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# Application of Administrative Law to Health Care Reform: The Real Politik of Crossing the Quality Chasm

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# APPLICATION OF ADMINISTRATIVE LAW TO HEALTH CARE REFORM: THE REAL POLITIK OF *CROSSING THE QUALITY CHASM*

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## I. INTRODUCTION

In a well-written editorial in the British Medical Journal,<sup>2</sup> Kelley and Tucci provide insight into the deficiencies of the Institute of Medicine's book, *Crossing the Quality Chasm: A New Health Care System for the 21<sup>st</sup> Century*.<sup>3</sup> The authors observed that *Crossing the Quality Chasm* has, "received only a subdued response," especially when compared with the public outcry after the Institute of Medicine's prior publication *To Err is Human: Building a Safer Health Care System*, that reported that up to 98,000 Americans die each year from errors in our health care system.<sup>4</sup> Kelly and Tucci offer two interrelated reasons for the divergent public responses between these two Institute of Medicine publications: (1) the ambitious goals of the Institute of Medicine outlined in *Crossing the Quality Chasm* are supported only by a general outline for an action plan, and (2) the underlying complex adaptive system theory is only in a nascent stage of development.<sup>5</sup> Thus,

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<sup>2</sup>Mark A. Kelley & James M. Tucci, *Bridging the Quality Chasm: To Improve Health Care We Need to Understand the Motivations of Those Who Work In It*, 323 BRIT. MED. J. 61 (2001).

<sup>3</sup>COMMITTEE ON QUALITY HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, *CROSSING THE QUALITY CHASM: A NEW HEALTH CARE SYSTEM FOR THE 21ST CENTURY*, available at <http://www.nap.edu/catalog/10027.html> [hereinafter "CROSSING THE QUALITY CHASM"].

<sup>4</sup>COMMITTEE ON QUALITY HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH CARE SYSTEM* (Linda T. Kohn, et al. eds., 2000).

<sup>5</sup>Kelley, *supra* note 2, at 62.

Kelly and Tucci are suggesting that the generalities associated with an esoteric economic theory do not capture the public's imagination like an excessive body count.<sup>6</sup> This is, without a doubt, true. Accordingly, the authors recommend that we need to, "explore the motivations and incentives of those who provide care"<sup>7</sup> before complex adaptive system theory is allowed to become an integral part of patient care. Unfortunately, while Kelley and Tucci's conclusion is logically sound, it is likely to go unheard by governmental health care reformers because it ignores the "Real Politik" of our health care delivery system.

"Real Politik," a term in vogue at the height of the Cold War, contemplates that in practice, governmental bodies attempt to expand their spheres of influence and control by the application of economic leverage.<sup>8</sup> The federal government is clearly interested in expanding its influence into health care because of its cost.<sup>9</sup> Americans spend over one trillion dollars — forty-four percent of which is paid for by the federal government — on health care each year.<sup>10</sup> To control the cost of health care, governmental reformers proposed the Health Securities Act of 1993<sup>11</sup> as a frontal assault on the American health care system. But, to the reformers' chagrin, the Health Securities Act was dead on arrival, as much from the message as the messenger.<sup>12</sup> Undeterred by having the front door of reform barred by a plurality of interests, the reformers shifted gears to use a side entrance to legislative reform — administrative agency law. Presently, health care reformers are using administrative law to institute many of the core concepts of the Health Securities Act.

Thus, to understand the cool media response to the release of *Crossing the Quality Chasm*, which provides only a general blueprint for health care reform, the Real Politik of administrative agency law must be grasped; moreover, once the machination of agency law is grasped, it is possible to reasonably predict where health care reform is heading.

Accordingly, Part II of this Article provides an overview of federal administrative agency procedure; Part III sets forth the argument that if Institute of Medicine had desired a media event associated with the release of the *Crossing the Quality Chasm* it would have been arranged; Part IV argues that the absence of orchestrated media response was intended to facilitate the health care reform through promulgation of agency regulations. Part V examines the potential for the National Technology Transfer and Advancement Act of 1995<sup>13</sup> to facilitate the rule making of federal agencies concerned with health care. This Article concludes that *Crossing*

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<sup>6</sup>*Id.*

<sup>7</sup>*Id.*

<sup>8</sup>WEBSTER'S NEW WORLD DICTIONARY OF AMERICAN LANGUAGE (2d ed. 1974).

