increasing pressure put by funding agencies on well-defined translatable research outcomes have all conspired to create a working environment rich with regulatory oversight defined and managed by external authorities rather than by the scientists themselves. These forces have worked in tandem with the growing numbers of scandals involving scientific misconduct. Moreover, they are amplified by the hyperbolic sentiments often espoused by investigators as they attempt to garner continued societal support for their work. Together, these trends have created a crisis whose only substantive resolution requires the transition from self-governance to independent regulatory oversight. The net result of these changes in governance is more rules and regulations overseen by more regulatory bodies with minimal professional input in the planning process, in management, or in the assessment of outcomes.

Those of us who work in any contemporary clinical or research environment, including clinical cardiovascular care and cardiovascular research, have witnessed a seemingly unrestrained increase in regulatory requirements governing professional activities. The historical forces that have led to this situation are clear and in many respects understandable: Society expects—and has a right to expect—that those privileged professions act in a fully responsible way to meet their obligations to the society that has empowered them, to be trustworthy, to work toward achieving individual and social good, and to do so without real or perceived conflicts of interest or commitment. The progressive loss of self-determination by physicians and scientists is the result of these changing forces in a society that has become increasingly sophisticated, objectively critical, and its members themselves progressively more self-determined and unwilling to accept even highly and uniquely knowledgeable professionals as unquestioned authorities. This evolution also derives from a more precise and socially acceptable definition of professional autonomy than simple self-determination. “Physician autonomy,” as Emanuel and Pearson point out, “is not equivalent to the liberty to treat patients however physicians want, but [is] fundamentally rooted in the effort to promote patients’ best interests.” By analogy, scientist autonomy is bound to the effort to uncover nature’s truths in order to promote society’s best interests. This latter goal is, in fact, a general requirement for all autonomous professions.

Although one can understand the rationale for moving from professional self-determination to centralized, institutional regulation of physicians and scientists, I find a fundamental question underlying this transition unanswered: Does centralized regulation enhance the likelihood that physicians and scientists will consistently act in society’s best interests? The assumption has always been that regulatory oversight and intervention prevent, or at least limit, poor performance or malfeasance. However, there is no evidence, to the best of my knowledge, in clinical medicine or in scientific research that supports this claim. In this era of evidence-based practice, one would hope that there would be supporting outcomes from controlled studies that justify this rush to regulation, rather than *prima facie* assertion. Alas, this is not the case. As an example, consider the impact of regulatory intervention on the quality of health care. Sutherland and Leatherman reviewed the evidence supporting the relationship, if any, between regulatory intervention and quality improvement. They found sparse evidence available to address this issue, most of which was drawn from observational studies in the areas of institutional regulation, professional regulation, and market regulation. They observed that the relationship between regulation and quality improvement is associative rather than causal, and statistically marginal at best. This important example highlights the fact that even in this key area in which regulators have the most to gain from demonstrable evidence supporting a strong causal relationship between regulation and outcome, little or none exists. One can imagine how much weaker the evidence is for areas such as the requirement for continuing education for clinical practice accreditation or required (and annually or biannually recurring) educational experiences (eg, online modules) in patient privacy law, pain management, fire safety, the responsible conduct of research, etc. Yet we are required to participate in these programs, with lack of participation potentially leading to a loss of clinical privileges or of licensure for physicians or a loss of grant funding for researchers.

The research community is clearly not immune to this increasingly burdensome regulatory environment, as anyone who performs National Institutes of Health-sponsored research is aware. The regular reporting requirements for institutional approvals and processes governing human subjects research, animal care, radioisotope safety, conflict of interest, publication deposition in publicly accessible open-access databases, etc, consume an enormous amount of time and effort, on the part of the investigator and the sponsoring institution, as well as the administrators who respond to and review these required reports. In fact, a recent study of the National Institutes of Health–funded research community reported that an amazing 42% of a researcher’s time is spent on regulatory matters rather than on the research for which (s)he has been funded.

The Internet and electronic communication make the implementation of any regulatory requirement extraordinarily simple—frankly, too simple, which leads to the establishment of such programs without a consideration of their unintended consequences for the participants or their lack of demonstrable benefit for society. How often do we each receive e-mail messages about new reporting or educational requirements mandated by the government, licensing bodies, hospitals, or universities? The required regulatory responses increase without any consideration given to the increasing burden in time, cost, or redundancy of many of them (eg, multiple conflict-of-interest formats from the National Institutes of Health, hospitals, universities, and journals), with no effort made to streamline or consolidate them or to eliminate those older regulations of little current relevance. In clinical medicine, for example, estimates suggest that 1 hour of inpatient care generates 36 minutes of required paperwork. From a systems-wide perspective, the Health Care Financing Administration has amassed 130000 pages of Medicare and Medicaid rules and instructions that, in part, define these requirements (which, by the way, is three times the size of the Internal Revenue
This regulatory burden clearly contributes hugely to the cost of clinical care. Recent calculations by the Office of Information and Regulatory Affairs suggest that the federal government alone currently imposes more than 10 billion hours of paperwork compliance annually. Given the average hourly rate for a general compliance officer of $30.66, as indicated in the Bureau of Labor Statistics’ Occupational Employment Statistics listing, Batkins estimates the annual cost of meeting this regulatory burden to be more than $300 billion, an expense that must be borne in its entirety by the consumer, the taxpayer, and the sponsoring institution.

