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New Governance and Health Care Regulation.

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NEW GOVERNANCE AND HEALTH CARE REGULATION

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ABSTRACT

This paper explores a new approach to health care regulation, referred to generally as new governance. New governance is not a unitary theory of law but rather is a collection of approaches to regulation which lie between an open market system and a very prescriptive regulatory regime, often characterized as command and control regulation. Originally developed in Australia, the various approaches to new governance have been implemented in Europe and North America as well, generally in highly technical arenas in matters concerning safety and the environment The paper considers the application of new governance in health care, primarily in the context of medical errors, but also considers application so this doctrine to licensure as well.

KEYWORD: *new governance; health care regulation; regulatory reform; responsive regulation; meta-regulation*

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I. INTRODUCTION

In the context of health care delivery there are multiple elements, which are brought to bear in the broad structure of a given system, as well as in its operational details. There is a growing awareness of the role of law as a core element in health care, both to define the structure and operations of a system, as well as to recognize and protect the rights of individuals involved in that system. The focus of this article is on one aspect of law as it touches on health, the role of regulation. Generally, regulation is thought of in reference to a given program or initiative, but in the context of this paper, regulation will be looked at more broadly as a tool that can assist governments with enhancing the oversight of current programs, as well as a mechanism that can facilitate necessary systemic changes. This paper will address an emerging area of administrative law, new governance, a broad generic term that encompasses a series of reform efforts designed to promote a more responsive and flexible regulatory structure. While the consideration of new governance may be somewhat broad in nature, this stream of legal theory will be considered in the context of hospital regulation and more specifically in reference to the ongoing problem of medical errors in the acute care setting and the debate over charity care obligations of non-profit hospitals. While the basis of analysis will be drawn from the United States, the applications of new governance models can extend to any regulated health system.

II. BACKGROUND

While individual legal regimes approach health care regulation in different ways, most regulatory schemes will fit into one of four areas: command and control, the use of economic instruments, self-regulation and voluntarism. [1] Command and control is the most familiar style of government regulation as it entails development and enforcement of legal mandates through statues and supporting administrative policies, and as such, is a system of direct government control over a particular issue. The use of economic instruments rests on government policies that reward or penalize behaviors by creating financial incentives to leverage performance. Self-regulation entails the development of control mechanisms by the regulated that determine both the standards to be applied, as well as the manner of enforcement. A typical process here would be accreditation. Voluntarism is based on an entity or individual behaving in a responsible manner on their own volition, without any public or private oversight. It is

[1] *See generally* NEIL CUNNINGHAM & PETER GARBOSKY, SMART REGULATION: DESIGNING ENVIRONMENTAL POLICY 424-26 (1998).

within this fourfold universe that legal theorists are beginning to posit new approaches to the regulation of the health sector based on the premise that none of the four models mentioned are independently, or collectively, satisfactory. Legal scholars have argued that the four approaches noted must be altered to fit current and future realities of governance, as well as health care delivery.[2]

III. NEW GOVERNANCE MODELS

It is thus a reaction against traditional regulation, most typically commands and control, that has spawned a series of related legal regulatory models, collectively referred to as new governance.[3] Broadly defined, new governance is a legal development, which calls for greater flexibility in the approaches governments take in controlling particular sectors of activity whether it be health, environment or criminal justice, etc. It is not a rejection of regulation per se, but new governance is rooted in concepts of law that are tailored to individual actors and problems, while still retaining the option to use more direct legal mandates for areas of persistent difficulty. In some ways new governance models can be analogized to a form of public contracts between regulator and the regulated party. Part of the challenge in developing a general sense of new governance is that the nomenclature, which accompanies theories in this area, often varies. Perhaps the most established model of new governance is responsive regulation, a concept that was developed by Australian legal scholars. Responsive regulation is a form of government oversight that envisions regulated parties negotiating enforceable conditions with the regulator, the creation of a hierarchy of sanctions, that match the degree of infringement, and thirdly, crafting a role in decision making and monitoring for members of the public.[4]

In addition to responsive regulation, Australian academics have posited two other forms of new governance: meta-regulation and restorative justice. Meta-regulation is a form of regulation in which a regulated entity focuses its efforts on solving a given problem that may be identified by government, or may reflect a self-recognition on the part of the regulated of a particular

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[2] *See generally* JOHN BRAITHWAITE ET AL., THE GOVERNANCE OF HEALTH SAFETY AND QUALITY: A DISCUSSION PAPER (2005).