<sup>9</sup>Thomas R. McLean, *Implication of Patient Safety Research and Risk Managed Care*, 26 S. ILL. L.J. 227 (2002).

<sup>10</sup>Shelia Smith et al., *The Next Decade of Health Spending: A New Outlook*, 18 HEALTH AFF. 86 (1999).

<sup>11</sup>H.R. 1200, 103d Cong. (1993).

<sup>12</sup>William M. Sage, *Enterprise Liability And The Emerging Managed Health Care System*, 60 LAW & CONTEMP. PROBS. 159 (1997).

<sup>13</sup>15 U.S.C. § 3701 (2001).

the *Quality Chasm* is only the first of many public announcements of coming health care reform regulations. Thus, the “Real Politik” of *Crossing the Quality Chasm* is that all interested parties immediately need to provide comment in health care publications, before the publications form the foundation of a new federal regulation.

## II. PRACTICAL ADMINISTRATIVE LAW

Administrative agencies exist to transform general governmental policy into operational reality.<sup>14</sup> Congress has broad discretion to delegate its powers, including rulemaking, to administrative agencies.<sup>15</sup> Unless the delegation is associated with an unintelligible standard, courts will not second-guess congressional delegation of power. From a practical point of view, a standard such as, “to make regulations that are in the public’s interest,” is sufficient to be intelligible to the courts.<sup>16</sup> Once the agency receives the delegation “green light,” it is free to begin the research that will lead to a proposed regulation. In short, Congress delegates with broad-brush strokes leaving the details to be filled in later as the agency acquire expertise.<sup>17</sup>

Agencies are not unfettered. The Administrative Procedure Act (APA) requires that the administrative agency subject a proposed rule to, “notice, comment, and hearing,” as the procedure for proper promulgation.<sup>18</sup> It is through proper promulgation that a proposed rule becomes a federal regulation. In general, this means that the agency must publish the proposed regulation in the Federal Register, provide interested parties with sufficient opportunity to comment, and then consider whether the rule needs to be revised in light of the comments received.<sup>19</sup> The purpose of the public’s involvement is to allow interested parties the opportunity to object on the record to the substance of the proposed rule.<sup>20</sup> In addition, the agency must disclose any technical basis for the proposed regulation.<sup>21</sup> Because of the time and effort an agency must invest to promulgate a regulation under the APA, the agency acquires true expertise in the subject matter.

During subsequent review of an agency’s promulgation, such expertise is a benefit to the agency because the judicial system will defer to the expertise of agency, as it would any expert.<sup>22</sup> Unfortunately, promulgation of regulation also has a downside. Because promulgation of a regulation requires substantial sums of

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<sup>14</sup>JOHN H. REESE, ADMINISTRATIVE LAW PRINCIPLES AND PRACTICE 7 (1995).

<sup>15</sup>Mistretta v. United States, 488 U.S. 361 (1989).

<sup>16</sup>Nat’l Broadcasting Co. v. United States, 319 U.S. 190 (1943).

<sup>17</sup>New York Coalition of Recycling Enters. v. City of New York, 598 N.Y.S. 649, 658 (1990).

<sup>18</sup>See Administrative Procedure Act, 5 U.S.C. § 706 (2001).

<sup>19</sup>Christopher J. Nowicki, *A Step Back From Chevron? An Analysis of Kelley v. EPA*, 9 ADMIN. L. J. AM. U. 221, 230-31 (1995).

<sup>20</sup>Marathon Oil Co. v. EPA, 564 F.2d 1253 (9th Cir. 1977).

<sup>21</sup>Conn. Light & Power Co. v. Nuclear Regulatory Comm’n, 673 F.2d 525 (D.C. Cir. 1982).

