May 16, 2007

Dear Congressman Paul,

We urge you to support our key points:

1. extension of whistleblower protection to all physicians
2. for a GAO investigation of bad faith peer review
3. for a Congressional hearing into hospital bad faith
4. for enforcement of all laws and regulations, including CMS and JCAHO regulations, that require standard due process in medicine

For your convenience, attached please find:

- "How to Get rid of a 'disruptive' physician" excerpts from, http://www.allianceforpatientsafety.org/howto.php

I would also like to draw your attention to the following documents:

- "How to Protect Physician Whistleblower – Patient Advocates – From Retaliation to Benefit Patients."

  A legal analysis of existing state and federal laws regarding significant shortcomings, loopholes … and suggested remedies for your consideration.

  http://www.allianceforpatientsafety.org/protect.pdf

- "White Paper for Patient Safety"

  In search of the "BLACK BOX" for a reliable and cost-effective quality control of the delivery of medical care

  http://www.allianceforpatientsafety.org/blackbox.pdf

Respectfully submitted,

Gil Mileikowsky, M.D.

Washington Whistleblower Week Coalition Member

Since Dr. Mileikowsky was or is neither a patient nor an employee of ETRMC, he is not part of the class protected by this statute. Accordingly, this code section cannot form the basis for a whistle blower claim.

Your reliance on *Business and Professions Code* § 2056 is similarly misplaced. That code section provides in pertinent part that:

> "It is the public policy of the State of California that a physician and surgeon be encouraged to advocate for medically appropriate health care for his or her patients. For purposes of this section "to advocate for medically appropriate health care" means to appeal a payor's decision to deny payment . . .or to protest a decision, policy, or practice that the physician . . .reasonably believes impairs the physician's ability to provide medically appropriate health care to his or her patients." [Emphasis added]

As expressly stated in the statute, the policy seeks to codify the holding of *Wickline v. State of California, 192 Cal.App.2d 1630.* Thus, the statute seeks to protect physicians whose employment or contract is terminated in retaliation for the advocacy of appropriate medical care of his or her patients. The classic example is a doctor who is terminated for performing tests and procedures which he or she deems medically necessary, but which the payor deems too costly.

There has never been an allegation -- nor can you concoct one at this late date -- that Dr. Mileikowsky was retaliated against for advocating for medically appropriate health care for his patients or protesting a decision, policy or practice that impaired his ability to provide appropriate care to his patients. Rather, Dr. Mileikowsky has previously argued that he was retaliated against for raising quality of care concerns regarding other physicians on staff at ETRMC. Accordingly, Dr.

200. Your contention that "[t]he retaliatory actions are in violation of public policy of the State of California, including *Health & Safety Code* §1278.5 and *Business & Professions Code* § 2056, aimed at protecting the health and safety of the general public by providing members of the public and health care providers protection from retaliation for engaging in reporting violations of statutes" is flat out wrong. The statutes referred to – *Health and Safety Code* § 1278.5 and *Business and Professions Code* § 2056 – do not provide a statutory basis for a whistle-blower claim. *Health and Safety Code* § 1278.5 provides, in pertinent part that:

> "No health facility shall discriminate or retaliate in any manner against any patient or employee of the health facility because that patient or employee, or any other person, has presented a grievance or complaint, or has initiated or cooperated in any investigation or proceeding of any governmental entity relating to the care, services, or conditions of that facility." [Emphasis added]

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Physician Peer Review Reform –
Peoria, IL Physician Whistleblower Dr. Gil Mileikowsky

The Need for Reform: *The Health Care Quality Improvement Act (HCQIA) seeks to "improve the quality of medical care" through "effective professional peer review." Unfortunately, a large number of hospitals have learned to exploit the unqualified immunity provisions in the peer review process to punish physician whistleblowers who speak out against hospital practices that threaten the safety of patients and the quality of medical care at the institution. Victims of "sham" or "bad faith" peer review rarely gain access to any independent due process proceeding to challenge this unique form of retaliation, which in many cases results in the end of their career as a physician. Bad faith peer review against one physician can and does persuade hundreds of others to remain silent rather than advocate on behalf of their patients. When doctors are silenced, it is the American public, as medical patients, that suffers. Congress needs to extend whistleblower protections to all physicians so that when they speak out in defense of our right to excellent medical care, they are able to defend themselves.*

The story of Dr. Gil Mileikowsky:

- **June 12, 2000, during a routine OB/GYN department meeting, at Encino-Tarzana Regional Medical Center (ETRMC), the topic on the agenda was "what criteria should trigger review of a medical record?" I suggested that any record of a patient who was readmitted within 30 days after a surgery should be reviewed for possible complications. The department turned down my proposal.**
- **June 13, 2000, I am shocked to learn that physicians who are significant income providers at ETRMC escape the scrutiny of peer-review.**
- **June 14, 2000, I report my findings to the IMQ, DHHS and JCAHO.**
- **June 19, 2000, I became a designated expert in a battery and medical malpractice case against ETRMC due to the removal of both fallopian tubes of a patient without her consent.**
- **June 23, 2000, the CEO of ETRMC required that I be escorted by his security guards while on the hospital premises.**
- **November 13, 2000, I provided the FBI, healthcare fraud division, sensitive information regarding the loss and mishandling of embryos, eggs and sperms in the in-vitro fertilization laboratory of ETRMC.**
- **November 16, 2000, my clinical privileges were summarily suspended, by ETRMC, without any good cause, for non-existent, alleged "imminent danger."**
- **For a more detailed and updated history, please see, "How to get rid of a disruptive physician," at: http://www.allianceforpatientsafety.org/howto.php .**

How to Get Rid of a "Disruptive" Physician

1. **Failure to provide the physician a reappointment application**

2. **Changing the Bylaws of the Hospital**
   - Include measures against "disruptive" physicians.
   - Waive due process rights.
   - Sanctions for reporting hospital misconduct to outside agencies.

3. **Make the Physician's Life as Miserable as Possible,**

   e.g. "escort" by hospital security guards

4. **"Go for the Jugular" - Suspend summarily physician's clinical privileges under the false pretense of "imminent danger."**

   This triggers automatic reporting of physician to state medical boards, National Practitioner Data Bank, malpractice insurance carriers, medical insurance carriers, … .

   The association of a summary suspension with the required "exhaustion of administrative remedies," protracted over many years, assures the demise of the physician's career, without any possible court's intervention. The hospital wins by attrition.