[3] In 2002, the American Hospital Association convened a taskforce on regulation that identified seven models of regulation in the American hospital context, command and control, public utility regulation, inspection, reporting and disclosure, performance-based regulation, delegated regulation and market-based regulation, which is actually quite close to the fourfold classification noted in this article that came out of the new governance area. *See generally* Am. Hosp. Sass's. Taskforce on Regulation Relief and Reform, Final Report, App.E, Hospital Regulation (2002).

[4] *See generally* IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE (1995).

issue that has resulted in problems. Meta-regulation allows individuals and entities to devise solutions to a given problem based upon their own creativity and logic, an approach that may be highly tailored by a given actor, and possibly not result in a solution of general applicability across an industry. Restorative justice looks at a law as a vehicle to heal those impacted by problems, and the process of healing is not punitive, but rather involves a candid admission about the nature and causes of a given problem, and requires genuine introspection on the part of regulated to learn from past mistakes. Another form of new governance crafted in the American context is management based regulation, which includes elements from responsive and meta-regulation. Management based regulation is a mechanism that directs regulated entities to engage in planning processes that are self determined to meet a particular public goal.[5] Unlike two other traditional means of industry regulation (technology-based regulation, which intervenes at the action stage of organizational behavior, and performance-based regulation, that concerns outputs), management-based regulation is focused on planning. The rationale underlying regulatory intervention at the planning stage is that sound planning will spark good internal management, resulting in achievement of both private and public goals. The planning process is heavily dependent on information, and the nature and type of information used in planning may be largely self-determined by the regulated entity. Uses of information in management -based regulation for planning purposes are distinguished from the information mandates of collection and disclosure that are so prevalent in institutional health care regulation. It should be noted that management-based regulation and the other new governance models noted are not just theoretical constructs, but have been applied in various ways in national legal systems in health care and other sectors. For example, management-based regulation can be seen in occupational health, food safety and pollution prevention; responsive regulation and restorative justice are evident in various criminal and civil law contexts respectively.

Before focusing on applications of new governance in health care, it is important to consider why the search for alternative models of regulation, outside of command and control methods, is compelling. While a detailed overview of health care regulation in the United States is beyond the scope of this article, review of this area quickly leads to the conclusion that its both voluminous and costly. Health care regulation in the United States, dominated by command and control models, can be characterized on its own as a major enterprise, estimated to cost close to $340 billion dollars annually, constituting a tax of $1,500 on the average American family.[6]

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[5] *See generally* Cary Coglianese & David Lazer, *Management Based regulation: Prescribing Private Management to Achieve Public Goals*, 37 L. & SOC'Y REV. 691 (2003).

[6] *See generally* Christopher Conover, *Health Care Regulation, A $169 Billion Hidden Tax*, 527

Cost estimates of the regulatory system in American health care reflects the scope of activities made up by extensive sets of mandates existing at local, regional and national levels of government, covering virtually all aspects of the delivery system. In addition, there are also very active private regulatory entities, such as the Joint Commission on Accreditation of Health Organizations (JCAHO) which have great influence as well, and add further complexity to the regulatory arena.[7] Compliance activities consume large amounts of time and resources for both individual and institutional providers alike.