<sup>22</sup>Vt. Yankee Nuclear Power Corp. v. Natural Resources Def. Council, Inc. 435 U.S. 519 (1978).

money, an administrative agency also acquires a vested interest in having that regulation become law to justify its existence.

Because a properly promulgated regulation has the force of a law, in essence the administrative agencies are a non-elected “fourth branch” to our government.<sup>23</sup> To illustrate the power of an agency to make law through the promulgation of regulations, consider the evolution of the recent final Privacy Rule regulations for electronic medical records from its Congressional inception of its final form.<sup>24</sup>

Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA)<sup>25</sup> to provide in part for the regulation of electronic medical record. The Act authorized the Secretary of Health Human Services (HHS) to develop regulations in the event that Congress did not act within two years to develop specific legislation for electronic medical records.<sup>26</sup> But following the time honored principle of general, rather than specific delegation, all that the Secretary of HHS was charged with was adopting “standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically.”<sup>27</sup> It was a pretty sure bet in August 1996, when HIPPA was passed, that Congress would not provide supplemental detail. First, because HHS already possessed expertise in health care delivery. Second, and just as important is the fact that providing political detail can create political liability.<sup>28</sup> Therefore, it is reasonable to conclude that after the HIPPA’s effective date of July 1, 1997, HHS dutifully, if only informally, began its research and drafting of the Privacy Rule.

The Department’s research must have included a review of a general outline for the management of electronic medical records published by the Institute of Medicine earlier in the decade. Many of the general principles on electronic medical records that were announced in *The Computer-Based Patient Record: An Essential Technology for Health Care*<sup>29</sup> were subsequently incorporated into the final Privacy Rule. That is, to gain the necessary expertise to provide the detailed regulations on electronic medical records, HHS turned to, and naturally adapted, the recommendation of another quasi-governmental agency. For two years after the effective date of HIPPA, HHS worked laboriously drafting the 900-page set of

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<sup>23</sup>FTC v. Ruberoid Co., 343 U.S. 470, 478 (1952) (Jackson, J., dissenting).

<sup>24</sup>Standards for Privacy of Individually Identifiable Health Information, 66 Fed. Reg. 12738-02 (Feb. 28, 2001).

<sup>25</sup>Pub. L. No. 104-91, 110 Stat. 1936 (1996).

<sup>26</sup>*Id.* at 1980.

<sup>27</sup>*Id.* at 1173.

<sup>28</sup>HIPPA when passed was it popularly known as the “Kennedy-Kassabaum Act” because it increased the portability of health care insurance — a political asset, but as the detailed onerous regulations were published, the eponymous recognition of the Act’s sponsors has faded.

<sup>29</sup>*See generally* COMMITTEE ON IMPROVING THE PATIENT RECORD, INSTITUTE OF MEDICINE, *THE COMPUTER BASED PATIENT RECORD: AN ESSENTIAL TECHNOLOGY FOR HEALTH CARE* (Richard S. Dick & Elaine B. Steen eds., 1997), available at <http://www.nap.edu/catalog/1813.html>.

regulations controlling the transmission of electronic medical records.<sup>30</sup> Ultimately, because of an extension provided by the new HHS Secretary, Tommy Thompson, HHS received over 63,000 comments on the proposed Privacy Rule.<sup>31</sup> Despite this massive public input, relatively little substantive change was made in the comprehensive Privacy Rule. Having committed two years of time adapting public information from other agencies, HHS had become (rightfully) confident of its expertise of electronic medical records. Thus, HHS was able to dismiss many comments to the proposed Privacy rule with statements like “[w]e have decided, for a number of reasons, to retain the approach as presented in the proposed rule.”<sup>32</sup>