5. **Use State Medical Board as a proxy to suspend physician's license**

6. **Character Assasination and use of deceptive language.**

   The physician is **"crazy,"** a **"drug addict," "impaired," "incompetent,"** suffers from **"organic brain disorder"** …

   The physician is accused of "**assault**"…

7. **Expulsion from Medical Societies**

8. **Initiate frivolous lawsuits against the physician**

   e.g. SLAPP (Strategic Lawsuit against Public Policy)

9. **Attempt to physically injure and intimidate the physician and family**

For details see: http://www.allianceforpatientsafety.org/howto.php

HOW TO PROTECT PHYSICIAN

WHISTLEBLOWER – PATIENT ADVOCATES –

FROM RETALIATION TO BENEFIT PATIENTS

– a legal analysis regarding Summary Suspension, Retaliation, Peer Review and Remedies,

by Dr. Gil Mileikowsky, MD and Bartholomew Lee, Attorney at Law.*
Correspondence is invited: blee@slksf.com.

* Member of the California Bar, of counsel, Spiegel Liao & Kagay, San Francisco, California. Dr. Mileikowsky is a client of the firm. The views expressed herein are ours and not those of the firm, its partners or its counsel. We are grateful to Dr. Nick Yaqub, also a client of the firm, for valuable insight and analysis but the views expressed herein are not necessarily his either.

INTRODUCTION – THE OVERRIDING PUBLIC INTEREST IN SAVING LIVES:

More than half a million people have died in a recent three year period as a result of medical error and complications in the United States.[1] The World Health Organization (WHO) and others say that American health care ranks low among the nations – third-world care at twice the cost, in effect. The RAND Corporation finds: "all adults ...are at risk for receiving poor health care, no matter where they live; why, where and from whom they seek care; or what their race, gender or financial status is."[2] It is, however, unlikely that the situation will improve by itself. Physicians who try to diminish patient risk and improve patient care and safety are often targeted for retaliation. The integrity of the House of Medicine is thus at risk, as is health care itself. The following proposals to counter, limit and deter retaliation will decrease overall costs. [3]

It is a paradox of modern American medicine that patients don't get what is paid for, quality care. The Health Care Quality Improvement Act[4] and substituted state legislation has failed to protect patients and prejudices their safety.

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[1] *Patient Safety in American Hospitals*; HealthGrades Quality Study, July 2004 at p. 1; http://www.healthgrades.com/media/english/pdf/HG_Patient_Safety_Study_Final.pdf .

[2] See: *The First National Report Card on Quality of Health Care in America* by the Rand Corporation at p. 1; http://www.rand.org/pubs/research_briefs/2006/RAND_RB9053-2.pdf .

[3] See the diagrams in the appendix on the economic impact of lack or patient safety.

[4] 42 U.S.C. §11101 *et seq.*, the Health Care Quality Improvement Act of 1986 (HCQIA) as amended; 45 C.F.R. §60.1 *et seq.* (2003).

THE PROBLEM: PATIENT SAFETY ADVOCACY RISKS IMMEDIATE PROFESSIONAL DESTRUCTION:

"***A lie can travel halfway round the world while the truth is putting on its shoes***," said Mark Twain.

Physicians who speak out can suffer the irreversible defamation of a public report of accusation alone, in the context of hospital discipline of physicians. These physicians may or may not have done anything wrong, and may well have simply done too many things right for the comfort of some. Protecting physician patient-safety advocates from retaliatory discipline is essential to improve the quality of delivery of care.[5] Physicians who advocate for patients' safety must be protected from institutional retaliation, for the sake of the patients as well as the physicians. As Harvard Professor Alan Dershowitz stated: "Physicians who are entrusted with the care of their patients can see their professional careers destroyed if they dare to challenge a hospital's practices. When a 'whistleblowing' physician is retaliated against, it threatens not only the physician's livelihood, but the care of all patients. This ... affects every patient and potential

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[5] Many physicians have reportedly suffered such retaliation. See http://www.allianceforpatientsafety.org/retaliation.php for specifics. One type of retaliation follows assistance to a patient suing for malpractice. A paradigm case, now forty years old, is *Rosner v. Eden Township Hospital District,* 58 Cal.2d 592, 375 P.2d 431, 25 Cal.Rptr. 551, 599 (1962): "Dr. Rosner opposed election to the board of directors of a slate of candidates endorsed by members of the medical staff and that he has apparently testified for plaintiffs in malpractice cases." The common law has long provided witness immunity, perjury excepted, but that salutary doctrine has eluded the administrators of physician discipline and peer review. A set of suggested revisions by the California Medical Association to a pending bill in the California legislature, AB 632, could protect physicians who testify as patient advocates. It is such testimony that often provokes retaliation, which is ironic because such testimony is public participation in official proceedings. A communication to a hospital or medical staff about a practitioner enjoys a qualified immunity: *Hassan v. Mercy American River Hospital* (2003) 31 Cal. 4th 709.

patient in America." [6] The chilling effect on physicians resurrects the old Code of Silence that formerly frustrated so many meritorious medical malpractice cases.

Unfortunately for patients, the old proverb "the way to Hell is paved with good intentions" applies. This is so because the presumably good intentions behind laws regulating medical practice have been defeated by conflicting economic interests. According to extensive research by Harvard's Professor Lucian Leape,[7] it is not in any hospital's best economic interest to reduce errors and complications He notes that there are no warrantees in medical care and he reports "… perversely, under most forms of payment, healthcare professionals receive a premium for defective products, physicians and hospitals can bill for the additional services that are needed when patients are injured by their mistakes." Inasmuch as hospitals profit from high-cost, high-complication bad medicine they have every incentive to encourage it, making more than enough money to pay premiums for malpractice insurance, at most a nuisance. Persistent bad medicine is encouraged all the more by retaliation against those who oppose it, especially because effective good faith peer review that reduces errors and complications would diminish hospital revenues.[8] In the present environment, dollar signs trump patients' vital signs.

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[6] From a 2005 statement by Prof. Dershowitz's office, reported by the Association of American Physicians and Surgeons, http://www.aapsonline.org/press/nr-12-20-2005.php .

[7] Leape and Berwick, *Five Years After* To Err Is Human – *What Have We Learned*, Journal of the American Medical Association, (JAMA, 2005; 293:2384-2390) (Vo. 293, No. 19, May 18, 2005 "Special Communication").

[8] See appendix of simplified diagrams; further research is suggested to advance the policy goal of effective and never retaliatory peer review to promote better patient care. The background inference is: Ineffective physician peer review promotes bad medical care by immunizing it from remedy, and frustrates good medical care by hampering better medical practices and punishing physicians who advocate better patient care.