The typical reaction of public authorities to problems in the delivery system is to enact new laws or issue regulations, creating a layering effect of requirements, with a lack of coordination between new and existing mandates. Even with the passage of laws or issuance of regulations, which create new oversight initiatives, existing rules in similar or related areas may not be abandoned. Ultimately the issue of assessing regulations is not one of just cost and volume, but determining whether a given regulation is effectiveness in meeting stated goals. In the abstract it is difficult to argue the pros and cons of the health regulatory regimes in the U.S., but the current enterprise is challenged by serious quality, cost and access issues appear not to be addressed through massive regulatory oversight.[8] Also troublesome is that given the costs of the American health system generally and in the area of regulation, it falls short in several key public health indicators compared to other OECD nations.[9] Some health policy experts argue in the face of ineffective regulatory schemes that government oversight would be better replaced by free market mechanisms, but that position is also problematic in that incentives here may not necessarily protect public interests.[10] Enhancement of individual and population health is a government responsibility, and such an obligation must be grounded in law and process. The tools of law must be carefully applied, as both a matter of infrastructure and a mechanism to facilitate general and specific health goals. Regulation is not an end onto itself, and as such in the United

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CATO INSTIT. POL'Y ANALYSIS 3 (2004). A newly issued study on health care costs generally which projects that American health care spending will double in the next decade, consuming close to 20% of the GDP, *see* John Poisal et al., *Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact*, http://content.healthaffairs.org/cgi/content/full/hlthaff.26.2.w242v1/DC1

[7] *See* The Joint Commission, http://www.jointcommission.org

[8] *See generally, e.g.*, Peter V. Lee & Emma Hoo, *Beyond Consumer-Driven Health Care: Purchasers Expectations of All Health Plans*, 25 HEALTH AFFAIRS 544 (2006). This short piece focuses on the development of consumer driven health care in the U.S., but is a good example of how core underlying problems in the American system need to be addresses.

[9] *See* OECD Health Data 2006: How Does the United States Compare, http://www.oecd.org/dataoecd/29/52/36960035.pdf (last visited Feb 22, 2007).

[10] *See e.g.* John Cogan, *A Healthy Debate: Health Care Reform*, http://www.hoover.org/publications/uk/2934081.html (last visited Feb 22, 2007).

States, as well as other nations, the effectiveness of any regulatory scheme must be a continual matter of study and necessary changes to reform legal tools must be pursued.

IV. MOVING NEW GOVERNANCE INTO HEALTH

A. Medical Errors

In 1999 the Institute of Medicine (IOM), a non-governmental research group, issued its now famous report "To Err is Human", which was an indictment leveled against American hospitals.[11] The IOM Report noted that between 44,000 to 98,000 patients died in U.S. hospitals as a result of preventable errors. The Report generated considerable controversy as some argued that the assessment lacked rigor, and as a result, the numbers of preventable deaths were grossly inflated. Others argued that the number of preventable deaths in American hospitals, caused by preventable errors, is much higher, perhaps over 200,000.[12] To a great extent, the merits of the IOM Report have almost become secondary to the wide spread recognition in the United States, the United Kingdom., Canada and Australia, in particular, that the number of preventable medical errors in hospital is far too high, and that appropriate measures must be taken to address this problem.[13] In the American context, the "medical error epidemic" is laced with irony in that the U.S. tort system is very active in the acute care arena, and in addition, the hospital sector has been subjected to multiple public and private quality regulations.

The initial IOM Report, and similar analyses, has sparked considerable introspection in hospital and medical communities in the developed world. Significant efforts have gone into identifying medical errors, analyzing the causes of such errors and developing medical treatment guidelines to prevent future mistakes.[14] Practices from other industries to identify and control errors were mirrored in health care, particularly those adopted by the aviation field. Even before the IOM Report, the U.S. Joint Commission on Accreditation of Healthcare Organizations (JCAHO) had developed a

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[11] *See generally* LINDA T. KOHN ET AL. EDS., TO ERR IS HUMAN: BUILDING A SAFER HEALTHCARE SYSTEM (2000).