This approach to minimizing the comments is well within the prerogative of an agency. Agencies know that their opinion carries weight because of their expertise. All experts are by nature, resistant to revising a formed opinion unless they are confronted with substantial evidence to the contrary. Agencies are no different. If the agency is challenged in court because it summarily dismissed comments, the interested party will have a difficult time prevailing against the agency because, as an expert, deference is given to the agency.<sup>33</sup> This means that to prevail against the agency judgment on what is properly included in a regulation, the interested party must show more than the agency’s interpretation of Congressional delegation as an arbitrary choice of one of several possible choices.<sup>34</sup> To prevail after the agency provides a rational basis for regulation, the opponent must provide substantial evidence that the regulation is misguided.<sup>35</sup> Thus, once proposed, as a regulation reaches the comment stage of promulgation, the judiciary is limited in the extent that it can compel the expert agency to revise a well-rationalized regulation.<sup>36</sup>

### III. THE LOW PROFILE RELEASE OF *CROSSING THE QUALITY CHASM* WAS INTENTIONAL

Like-minded health care reformers orchestrated the media feeding frenzy associated with the release of *To Err is Human*.<sup>37</sup> Although the Institute of Medicine has long been concerned with patient safety, for most of its history, it has operated out of the limelight. But, in the wake of Congress’ failure to pass the Health Security Act, concern for patient safety began to rise as horror stories of the excesses of managed care medicine increased.<sup>38</sup> In response to concerns that managed care organizations were harming patients by either the outright denial of medical

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<sup>30</sup>Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59918-01 (Nov. 3, 1999).

<sup>31</sup>Lovern, *Privacy In Spotlight’s Glare, Kennedy to Fight Proposal to Ease Disclosure Rules*, MOD. HEALTH CARE, Mar. 25, 2002, at 6.

<sup>32</sup>65 Fed. Reg. 82462, 82601 (45 CFR 160, 164) Dec. 28, 2000.

<sup>33</sup>FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

<sup>34</sup>Beth Israel Hosp. v. NLRB, 437 U.S. 483 (1978).

<sup>35</sup>Bowman Transp., Inc. v. Arkansas-Bear Freight Sys., Inc. 419 U.S. 281 (1974).

<sup>36</sup>However, sufficient bad press during the comment period may result in increased Congressional oversight.

<sup>37</sup>McLean, *supra* note 9.

<sup>38</sup>*Id.*

treatment, or alternatively by inducing physicians to provide suboptimal care, several organizations both within the government (*e.g.* Agency for Healthcare Research and Quality (AHRQ), and outside of the government (*e.g.* National Patient Safety Foundation and the National Quality Foundation), have appeared with a mission to improve patient safety. Additionally, several other governmental agencies, like the Veterans Administration and Health Care Finance Administration, are in the process of “re-inventing” themselves so that patient safety receives much greater emphasis. All of these organizations banded together with the Institute of Medicine to focus media attention on patient safety.

The evidence that these organizations are coordinating their efforts is circumstantial.<sup>39</sup> Institute of Medicine members serve in leadership positions in fledging patient safety organizations.<sup>40</sup> Such membership is not coincidental. Although the Institute of Medicine’s policy is to release its reports directly to the public, the new patient safety organizations were able to digest the Institute of Medicine’s *To Err is Human* and adopt the figures and conclusions within days. Within a week of the release of *To Err is Human*, former President Bill Clinton adopted the report’s recommendation to make the AHRQ the central agency for patient safety oversight.<sup>41</sup> As a result of the media blitzkrieg, it seemed at the time that one could hardly go more than a day without reading a newspaper article or hearing a television station advertisement for a media tabloid news story about patient safety.

The media response to the release of *To Err is Human* leaves little doubt the Institute of Medicine, and other interested governmental organizations, could have orchestrated a media frenzy associated with the release of *Crossing the Quality Chasm*. But, Kelly and Tucci are correct. The media has been strangely silent on the release of *Crossing the Quality Chasm*.<sup>42</sup> Certainly, there are newsworthy stories contained in this report. For example, the flyleaf contains the mission statement that the “Institute of Medicine, shaping the future of health” is followed by the first sentence that asserts the “American health care delivery system is in need of fundamental change.”<sup>43</sup> When one considers that *Crossing the Quality Chasm* was published a little over a year after President Clinton assured America that it had the best health care system in the world,<sup>44</sup> such radical change in our health care system should have been worth an editorial comment. Moreover, *Crossing the Quality Chasm* took notice that the Medical Expenditure Panel Survey found that fifteen medical conditions account for the majority of medical costs.<sup>45</sup> In the context of

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<sup>39</sup>*Id.*

<sup>40</sup>McLean, *supra* note 9.