"Retaliation" is wrongful in many ways, on many levels and on various legal grounds, including its violation of Equal Protection of the Laws and of Due Process of Law. As one model of public protection by way of proscription of retaliation, the California Business and Professionals Code protects physicians against retaliation with respect to insurance companies, and medical groups.[9] This does not yet apply to hospitals that suspend or revoke privileges of physicians who are not employees.[10] It is both ironic and unjust that the members of the learned professions of medicine, who enjoy mere "privileges" at hospitals, have less protection as patient advocates than any employee including orderlies and night custodial staff, as valuable and necessary as their labors may be.

A summary suspension of a physician from practice in a hospital is just that: summary, without any process at all in which the physician can participate.[11] A registered report of a

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[9] This statute applies not just to insurance companies, but to anyone with the power to penalize a physician *and* the legal capacity to conspire to do so: *Khajavi v. Feather River Anesthesia Medical Group* (2000) 84 Cal.App.4th 32, 100 Cal.Rptr.2d 627. See, *e.g.*, California Business and Professions Code §2056 subdivision (c): "The application and rendering by any person of a decision to terminate an employment or other contractual relationship with, or otherwise penalize, a physician and surgeon principally for advocating for medically appropriate health care ... violates the public policy of this state. No person shall terminate, retaliate against, or otherwise penalize a physician and surgeon for that advocacy, nor shall any person prohibit, restrict, or in any way discourage a physician and surgeon from communicating to a patient information in furtherance of medically appropriate health care." See B. & P. C. §510 to the same effect. Amendments are pending to enlarge the retaliation protections to cover physicians with privileges, but without providing private causes of action to them beyond immediate losses.

[10] Hospitals often employ some specialized physicians, and related organizations (in California often denominated "foundations") may employ "hospitalist" physicians, but most physicians admitting patients into hospitals are not employees. According to hospital industry lawyers protections are available to employees only.

[11] And when a physician can participate, California law permits the hospital by-laws to deny legal representation in the proceedings. The California governor vetoed the predecessor

summary suspension of a physician ends that physician's career. The physician is condemned before any hearing is even initiated. This is professional capital punishment before trial.[12]

Once a hospital reports a physician's summary suspension to a state medical board or agency, it creates an avalanche effect by mandatory reporting to the National Practitioners Data Bank, (NPDB). Other hospitals will then deny that physician's clinical privileges as well, followed by suspension of medical liability insurance coverage and preclusion of participation with medical insurance providers. Moreover, there is no penalty for a false report and no private judicial redress available, unlike for example a private libel. Making the problem worse, there is no administrative remedy for a state Medical Board's continuing to post an accusation which that Board has itself found to be unfounded.

California statute (SB 2565) in part because it "would mandate legal representation" (veto letter September 30, 1988). Accused felons have more rights in this regard: *Gideon v. Wainright* (1963) 372 U.S. 375, and Anthony Lewis, GIDEON'S TRUMPET (Random House, 1964). Hearing officers are, however healthcare lawyers, and lawyers and doctors think differently, leading to challenges for unrepresented physicians. See Martin J. Stillman, MD, JD, *A Difference of Degree*, JAMA 2003;290:1135-1136, Journal of the American Medical Association, Vol. 290, No. 9, Sept. 3, 2003 pps 1135-36: "The way each [professional education] shapes one's thinking and approach to problem solving helps to account for a principal difference in how physicians and lawyers deal with their working environment. Specifically, physicians find comfort in a world of definites, while lawyers feel at ease with indefinites." See also: Anon., *Lawyerly Comments*: "We [physicians] dislike the adversarial system because we have no data to convince us that it results in truth finding. Our entire orientation focuses on truth finding. This cultural chasm likely cannot be crossed. Our training emphasizes the difference. Our subcultures make us distrust the other side..." http:/medrants.com/archives/2005/03/18/lawyerly-comments/.

[12] "'No, no!' said the Queen. 'Sentence first--verdict afterwards.' " Lewis Carroll, ALICE'S ADVENTURES IN WONDERLAND (1865) ch. XII, Alice's Evidence, cited and quoted in *People v. Casillas* (2001) 92 Cal.App.4th 171, 111 Cal.Rptr.2d 651, 658.

The goal to be achieved, immediately lest it become meaningless, is “name-clearing” of the physician advocate, besmirched and tainted by suspension or worse. This is a matter of substantive and not procedural due process of law. Unless a physician can prevent the professional libel of a public report of the summary suspension, other remedies for retaliation are for all practical purposes moot, too late and ineffective. "Substantive" due process in economic matters is much disfavored since about 1905. On the other hand, protection of many constitutional rights other than property rights amounts to substantive due process in disguise. The notion of a substantive right to protect one’s good name is implemented by the procedure of a "name-clearing hearing." It is well established in a leading California case that a professional has a liberty interest in his professional reputation (name) that is distinct and separate from property interest in his medical license.[13]

The California Supreme Court ruled with respect to the California Constitution: "It is clear that the due process clause of article I, section 7(a) is self-executing, and that even without any effectuating legislation, all branches of government are required to comply with its terms. Furthermore, it also is clear that, like many other constitutional provisions, this section supports an action, brought by a private plaintiff against a proper defendant, for declaratory relief or for

[13] *Katzberg v. Regents of University of California* (2002) 29 Cal.4th 300, 305 (application of the California Due Process Clause, mandamus relief available under Code of Civil Procedure §1085 but not money damages) (*Katzberg*); *Gray v. Superior Court* (2005) 125 Cal.App.4th 629, 637 (*Gray*).

injunction.... "[14] One's good name is a liberty interest and substantive interest, and the law protects liberty interests more than property interests.[15]

In this case, a professor of medicine at a University of California medical school and Chair of its Department of Radiology was investigated for alleged misappropriation of funds. At the conclusion of investigation the University announced that it initiated "appropriate personnel actions," but did not name any specific employee. The professor was then removed as the Chair, but remained tenured at the medical school and a staff physician at its medical center. The California Supreme Court held that "[a]lthough the department chairmanship was an at-will position, terminable without cause at the discretion of the chancellor of the ... campus (and hence plaintiff concedes that he had no due process *property* right to that position), it is well established that an at-will [public] employee's *liberty* interests are deprived when his discharge is accompanied by charges that might seriously damage his standing and associations in his community or impose[ ] on him a stigma or other disability that foreclose[s] his freedom to take advantage of other employment opportunities." [16]

To establish the right to a name-clearing hearing a petitioner " ... must first establish that the due process clause applies by showing a protected liberty or property interest."[17] A liberty

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[14] The court here cites: *Skelly v. State Personnel Board* (1975) 15 Cal.3d 194 [124 Cal.Rptr. 14, 539 P.2d 774 – holding that the Due Process Clause controls physician termination (Civil Service)]; Friesen, State Constitutional Law: Litigating Individual Rights, Claims, and Defenses (2d ed. 1996) 7-5(a), pp. 416-418. *(Katzberg*, 29 Cal.4th at 3007).