[12] *See generally* HEALTH GRADES, HEALTH GRADES QUALITY STUDY: PATIENT SAFETY IN AMERICAN HOSPITALS (2004), http://www.healthgrades.com/media/english/pdf/HG_Patient_Safety_Study_Final.pdf (last visited Feb 4, 2006). For an alternative view of the medical error issue, *see generally* Maxine M. Harrington, *Revisiting Medical Error: Five Years After the IOM Report, Have Reporting Systems made a measurable Difference*, 15 HEALTH MATRIX 329 (2005).

[13] *See* BRAITHWAITE, *supra* note 2, at 16-19.

[14] *See generally* Barry R. Furrow, *Medical Mistakes: Tiptoeing Toward Safety*, 3 HOUS. J. HEALTH L & POL'Y 181 (2003); Brian A. Liang, *The Adverse Event of Unaddressed Medical Error: Identifying and Filling in the Holes in the Health Care and Legal Systems*, 29 J. L. MED.& ETHICS 346 (2001).

system for identifying, voluntarily reporting, and analyzing hospital based medical errors.[15] Another private group, the National Quality Forum (NQF), endorsed 27 safety practices that should be used in applicable clinical settings to reduce the risk of harm to patients. The NQF safety practices include use of eleven recommendations for specific clinical care processes, seven recommendations for information transfer and communications, as well as recommendations for the use of physician order entry systems (CPOE), and evidence based referrals for high-risk procedures.[16]

From a regulatory standpoint, the medical error crisis lead to a variety of responses in the United States. At the national level, a series of activities occurred among a number of health care agencies motivated by a need for greater public accountability in the face of this problem: the creation of a knowledge base concerning errors and the promotion of cultural changes at the institutional level that involved considerable focus on identifying and correcting deficiencies in patient care. Federal legislation was enacted in 2005 to establish regional Patient Safety Organizations to voluntarily collect reported data on medical errors from physicians and other providers, analyze this data to discern patterns and trends, and feed the data into a national database.[17] In addition to federal activity, regional governments, states, became very active in responding to medical errors occurring in hospitals in their respective jurisdictions. By 2002, 20 states had enacted legislation mandating the reporting of adverse events as part of their hospital licensing requirements.[18] Minnesota became the first of several states to require that the list of 27 adverse events measures developed by the National Quality Forum (NQF), referred to as "never events", be reported to the Minnesota Department of Health.[19] Pennsylvania, another pioneering state in the medical error area, established a special government agency, the Patient Safety Authority, to deal with medical error problems.[20]

Interestingly enough, in the midst of policy changes and new regulatory initiatives occurring as a result of the medical error crisis, a response to these issues was crafted by the U.S. Centers for Medicare and

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[15] JCAHO, *Sentinel Event Policy and Procedures*, http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/ (last visited Jan 25, 2007).

[16] *See generally* THE NATIONAL QUALITY FORUM, SAFE PRACTICES FOR BETTER HEALTHCARE: A CONSENSUS REPORT (2003).

[17] Patient Safety and Quality Act of 2005, Pub. L. No. 109-41 (2005).

[18] *See generally* JILL ROSENTHAL & MAUREEN BOOTH, DEFINING REPORTABLE ADVERSE EVENTS: A GUIDE FOR STATES TRACKING MEDICAL ERRORS (2003), http://www.nashp.org/Files/GNL50.pdf

[19] Minnesota Medical Association, *Pawley, Hanovich, Attend Ceremonial Signing of Adverse Events Law*, http://www.mmaonline.net/News/fullstory,cfm?recNum=2807 (last visited Feb 22, 2007).

[20] Medical Care Availability and Reduction of Error (MCARE) Act, 40 Pa. Cons. Stat. Ann. §1303.303 (West 2004).