<sup>41</sup>*Id.*

<sup>42</sup>*See* Kelley, *supra* note 2.

<sup>43</sup>*See* CROSSING THE QUALITY CHASM, *supra* note 3.

<sup>44</sup>President Bill Clinton, Remarks on Health Care (Dec. 7, 1999), *available at* 1999 WL 1115218.

<sup>45</sup>*See* CROSSING THE QUALITY CHASM, *supra* note 3.

*Crossing the Quality Chasm*, the inescapable conclusion is that these conditions will be the first to be subjected to new regulatory guidelines promulgated by the AHRQ.<sup>46</sup>

Given that the Institute of Medicine and other interested parties could have placed the newsworthy *Crossing the Quality Chasm* in the limelight, the absence of media attention points to an inescapable conclusion: media scrutiny of *Crossing the Quality Chasm* was unwanted. When the Health Security Act died a very public premature death,<sup>47</sup> patient care advocates and those in Congress concerned with controlling medical cost inflation learned a valuable lesson: reforming the health care system in this country would not be possible by a frontal assault characterized by the passage of a revolutionary piece of legislation. Rather, to reform the health care system, a more circumspect approach using administrative law would have to be used. But to use administrative law to reform our health care delivery system would require not only that Congress delegate to an administrative agency the charge of regulation of health care quality, but also that the designated agency be granted “lead time” (out of the limelight) to become an “expert.” This latter activity — acquiring expertise — occurs most efficiently out of the limelight.

#### IV. USING ADMINISTRATIVE LAW TO ADVANCE HEALTH CARE REFORM

The Healthcare Research and Quality Act of 1999 created the AHRQ.<sup>48</sup> Congress delegated to AHRQ the mission of enhancing “the quality, appropriateness, and effectiveness of health services through the establishment of a broad base of scientific research.”<sup>49</sup> However, as used here, the word “research” clearly contemplates cost-effective measures.<sup>50</sup> Certainly, the direction that Congress provided to AHRQ to promulgate health care quality guidelines is no more specific than the Congressional direction provided to HHS for the promulgation of regulations for electronic medical records. President Clinton’s direction was only minimally more specific in that the President charged the AHRQ with monitoring provider quality and stimulating the development of evidence-based medicine.<sup>51</sup> To facilitate the Agency’s mission, the AHRQ will receive \$25 million for safety research and another \$40 million to train individuals to become medical safety experts.<sup>52</sup> In short, Congress has delegated authority and the funds needed for the AHRQ to develop safety-driven CQI clinical guideline regulations; all that is needed is some lead time for the AHRQ to gain expertise.

Using the HIPPA timeline model as a general model for an administrative agency time line, one would predict that if the AHRQ is given two to five years of lead time to become an expert in health care delivery, AHRQ will be prepared to publish in the Federal Register a proposed set of regulations to control the “quality” of health care.

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<sup>46</sup>Thomas R. McLean, *The Institute of Medicine and the Risk Managed Care Revolution*, 96 GREATER KANSAS CITY METRO. MED. SOC’Y BULL. 16 (2001).

<sup>47</sup>Sage, *supra* note 12.

<sup>48</sup>42 U.S.C. § 299(A) (2000).

<sup>49</sup>*Id.*

<sup>50</sup>*Id.*

<sup>51</sup>See President Clinton, *supra* note 44.

<sup>52</sup>*Id.*



Thus, perhaps as early as next year, interested parties in health care quality should be prepared to provide comment on the purposed regulations. In the meantime, just as the HHS looked to the Institute of Medicine and other agencies for the knowledge necessary to become the expert in electronic medical records, one would conclude that the AHRQ has and will look to the Institute of Medicine and other agencies to acquire expertise in health care quality. The late administrator for the AHRQ, John Eisenberg was a member of the Institute of Medicine. Moreover, one would predict that just as HHS filled in the details omitted from the Institute of Medicine's *The Computer-Based Patient Record: An Essential Technology for Health Care*<sup>53</sup> to produce the comprehensive privacy rule, the AHRQ will fill-in omitted details from the Institute of Medicine's *Crossing the Quality Chasm* to produce comprehensive clinical guidelines to regulate the quality of health care. Not surprising, this is precisely where the AHRQ is today.