[15] *Santa Monica Beach, Ltd. v. Super. Ct.* (1999) 19 Cal.4th 952, 973 fn.4; *Brown v. Los Angeles County* (2002) 102 Cal.App.4th 155, 169.

[16] *Katzberg* at 305, italics original, internal quotations omitted.

[17] *Gray*, *supra*, 125 Cal. App.4th at 637, internal quotation omitted.

interest is shown if "the accuracy of the charge is contested, there is some public disclosure of the charge, and it is made in connection with the [petitioner]." Thus the liberty interest a physician has in his or her good name justifies an immediate opportunity for at least a temporary restraining order, followed by injunctive relief, against at least registration or publication of a summary or otherwise unadjudicated suspension.

THE LAW TODAY FAVORS BAD MEDICINE:

Once a hospital hearing to test a summary suspension commences, the administrative process controls the suspended physician. Due to the "doctrine of exhaustion of administrative remedies" no court will intervene to prevent administrative dissemination of the defamation of the report of the summary suspension, even though there has been no adverse finding or adjudication. "Exhaustion of administrative remedies" usually means exhaustion of physician resources, in litigation and its antecedents, especially inasmuch as the physician cannot practice medicine.

Furthermore, due to the abuse by hospitals of that doctrine, hospitals can prolong that administrative process with many delays, *e.g.*, by an ostensibly favorable ruling of the hospital's appeal board granting yet another, new "hearing" to the still suspended physician.[18] That is a most effective strategy, at worst malicious prosecution, at best "good intentions gone awry," to exhaust the physician as an adversary emotionally, financially and physically. Hence, the hospital wins by attrition before any litigation is even possible.

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[18] *United States v. Antelope,* 395 F.3d 1128, 1133, (9 Cir., 2005) disapproves of legal proceedings that look " ... like a never-ending loop tape..."

In the end, the physician's "exhaustion of administrative remedies" may be futile.[19] It all too often ends up with a final blow by the governing board of the hospital (even if members of that board may believe that this physician is innocent). This is so, because a ruling by the governing board in favor of the physician, would open the door to claims for monetary damages for the physician against the hospital. The board in its perceived fiduciary responsibility will wish to prevent such a financial loss.[20] The hospital simply must bury its mistake,[21] and take advantage of the reluctance of judges to substitute judgment for medical professionals in staff matters.[22] Moreover, a physician who can get to court generally at most wins a remand to the administering hospital, for yet another round of hearings.

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[19] And that exhaustion must await the end of all administrative proceedings, whatever the risk of prejudice; see, *e.g.*, *Eight Unnamed Physicians v. Medical Executive Committee [etc.]* (May 2, 2007) – Cal. App. 3rd –, 2007 WL 1272062, 2007 CDOS 4863.

[20] Such a board is arguably disqualified by this conflict of interest under such cases as *Gibson v. Berryhill* 411 U.S. 564, 570-71, 577 (U.S., 1973) deriving from Lord Coke's decision on the financial conflict of a disciplining London medical society in *Dr. Bonham's case,* 8 Coke's Reports 107a, 114a C.P. 1610 (Court of Common Pleas, 1610 [AD]. But see *Weinberg*, *infra*, note.

[21] An example may be *Weinberg v. Cedars Sinai Medical Center*, 119 Cal.App.4th 1098, 15 Cal.Rptr.3d 6 (2004), in which the Court of Appeal, by Curry, J., held that:
(1) as matter of first impression, board's decision was subject to deferential judicial review;
(2) board accorded requisite great weight to recommendation of peer review committee;
(3) "rule of necessity" precluded claim that board was structurally biased against physician;
(4) hospital governing bodies are authorized by statute to act in all peer review proceedings; and
(5) board's contact with chief of staff was authorized by medical staff's constitution.

[22] In California, *Westlake Community Hosp. v. Superior Court* (1976) 17 Cal.3d 465, 482-486 requires successful writ proceedings before damages claims. See the unpublished opinion in *O'Meara v. Palomar-Pomerado Health System* (2007), 2007 WL 731376 (Cal.App. 4th Dist.) for an application of this rule.

When it is understood that hospitals' attorneys drafted the amended federal Health Care Quality Improvement Act (HCQIA – 1989), the insertion of a quasi-judicial immunity provision can also be explained.[23] The effect if not the object was not so much protection of physician participants in good faith peer review; rather it was the perhaps unintended consequence of protection of hospitals that sponsor bad faith peer review. Hence, only very few injured physicians in the last 20 years have been able to get past the twin peaks of judicial deference to medical prosecutors and administrators and immunity for the complicit as well as the innocent.

As if this were not enough, the HCQIA also provides that a peer review body's failure to meet the conditions described in the law does not constitute failure to meet the applicable standards. In other words, failure to comply with this particular law is not a violation of this particular law.[24] Such a caveat sacrifices the health care quality improvement spirit of the law by gutting the letter of the law. In effect, the hospitals' lawyers' lobbying has loaded the dice.

The public cannot expect this process to be either fair or reasonable. An objective observer could join advocates [25] in concluding that at this time, the "peer review" disciplinary hearing process is rigged to a point way beyond any "stacked deck" of cards.

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[23] "Pittsburgh [Penn.] lawyer John Horty, who is nationally known for his work on hospital legal issues, said the immunity provision ...came out of discussions he'd had with [two members of Congress]." Steve Twedt, *Rules of Fair Play Don't Always Apply,* from: Post-Gazette.com, "the interactive edition of the Pittsburgh Post Gazette" October 27, 2003.

[24] "A professional review body's failure to meet the conditions described in this subsection shall not, in itself, constitute failure to meet the standards of subsection (a)(3) of this section." 42 U.S.C. § 11112(b)(3) but *compare* Lewis Carroll, ALICE'S ADVENTURES IN WONDERLAND (1865), cited note, *supra.*

[25] See, *e.g.*, D. Townsend (JD), *Hospital Peer Review Is a Kangaroo Court*, Medical Economics, Feb. 7, 2000. http://www.memag.com/memag/article/articleDetail.jsp?id=122302 .