Medicaid Services (CMS), which fits into the area of new governance. More specifically, one regulatory program developed as a way to enhance medical quality and thus reduce errors, the Quality Assessment Performance Improvement (QAPI), appears by chance to mirror new governance approaches, and can be characterized as a form of management-based regulation referred to earlier in the article. Specifically, the QAPI program imposes four sets of requirements on hospitals: first, the development of an ongoing, hospital-wide program that measures reduction in medical errors; second, a clearly defined policy on supporting data to identify and measure quality; third, a priority-setting process for improvements that tracks and analyzes adverse patient events and implements preventive actions; and fourth, the implementation of quality improvement projects proportional to the scope and complexity of a given hospital's services.[21] Like the new governance model, management-based regulation, QAPI is a planning model, which allows for considerable discretion on the part of the regulated hospital to design its own program to address error problems that are particular to the institution. In keeping with new governance generally, QAPI does not abandon regulation, as it is not an open-ended control mechanism just as the regulator, CMS, does not dismiss the possibility of more prescriptive controls, should self initiated processes fail. The QAPI regulations place responsibility for program operations on hospital leadership (board, medical staff), and individual institutional programs must be evaluated as part of the CMS regulatory certification processes. Even with flexibility, major failures in designing an error reduction program could lead to termination of federal reimbursement.[22]

It is unlikely that CMS thought consciously about new governance when it designed the QAPI program, but certainly it was an effort created to spark creativity in problem identification and response. Even with considerable introspection concerning medical errors, there continues to be a need to better define the scope of these problems and to identify viable solutions, which are feasible in individual circumstances. The QAPI model, to some degree, is taken from earlier regulatory initiatives in the U.S. nursing home industry in a program that made more reimbursement available for homes that developed innovative approaches to achieving higher quality of services.[23] The major test for QAPI is whether a regulatory agency, CMS, which has a strong tradition of command and control regulation, and a culture which supports prescriptive intervention, will tolerate a new approach to regulatory control, which is far more fluid

[21] *See* Conditions of Participation for Hospital Quality Assessment and Performance Improvement, 68 Fed. Reg. 3438-39.
[22] *See id.* at 3435, 3443 and 3446.
[23] *See* BRAITHWAITE *supra* note 2, at 23.

and less defined. In fact, the greatest challenges faced by those invoking new governance approaches will be to successfully integrate such approaches into existing government regimes that are highly directive, underpinned by legal requirements which not only support, but require considerable oversight over given activities. As noted, the QAPI program discussed is structured in such a way that if the flexibility model wanes, traditional command and control mechanisms are readily available to be drawn upon, but this dependence on traditional regulation is not outside the concepts of new governance.

B. Licensure and Charity Care

New governance approaches in health care regulation should also be considered as vehicles to do more than offer regulators another avenue among a menu of traditional oversight formats. Rather, new governance avenues present possibilities for major shifts in the way regulators exercise authority over regulated entities. One possible arena to consider regulatory alterations in health regulation can be found in the case of hospital licensure. Licensure stands out as perhaps the most basic form of health care institutional control.[24] In the American context, hospitals (as well as other institutional health providers) have been subjected to state licensure requirements since the 1920s. In general, hospital licensure establishes a baseline set of requirements for entry into the acute care sector, and ensures an ongoing compliance with operational mandates. By and large licensure is not an area likely to be characterized as progressive regulation, but rather represents a fundamental exercise of state police powers directed toward fundamental public health goals. Parallel to licensure is the Medicare (elderly health care insurance run by the Centers for Medicare and Medicaid (CMS)) certification process which, through state licensing authorities, applies a separate set of standards to hospitals, known as the Conditions of Participation.[25] Perhaps the most significant level of hospital oversight is the application of private sector standards under the auspices of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

None of the three hospital control processes noted (licensure, Conditions of Participation, JCAHO accreditation) are static, but old requirements are updated and new requirements are added with changes in

[24] *See generally* Mitchell J. Wiet, *Darling v. Charleston Community Memorial Hospital and its Legacy*, 14 ANNALS OF HEALTH LAW 399 (2005); *see also* John D. Blum, *Feng Shui and the restructuring of the Hospital Corporation: A Call for Change in the Face of the medical Error Epidemic*, 14 HEALTH MATRIX 5, 13 (2003).