The "Real Politik" of AHRQ, or for that matter any agency, is that it moves from general to specific by launching "trial balloons."<sup>54</sup> If a general notice to the public does not provoke a negative response from interested parties, the agency hones the detail to an even finer level. Alternatively, if a negative response is encountered, the agency can quietly retreat and shift gears. Thus, as the AHRQ combs the data for what constitutes quality health care, the AHRQ has no desire to be micro-managed by public comment (which could trigger increased Congressional oversight). Hence, the reason that neither the Institute of Medicine, nor any other health care reform organization wishes to organize a media frenzy is because it would interfere with the AHRQ's feeling its way through politically sensitive issues. Accordingly, all that *Crossing the Quality Chasm* was intended to do was to provide general notice that fifteen common conditions (and their associated surgery interventions) were targeted for regulation.<sup>55</sup>

Since a spontaneous negative response did not follow the release of *Crossing the Quality Chasm*, the AHRQ has now moved to a more specific level. In a recent publication by the AHRQ, the agency indicated that it has refined its target for regulation to the perioperative surgical management of the fifteen conditions cited in *Crossing the Quality Chasm*.<sup>56</sup> Specifically, the AHRQ stated that "clear opportunities for research" exist for elucidating the evidence for the use of preoperative use of antibiotics, antibiotics, antithrombotic therapy and informed consent.<sup>57</sup> Once the AHRQ research has the evidence-based medical determination of what "works," a proposed regulation will be published in the Federal Register. It is to be expected that AHRQ will define the most cost-effective treatment for a particular situation as the standard of care. For example, if AHRQ identifies a

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<sup>53</sup>COMM. ON IMPROVING THE PATIENT CARE RECORD, INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCE (Richard S. Dick *et al.*, eds. 1997).

<sup>54</sup>BOB WOODWARD, MAESTRO: ALAN GREENSPAN'S FED AND THE AMERICAN ECONOMIC BOOM (James Naughton, narrator) (Simon & Schuster Audio 2000).

<sup>55</sup>CROSSING THE QUALITY CHASM, *supra* note 3, at 10.

<sup>56</sup>UNIVERSITY OF CALIFORNIA, MAKING HEALTH CARE SAFER: A CRITICAL ANALYSIS OF PATIENT SAFETY PRACTICES (Kaveh Shojania, M.D. *et al.* eds., 2000), at [www.ahrq.gov/clinic/ptsafety/](http://www.ahrq.gov/clinic/ptsafety/).

<sup>57</sup>*Id.*

(cheap) first generation cephalosporin antibiotic to be the most cost-effective treatment of post-cholecystectomy pneumonia, it would be expected that the AHRQ would propose a regulation that the standard of care for treating post-cholecystectomy pneumonia is with a first generation cephalosporin antibiotic. Failure to use a cephalosporin antibiotic, or to use more than a cephalosporin antibiotic for post-cholecystectomy pneumonia, would be deemed substandard care. Substandard care of course would provide the government with a rational basis not to provide reimbursement for such services.<sup>58</sup>