Ironically, bad physicians are rarely subject to such malicious prosecution. This is so because they are often significant income providers to the hospital and thus enjoy the protection of a hospital more concerned with revenues than patient well-being. This was the case in Redding, California for two heart doctors who did hundreds of sometimes fatal heart procedures, utterly unneeded, and full of risk.[26] All monitoring and inspection by several agencies failed to detect this enormity. When hospital managements, closest to the problems, are compensated only in proportion to revenue growth, patient safety suffers.

Often bad physicians, without the leverage of big revenue, simply agree to leave the hospital, provided the hospital does not report them to the state medical board, thereby minimizing its own exposures. They thus evade the "radar screen" of mandatory reporting. The public is not protected. The reporting system tells of summary suspensions of even outstanding physicians without adjudications, but cannot report cover-ups. Thus, the goals of the Health Care Quality Improvement Act are undercut by hospitals' economic conflicts of interest. Even motivated patients cannot get undistorted information about physicians.

Policy-makers, law-makers, courts, legislative staffs, federal and state agencies, employers, unions, and experts responsible for drafting public healthcare law appear not to grasp Professor Leape's point. The healthcare costs explosion will continue to erode the quality of delivery of medical care in America as long as bad medicine is lucrative. It is thus all the more

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[26] Stephen Klaidman, CORONARY – A TRUE STORY OF MEDICINE GONE AWRY (Scribner, New York, 2007). See also Melissa Davis, *Tenet Tangles with California Blue Cross,* from TheStreet.com, Nov. 4, 2003 regarding unneeded (60%) and expensive heart surgeries in Tenet hospitals. http://www.thestreet.com/_yahoo/stocks/melissadavid/10124365.html. Tenable damages allegations in the subsequent Redding litigations exceeded one billion dollars.

important, as a counter-force, to provide effective protection for all physicians and healthcare providers who show that they care about patient safety by standing up for it. Advocacy for patient safety is to be encouraged, not punished. These health care professionals are "whistleblowers," a legal term that well describes them as the people who call attention to wrongdoing. They are to be protected from the often inevitable retaliation against them. That retaliation, usually beginning with a summary suspension, destroys them professionally and compromises patient care deeply. Such protection is in the best interest of patients, the economy, and ultimately it is to the benefit of the many excellent physicians and the "House of Medicine" itself.

Remedies Proposed:

Although private redress can provide deterrents to retaliation, as discussed below, it is often too little, too late. An immediate resort to the judicial process of the *ex-parte* temporary restraining order to review a summary suspension would be more effective, followed by substantive litigation if need be. One model appears from administrative practice: in California, its Medical Board may summarily suspend a physician from all medical practice. The device is an Interim Order of Suspension (IOS). Such an order may, however, be challenged immediately in court, and a stay obtained.[27] Inasmuch as a summary suspension by a hospital quickly results in equivalently draconian effects on a physician's practice, an equivalently swift and sure remedy is only fair.

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[27] *Silva v. Superior Court (Heerhartz)* (1993) 14 Cal.App.4th 562, 17 Cal.Rptr.2d 577.

Thus, statute could and should provide for a way for a summarily suspended physician to obtain the judicial redress of an immediate stay of the suspension, or at least any report to the medical board of it, and a stay of the medical board making any report of the suspension until after a final and adverse adjudication. This is the necessary procedural vehicle to prevent effective retaliation. The courts may be relied upon to deny such immediate relief to any physician who, by reason of impairment or otherwise, does present any danger to the public. The career-ending report of a summary suspension should not be the unreviewable decision of an adversary hospital, but rather follow only a neutral adjudication.

PROPOSED STATUTORY AMENDMENTS TO DETER HOSPITAL RETALIATION:

Two initial ways to protect physicians whistleblowers could harness existing means of redress, to facilitate immediate judicial relief as well as ultimate remedy. One is to deny wrongdoers a shield under Health Care Quality Improvement Act HCQIA (1989). The second is to provide physician advocates a sword under the Civil Rights Act (1872).[28]

1) The shield is removed by an amendment to the HCQIA: "Retaliation against a physician or other health-care provider for advocacy for health care quality improvement, including testimony, is not immune, under this Act or any state law, to private judicial redress by

[28] The requisite "color of law" appears, hence the Equal Protection and Due Process Clauses are both enforceable by private actions for damages and attorneys' fees under the federal Civil Rights Act, 42 U.S.C. §§ 1981 *et seq.* That "color" appears because hospitals in California govern themselves with respect to peer review by way of "official proceedings" required by law whether they are public or private: *Kibler v. Northern Inyo County Local Hosp. Dist.* (2006) 39 Cal.4th 192, 138 P.3d 193, 46 Cal.Rptr.3d 41. Under federal law (Medicare) hospitals must afford peer review as a Conditions of Participation whether they are public or private.

way of damages and injunctive relief, and attorneys' fees." Immunity is the doctrine that precludes private redress irrespective of wrongdoing; judges for example, enjoy civil immunity, although they can be prosecuted criminally, impeached, or disciplined. Physicians on peer review disciplinary panels enjoy civil immunity under HCQIA.

2) The sword is provided by an amendment to the Civil Rights Act, §1983: "Retaliation, against a physician or other health-care provider for advocacy, including testimony, for health care quality improvement, by or in any institution that is governed by HCQIA or related state law, or funded directly or indirectly by the United States, is a denial of due process of law and equal protection of the laws, for which private judicial redress by way of monetary damages for all injury, and injunctive relief, and attorneys' fees, shall be available under this Act, notwithstanding any post-deprivation administrative remedy or any requirement of exhaustion of remedies." This amendment provides judicial redress for deprivation of the substantive right to speak out, testify and act in the pubic interest free of retaliation.

3) In California, amendment to the Unruh Civil Rights Act, Civil Code §51, can also provide a sword: "Retaliation by any person, organization, healthcare institution or the like, that is governed California law such as the Business and Professions Code, the Health and Safety Code, and the like, or funded in whole or in part, directly or indirectly, by the State of California or any of its subdivisions, districts or the like, against a physician-advocate or any other health care professional for advocacy, including testimony, for health care quality improvement, is a denial of equality before the law and due process of law, as they are guaranteed by the Constitution of this state, for which private judicial redress by way of monetary damages for all injury, and injunctive relief, and attorneys' fees, shall be available under this Act,

notwithstanding any post-deprivation administrative remedy or any requirement of exhaustion of remedies and without application of any provision of law respecting strategic litigation against public participation." This amendment[29] also provides judicial redress, under California law, for deprivation of the substantive right to speak out, testify and act in the pubic interest free of retaliation.