[25] Medicare and Medicaid Services (CMS) on Hospital Conditions of Participation (COP), 42 C.F.R. §482.1-482.66 (2006).

medicine, technology and health delivery.[26] Of the three processes, JCAHO accreditation tends to be the most flexible, allowing for some collaboration with the regulated, encompassing a goals-oriented approach, as opposed to a stringent compliance evaluation reflected in highly prescriptive government evaluations.[27] While JCAHO displays far more creativity in its approaches to hospital regulation, it is at most a quasi-public body and as such, lacks the ultimate authority of a government agency.

The core regulations, the state hospital licensing statutes, often are poorly harmonized with other legal mandates, and may reflect haphazard attempts to deal with immediate problems. More importantly, in a highly regulated sector, licensure is taken as a "given", but is not viewed as a tool to create more effective and meaningful oversight. A redesigned licensure process could, however, become a mechanism to implement creative approaches to regulation, and this maybe accomplished through application of new governance models. A responsive regulatory model could be applied to hospital licensure, combining elements of flexibility with retained, traditional baseline requirements. The retained core elements of licensure would ensure that all acute care facilities met standard operational mandates, but beyond that, regulators could negotiate additional requirements that would be both measurable and tailored to a given facility. Hospital licensure would no longer be composed of a uniform set of verifiable elements, but would be adjusted by regulators in ways that promote health needs of populations served by given institutions, and thus, contain variable mandates.

One example of how a responsive regulation model would operate in the hospital licensure context can be illustrated by reference to the current U.S. controversy concerning charity care.[28] Most American hospitals are non-profit entities, exempt from property, sales and income taxes. In order for hospitals to retain their tax exempt status, they must provide a community benefit; typically, but not exclusively measured by the provision of charity (free) care.[29] There is an ongoing controversy (manifest at local, regional and national levels of government) that is focused on allegations that hospitals are failing to provide requisite charity

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[26] *See, e.g.* Illinois Hospital Licensing Act, 210 ILCS 85/1-16 (2006) and the Georgia Regulation of Hospitals and Other Related Institutions O.C.G.A. §§ 31-7-1 to -16 (2006); both of which are reflective of changes in this area.

[27] Joint Commission on Accreditation of Hospitals, http://www.JointCommission.org/Standards /Requirements (last visited Jan 23, 2007).

[28] *See generally* Jack E. Karns, *Justifying the Non-Profit Hospital: Tax Exemption in a Competitive Market Environment*, 13 WIDENER LAW JOURNAL 383 (2004).

[29] *See* Provena Covenant Medical Center v. Illinois Department of Revenue, Ill. Cir. Ct. No. 2006MR00597, appeal filed 10/26/06. This is currently a leading case dealing with the variables needs to qualify for tax exemption in this case under state law.

care to warrant their tax exempt status. This dispute has resulted in various attempts to clarify the vagaries surrounding the law that defines community obligations. But creation of uniform standards is not only illusive, but perhaps not desirable. Rather, the public maybe better served by a new governance, responsive regulatory approach to charity care that allows regulators to negotiate with individual facilities concerning the specific community benefits that they must provide to retain their non-profit status. As licensed entities, hospitals are inherently imbued with a public health mission, and their tax status only serves to further reinforce such a mission.[30] Thus, it is reasonable for regulators to be proactive in ensuring that a hospital's charity obligations are linked to the public health needs of the communities that given hospitals serve. Use of responsive regulation in licensure affords a vehicle for state authorities to develop specific service obligations that serve public health goals in a more meaningful way. In addition, the element of public participation can be built into a responsive regulatory model to address charity care in that the constituencies can be formally involved in the administrative process that delineates explicit service obligations.