#### V. REAL POLITIK AND THE NEAR FUTURE OF AGENCY LAW

The AHRQ and other related agencies have come to realize that the National Technology Transfer and Advancement Act of 1995<sup>59</sup> (NTTAA) can facilitate promulgation of the specifics of technical regulations keeping the agency out of the limelight. Although intended for non-health care industries, NTTAA's stated purpose is "to speed the development of new products and processes by entering into cooperative research and development agreements which make available the assistance of Federal laboratories to the private sector."<sup>60</sup> Accordingly, the NTTAA directs that if a federal agency intended to develop standards for an industry, the agency "where possible [will] use of standards developed by private, consensus organizations."<sup>61</sup> The NTTAA therefore creates a win-win situation for government and private industry. The government benefits because it is able to transfer some of the costs associated with the promulgation of regulation of an industry to private enterprises,<sup>62</sup> while the private enterprises benefit by having a hand in writing the regulations that govern their operations. Thus, given that the NTTAA has been around for six years, it is not surprising that the government, as it moves from general to specific, is now quietly seeking to obtain pre-packaged specific standards from industry.<sup>63</sup> And while it is true that a governmental agency will have to provide notice that it intends to adopt a voluntary consensus organization's standards, it is not likely that agency will receive many negative comments.

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<sup>58</sup>Thomas R. McLean, *The Political Correct Language of Leadership by Example*. (Manuscript on file with the author).

<sup>59</sup>15 U.S.C. § 3701 (2001).

<sup>60</sup>*Id.*, § 3701(2)(2).

<sup>61</sup>§ 3701(12).

<sup>62</sup>*Veeck v. Southern Bldg. Code Cong. Int'l, Inc.*, 241 F.3d 398, 406 (5th Cir. 2001) (citing 63 Fed. Reg. 8545, 8554-55 (Feb. 19, 1998)). ("We believe that if code writing groups like SBCCI lose their incentives to craft and update model codes and thus cease to publish, the foreseeable outcome is that state and local governments would have to fill the void directly, resulting in increased governmental costs.").

<sup>63</sup>For example, consider the Department of Health and Human Service's call for voluntary consensus organization to step forward to help it develop guidelines for the treatment of Hepatitis. *See* Opportunity for Cooperative Research and Developmental Agreements (CRADAs) to Implement a Multicenter, Clinical Trial to Study Viral Resistance to Pegylated Interferon Therapy in Combination with Ribavirin in Patients Who Have Chronic Hepatitis C, Genotype 1, Specifically Focusing on African Americans, 66 Fed. Reg. 41252 (Aug. 7, 2001).

Against this backdrop enters the National Quality Foundation (NQF), which was formed in 1998, upon the recommendation of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.<sup>64</sup> The NQF is a non-profit organization whose membership is concerned with national health care quality improvement.<sup>65</sup> Membership is voluntary, and includes ARHQ and many of the large corporate purchasers of health care products and services. The NQF is thus precisely the type of private consensus organization stipulated by NTTAA.<sup>66</sup> In the wake of the announcement that our health care delivery system is in need of fundamental change,<sup>67</sup> Dr. Ken Kizer, Chief Executive Officer of the NQF, envisions NTTAA as a powerful weapon for "shaping the future of health."<sup>68</sup>

Specifically Dr. Kizer envisions the NQF — which he asserts is in compliance with the NTTA requirements for a "voluntary consensus organization" — is a vehicle for developing clinical guideline standards that the government will be "virtually compelled" to adopt.<sup>69</sup> In practice, under the Kizer model for health care reform, the NQF, using a consensus model with public input,<sup>70</sup> would develop and publish a clinical care standard; an example includes how many times a patient should receive percutaneous transluminal angioplasty [hereinafter "PTCA"] prior to being referred for surgical intervention.<sup>71</sup> Accordingly, this would mean that later, when the AHRQ moves from general to specific in formulating regulations on cardiac care, if the AHRQ chooses to regulate the number of PTCA a patient receives in the name of quality, if it is at all possible, the AHRQ is directed by the NTTAA to adopt the NQF's industrial driven consensus guidelines.

## VI. CONCLUSION

Kelley and Tucci's thoughtful editorial leads to a logical conclusion that a better understanding of complex adaptive system theory is required before it is applied to the field of health care.<sup>72</sup> Unfortunately, logic is not at issue with health care reform; the issue is the control of cost.

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<sup>64</sup>See <http://www.qualityforum.org>.

<sup>65</sup>*Id.*

<sup>66</sup>Telephone Interview with Elaine Powers, NQF (Sept. 12, 2001). (When the NQF was organized, it was organized specifically to function within the NTTA.).