4) Another avenue may effect better health care by means of deterrence. Enforcement of the criminal law has as one of its primary purposes deterrence, but it fails for it apparent near-random impact, compromised by implicit political considerations, delay, and leniency for the white-collared. Private enforcement, on the other hand, is distributed widely, not centralized, promoted by private incentives such as treble damages, and highly effective. An example is the treble damage action of the Clayton Antitrust Act[30] for violations of the earlier Sherman Antitrust Act.[31]

Inasmuch as so much of the revenue of the hospital industry comes from the federal government (*e.g.*, Medicare, Medicaid), systemic improvements in such federally funded care will also benefit all others receiving care from the industry. An amendment to the False Claims

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[29] The last clause of which is necessitated in California by the *Kibler* case, *supra*, holding that inasmuch as peer review proceedings are all official proceedings, California's prohibition of strategic litigation against public participation (its Anti-SLAPP law) comes into play. This law, when invoked, requires proof at the level of a preliminary injunction to proceed beyond the complaint stage (without discovery) and raises another barrier to relief against bad faith peer review. Retaliation in the absence of administrative review is directly actionable: *O'Meara v. Palomar-Pomerado Health System* (2007), 2007 WL 731376 (unpublished, Cal.App. 4th Dist.) cited note *supra*.

[30] 15 U.S.C. §§ 12-27, 29 U.S.C. §§ 52-53 (1914),

[31] 15 U.S.C. §§ 1-7 (1890)

Act[32] could provide private incentives to litigation for large amounts of money. This in turn could effect the deterrence needed to protect physician-advocates (and others) from retaliation. Such an amendment could provide: "Violations of statutory or regulatory conditions of participation in federally funded programs, by a recipient of direct or indirect federal funding, coupled with certification of compliance therewith, shall be fraud on the United States notwithstanding apparent compliance with any other regulation, or accreditation." [33]

Use of the False Claims Act with respect to Medicare Conditions of Participation (COP) requiring good faith, as opposed to retaliatory, "peer review" may provide some deterrence to bad faith peer review, almost always retaliatory, or anti-competitive.[34] It may be noted that Medicare affects only people over 65 years of age.[35] In practical terms, the effect of enforcement of law

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[32] 31 U. S. C. §§3729 - 3733.

[33] Relevant considerations include: Peer review is defined in part by HCQIA (1989). Medicare requires peer review. Failure to do peer review violates Medicare Conditions of Participation (COP). Violation of COP renders hospital Medicare billings false. Such false billings are actionable under the False Claims Act (FCA). FCA provides large financial incentives to avoid false claims for which there are also criminal penalties. The intent and the effect is to foster peer review, but perhaps differentially. By reasons of the sanctions associated with violations of COP, hospital resources could go to effecting and documenting peer review of treatment of older patients. Resources (beyond Medicare payments) including those required for peer review could move away from non-Medicare patients.

[34] The successful antitrust case that led to the HCQIA in 1989 was *Patrick v. Burget* (1988) 486 U.S. 94, 108 S.Ct. 1658, 100 L.Ed.2d 83; in *Poliner v. Texas Health Systems*, Not Reported in F.Supp.2d, 2006 WL 770425 (U.S.D.C., N.D.Tex. 2006) bad faith peer review by way of summary suspension led to a $366,000,000 jury verdict. See generally William W. Parmley MD, *Clinical Peer Review or Competitive Hatchet Job*, Journal of the American College of Cardiology (Vol. 36, No. 7; 2000).

[35] Certain issues could lead to a perceived need for an explicit requirement that any institution subject to Medicare Conditions of Participation must insure *institution-wide* good faith, non-retaliatory peer review and discipline: Where a set of laws indirectly effects significant protection to a class of persons not entitled to special protection, is this merely a privilege? Do

such that institutions must enable only good faith peer review because of Medicare constraints, protects all by protecting the favored. In other words, what the economists call "positive externalities" make for equitable results assuming effective enforcement of Medicare Conditions of Participation.

Denial of good faith peer review to the treatment of younger patients, at least as effective as that as required by law for treatment of older patients, is a denial of equal protection of the laws. To obviate this inequality, acceptance of any federal funding for any aspect of hospital care should by legislation be subject to explicit acceptance of Medicare-equivalent COP with respect to peer review. Violation of such extended COP should be subject to FCA enforcement. Patients are best equally protected by physician peer review only when the incentives to do it right are equal for younger and older patients. Moreover, all hospital care as affected by peer review is protected and promoted by "official proceedings." These proceedings cannot equitably be different for patients simply by reason of the patients' age. Any such invidious difference should be actionable under the Civil Rights Act. Questions of juridical standing may arise, but FCA claims for relief could be accompanied by Civil Rights Act Equal Protection claims for relief as well.

For the False Claims Act to provide deterrence, the private complainants, denominated "relators," need the encouragement of the monetary reward. Now, only the "original source" of

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others have any call on the law for similar protection? When does the Equal Protection Clause require that all be entitled to enjoy a privilege extended to the few by operation of law? Analogously, if enforcement of the criminal law protects rich people, is it a denial of Equal Protection to fail to enforce the law such that the poor are not equally well protected?

the information about the false claim proven qualifies to participate in the recovery.[36] An amendment is appropriate to enable all sources of the non-public information leading to the prosecution to share in the reward.

6) Another way to protect such physicians is to interpose a neutral evaluator unconnected to the hospital industry to process possibly retaliatory claims against physicians to determine merit. This would require creation by statute of a dedicated adjudicatory mechanism, not unlike the administrative courts system in the federal and many state governments. Awaiting such a development, an existing system for air industry safety could be adopted: The National Aeronautics and Space Administration (NASA) operates two anonymous safety-advocate reporting systems, one in healthcare for the Veterans Administration,[37] which could be adapted to physician-advocate reports of inadequate health care practices and instances. By this means, the physician-advocate avoids retaliation by means of officially sponsored anonymity. [38]

CONCLUSION: PUBLIC SAFETY MERITS NEW STATUTORY PROTECTIONS FOR WHISTLEBLOWERS:

The health of the public is at stake here. Physicians are closest to their patients and best able to advocate for better health care for them. Present healthcare industry structure and

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[36] *Rockwell International Corp. v. United States* - - U.S. - - , 2007 WL 895257 (No. 05-1272, March 27, 2007).

[37] See: Aviation Safety Reporting System, http://asrs.arc.nasa.gov/ and: VA Patient Safety Reporting System, www.nasa.gov/centers/ames/news/releases/2000/00_44AR_prt .

[38] The air safety "black box" instrument is an analogy. See Gil Mileikowsky MD, *In Search of the Black Box – For a Reliable and Cost-effective Quality Control of the Delivery of Medical Care* at http://www.allianceforpatientsafety.org/blackbox.pdf .

unintended consequences of regulatory legislation lend themselves to punitive legal proceedings against whistleblower patient safety advocates. A modest set of statutory amendments, prophylactic and remedial, especially to prevent premature reporting of summary suspensions, can counteract these inequities and rebalance the House of Medicine so it may Do No Harm.