C. Cautionary Notes

Changes in the format of regulatory law, such as those proposed under the auspices of new governance, should be considered to introduce efficiencies into legal processes, with the ultimate goal of creating a more optimal match between legislation and administrative implementation. No significant alteration of the established legal order ought to be undertaken lightly, and as such, a high burden must be placed on the part of reformers to justify particular reform initiatives as being both practical and efficient. As such, changes wrought by adoption of new governance models must be critically assessed, and regulatory tests such as cost benefit analysis, as well as other impact assessments, must be performed. Changes in the regulatory order will be expensive, for both government and industry, and so there needs to be adequate resources available, as well as consensus on the part of both the regulator and the regulated that proposed changes are necessary and feasible. A major barrier in any regulatory scheme is a persistent lack of trust among key parties, which places an even greater burden on regulatory reformers to justify new initiatives.[31] New governance is not a "magic bullet" but rather offers a series of approaches to regulation less rigid than traditional models of administrative oversight, and allows for a

[30] An interesting discussion of the quasi-public nature of the licensed hospital can be found in the New Jersey Supreme Court case of Griesman v. Newcomb Hospital, 192 A. 2d 817 (N.J.1963).

[31] *See generally* Neil McLaughlin, *Trust, that valuable, fragile asset*, 32 MODERN HEALTHCARE 16 (2002).

"bottom up" process to address given problems in a creative, less prescriptive fashion. It would be naive, however, to suggest that new governance, in practice, has been a universal success. In areas such as environmental and occupational health, as well as food safety, where new governance has been adopted, problems still persist. For example, advocates of new governance have cited innovations in food safety as a model for improving oversight by adoption of responsive regulation, but serious problems in this sector continue to be uncovered, underscoring the need for government oversight.[32] Flexibility and collaboration cannot be allowed to erode the importance of meaningful oversight and new governance strategies should be pursued to enhance effectiveness of regulation, not to diminish it. Finally, most proponents of new governance don't see such reforms as a wholesale replacement of traditional regulations, but rather view them as options that can coexist with more traditional sanctions that can be invoked when collaborative processes breakdown. Still, as noted previously, regulation is a mean and not and end, and should be adjusted to better comport to the needs of an evolving delivery system.

V. CONCLUDING THOUGHTS

New governance offers exciting approaches to government efforts to more efficiently oversee, and in some cases, actually influence the directions of health services. While the discussion in this article is heavily focused on the American regulatory experience, the fact is that new governance models apply to any national health system where the rules of law are utilized to oversee public health matters. Other examples of new governance applications could be seen in the adoption of restorative justice principles to medical malpractice through the use of apology as a vehicle both to mitigate and to foster healing. On the international side of health law, new governance models could be applied to cut through the barriers which exist in getting sustainable aid and needed technologies to the developing world. In environmental health areas, the spirit of new governance exists in the context of goals-oriented regulation, evidenced by use of the precautionary principle, but could lead to greater flexibility in this context as well. While new approaches to regulation offer great potential to regulators around the globe, it is always naive to cling to a hope that changing legal processes will be easily done. In addition, it is not merely a matter of altering legal procedures to effectuate changes along the lines of new governance, but the culture of regulation, rooted in prescriptive command and control processes, must also undergo change.

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[32] *See* Coglianese & Lazer, *supra* note 5, at 697-98; *see also* Annys Shin, *Outbreak Reveals Food Safety Net's Holes*, WASHINGTON POST, Dec 11, 2006, at A01.

Even in the de facto regulatory environment demonstrated by the QAPI program, there is a built-in mechanism to revert back to more traditional quality evaluation formats, which is not so much an outgrowth of regulatory hierarchies, but rather a reactionary stance against changes. In the case of hospital licensure, a complex web of control must be swept away for a more flexible model to be implemented, and this would require great commitment on the part of regulators to go beyond the status quo. At the end of the day, what needs to be focused on in bringing about changes to regulatory systems is awareness that while legal procedures are important tools, they should not be seen as ends in and of themselves. The ultimate goals of a regulatory scheme, such as enhancing public health, must be the guiding force underpinning the adoption of legal process.

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