How have we reached this level of regulatory scrutiny, especially in disciplines that are generally viewed as benevolent to the society in which they are practiced? Civil regulation of professions generally evolves as a response to growing public concern toward a sentinel event or events that portray a profession in a negative light. In this construct, regulation is meant to protect society from the “bad apple” in a professional workforce, invariably without regard to the prevalence of such bad apples, the absolute risk to which society is put by their persistence, and the burdensome consequences for the overwhelming majority of practitioners who are bona fide benevolent members of the profession. In this sense, regulation reflects an effort to eliminate risk for society and is the civil antithesis of the basic tenet of our system of criminal jurisprudence that one is innocent until proven guilty. Turning this fundamental maxim on its head, practitioners are now subject to onerous regulation to guard against that rare bad apple at any cost and in the absence of supporting evidence that the regulation makes a clear difference. Rather than focusing appropriate punishment on the guilty, these policies meant to safeguard the public from future rare events only serve to increase the burden on practitioners, the great majority of whom meet their professional obligations to society without fail. It is fair, then, to ask this question: Although it is clearly better to free many guilty persons rather than punish one innocent person, is it better to penalize the great majority of innocent persons with the burden of overwhelming regulation rather than risk the adverse consequences of rare bad actors without evidence that the regulations are effective at protecting society from them?

The relationship between punishment and regulation has been increasingly dissected in recent years by legal scholars. Within the criminal domain, the distinction between punishment and regulation is often vague at best; within the civil domain, this distinction is even more problematic, because legal measures bridging civil and penal sanctions have expanded in recent years. Sarat and colleagues reviewed these principles and concluded that it is futile to attempt to distinguish punishment from regulation; instead, they argue, one should attempt “to understand regulation and punishment in relational terms, with regulation the more inclusive concept.” They point out that legal criteria for the distinction emphasize those who authorize coercion, be it punishment or regulation, without regard for those who are affected by it. It is as if regulatory authorities wash their hands of the process from the perspective of those innocents who are targeted by their coercive decisions, well-intended though they may be. This disregard for those affected by a regulatory action likely reflects the evolving loss of the distinction between criminal and civil infractions and their consequences for the imposition of penalties (punishment or regulation). As Steiker points out, “The blurring or destabilization of the criminal-civil distinction is partly due to the increase in the sheer number of ‘hybrid’ legal institutions and practices: From civil penalties to punitive damages, civil forfeiture to criminal restitution, legal devices that are arguably criminal-civil hybrids seem to be more common than they were a century ago.” As a result, targets of civil regulation are treated as one would treat targets of criminal punishment, that is, rettributively in defense of the aggrieved and of society without regard for the innocence of the great majority and without any opportunity for constructive input from those targeted for regulation. Put another way, criminal punishment has become tacitly conflated with civil regulation, operationally and conceptually.

Please recognize that I am not arguing for a libertarian approach to the affairs of physicians and scientists. I agree with the Dutch economist Willem Buiter, who pointed out that “self-regulation is to regulation as self-importance is to importance.” Meeting the obligations that privileged professions have to society is of paramount importance and warrants societal oversight. I am, however, opposed to regulation for the sake of prevention without evidence of benefit; unnecessarily penalizing the innocent; establishing a tenor of extreme vigilance that assumes professional culpability; and consuming precious time and limited resources with ineffective bureaucratic mandates that could and should be better spent on the practice of our professions. If the practice of medicine and the conduct of science are based on accumulating evidence, then physicians and scientists should justifiably expect that the regulatory environment within which their disciplines are practiced should also be based on evidence of benefit—for the disciplines and for the society to which the disciplines are obligated. As with any outcomes assessment in clinical medicine, data should be accumulated to test the utility of a specific regulation and the regulation modified as the data are analyzed. Doing so is essential, lest we develop “[l]aws directed against opinions [that] affect the generous-minded rather than the wicked.” This era of professional regulation should, thus, be reformed to one of thoughtful, effective oversight in which physicians and scientists would feel that the outcomes and benefits for society and themselves are worth the effort.

Scrivens has explored some of these issues of regulatory burden, proof of benefit, and effectiveness in a recent article regarding the British National Health System. In it, she cogently reviews the issues that need to be considered in the development of an effective regulatory system. Among these are included a fundamental cost-effectiveness principle founded on the basis of demonstrable evidence: The system “must operate within a restricted cost envelope,” and must reduce “the administrative burden associated with both inspection and self-assessment,” which must be “proportionate to a demonstrable contribution to the improvement in regulation and the ultimate goal of improvement in the quality of healthcare.”

These highly rational principles can and should be applied to any and all regulatory burdens in clinical medicine or research. They should also include an analysis of the cumulative burden of disparate requirements for any individual in any institution, with some maximal acceptable limit. Who would govern this
oversight or be tasked with how best to streamline its analysis is unclear, but perhaps this could involve an institutional regulatory ombudsperson. Such ombudsmen from all healthcare institutions, academic medical centers, and biomedical research entities could form a national group that formally represents the practitioners (physicians and scientists) to their respective regulatory bodies at the national, state, and local levels. They could be tasked with providing formal input for all new or proposed regulations, minimizing redundant or extraneous regulations, and enabling practitioners to challenge formally questionable regulatory policies. This essential change in policy would provide an effective method to ensure appropriate regulation that is sensitive both to the needs of society and to its often adverse consequences for the great majority of physicians and scientists.

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