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NOTES:

Figure 1.

The Economic Impact of the Lack of Patient Safety

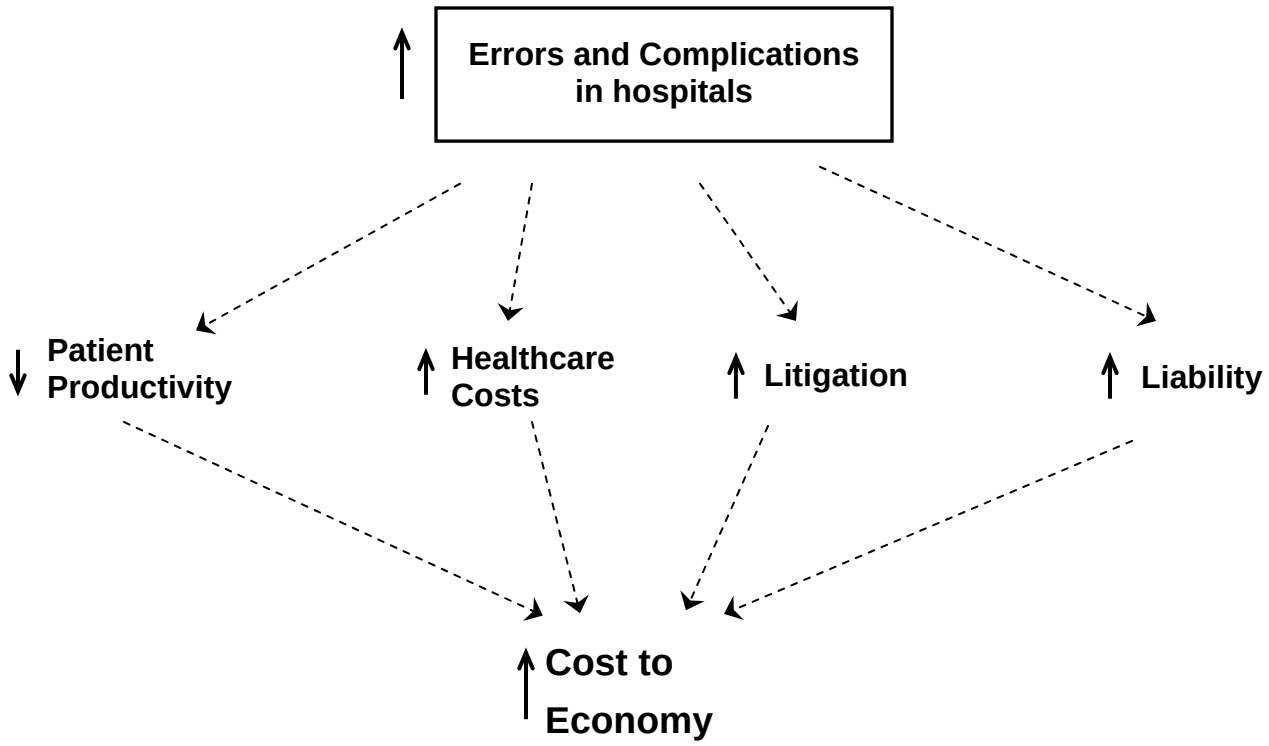


Figure 2.