<sup>67</sup>CROSSING THE QUALITY CHASM, *supra* note 3, at 1.

<sup>68</sup>*Id.*

<sup>69</sup>Ken Kizer, Remarks at the Cerner Millennium Health Imperative Conference, Kansas City, Mo. (Sept. 11, 2001).

<sup>70</sup>For example, the NQF invited the general public to comment on "never events" — events that should never occur in clinical medicine (*e.g.* wrong side surgery). See website of Nat'l Quality Forum, *supra* note 64.

<sup>71</sup>See Kizer, *supra* note 69. Multivessel percutaneous transluminal angioplasty (PTCA) is an expensive procedure that has a high re-application rate absent surgical intervention. At present, a patient could receive an unlimited number of PTCA and never be referred for cardiac surgery.

<sup>72</sup>See Kelley, *supra* note 2.

Having failed to pass the Health Securities Act, administrative agency law became the vehicle to implement health care reform. Agencies do not require detailed instructions to implement reform regulations; rather, the agency process intrinsically produces detail as it heads off in the general direction pointed to by congressional delegation. And while the Institute of Medicine and other interested parties could have arranged for *Crossing the Quality Chasm* to become a media frenzy, such attention would only put the AHRQ into the limelight, thereby providing a distraction to the AHRQ's bureaucracy. Operation of the AHRQ out of the limelight can only mean one thing: the AHRQ is compiling a comprehensive proposed rule that will be difficult to alter or amend even if 100,000 comments are received; or alternatively the AHRQ is planning to adopt a NQF standard that will receive minimal comment because parties concerned where involved in writing the NQF standard.

The Real Politik of administrative agency law is that if an interested party wishes to challenge a proposed regulation, it is imprudent to wait until the agency publishes the regulations and begins to accept comments to initiate a challenge to the agency's conclusions. The better strategy is to challenge future regulation while the agency is doing its research. That is, the communications that form the basis for future regulations must be scrutinized. For health care attorneys, this means that they should advise their clients to scrutinize medical opinions and documents released by any administrative agency, and to file any objections or reservations with the editors of any appropriate medical or surgical journals. Additionally, health care attorneys should be advising their clients to become members of the NQF and frequently monitor the NQF's web page for an indication of the content future regulations. Upfront negative publicity to clinical publication and NQF's activities is the best way to precipitate increase congressional oversight.<sup>73</sup>

Conversely, failure to scrutinize and criticize communications in medical reports and from the NQF will serve as a motivational force to transform general delegation language into specific regulations. Thus, unless the data in the Institute of Medicine's most recent communication on the relationship between the volume of pancreatic and esophageal resections and outcome is challenged,<sup>74</sup> one can reasonably expect that such a document could easily serve as a rational basis for the AHRQ to promulgate a regulation that restricts pancreatic and esophageal resection to a half-dozen "centers of excellence."<sup>75</sup> Having restricted pancreatic and esophageal surgery to centers of excellence, can a similar restriction be far behind for angioplasty and cardiac surgery?

In short, the Real Politik of *Crossing the Quality Chasm* is that if administrative agency recommendations and public disclosures concerning medicine are not scrutinized by the medical journal, the stage will be set for these same agencies to

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<sup>73</sup>INSTITUTE OF MEDICINE, INFORMATION TRADING: HOW INFORMATION INFLUENCES THE HEALTH POLICY PROCESS (Marion E. Lewin & Elise Lipoff eds., 1977), available at <http://www.nap.edu/openbook/0309057930/html>.

<sup>74</sup>MARIA HEWITT & DIANA PETITTI, INTERPRETING THE VOLUME-OUTCOME RELATIONSHIP IN THE CONTEXT OF CANCER CARE (2001).

<sup>75</sup>Thomas R. McLean, *Cybersurgeon: Innovation or a Means of Closing Community Hospitals and Displacing Physicians*, 20 J. MARSHALL COMPUTER AND INFORMATION TECHNOLOGY LAW 495 (2002).

promulgate regulations that will inexorably and unequivocally limit and restrict the physician's autonomy.