No Peer Review or **Sham Peer Review**

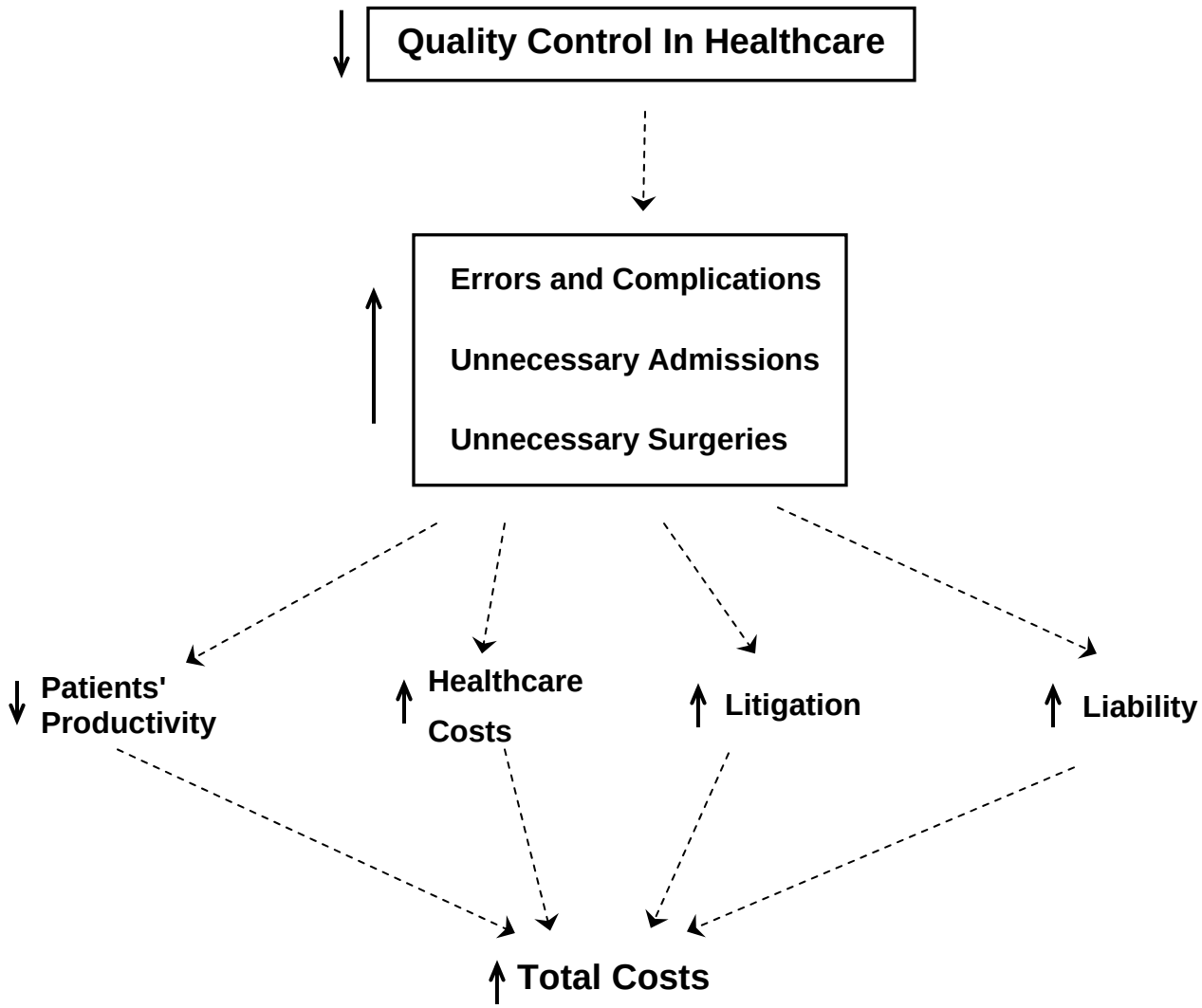
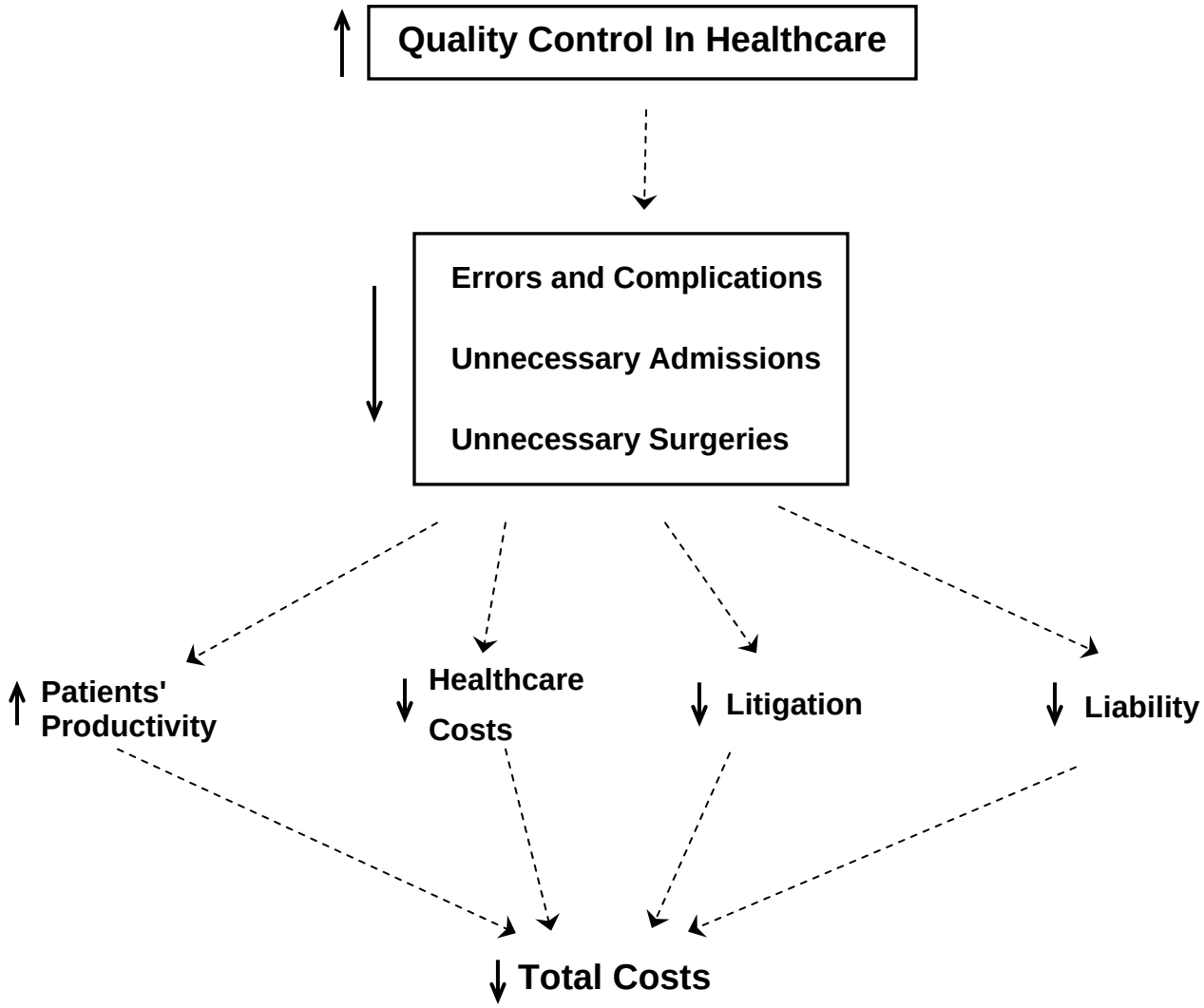


Figure 3.

Legitimate Peer Review



White Paper for Patient Safety:

In search of the "BLACK BOX"
for a reliable and cost-effective quality control of the delivery of medical care.

By Gil N. Mileikowsky, M.D.

Published in Medical Tuesdays newsletter:
http://www.delmeyer.net/HMCPeerRev.htm#by Gil N. Mileikowsky, MD

The reason airline transportation is the safest of all transports is due to the famous "black box" that provides the necessary first step, i.e. the accurate "diagnosis." Without that reliable "forensic" analysis, the "blind lead the blind."

The reason the Federal Aviation Agency (FAA) is effective is because it has jurisdiction over every aspect of the airline industry, including pilots, mechanics, flight attendants, management and manufacturers. It can prevent disasters because it has the power to act immediately, without the intervention of any other agency, e.g. the U.S. Department of Justice and its lengthy process. The FAA can ground, at once, a particular type of plane or an entire airline company, with good cause. Without it, planes would crash daily.

There is no such equivalent in the healthcare industry, however the taxpayer is spending billions of dollars on multiple layers of county, state, federal and not-for-profit agencies that are defective by design. On November 24, 2002, Dennis O'Leary, M.D., President of JCAHO (Joint Commission on Accreditation of Healthcare Organizations) said, "There are some who believe that this whole system has to be blown up and start over again, I happen to be one of those advocates."[1] In 2004, the GAO (Government Accountability Office) provided its own devastating analysis. [2]

Is it possible to have a "black box" in the health care industry? Absolutely, yes.

In clinical research, to evaluate new treatments we use randomized "double-blind" studies, where neither the physicians nor the patients know which pill is a placebo and which pill actually contains the drug. We can do the same when evaluating any error or complication in the health care industry, whether it's in the hospital, the doctor's office, the pharmacy, the manufacturer of a medical device, etc.

We have about 900,000 licensed physicians in the US and 100,000 of them are in California. That's a terrific, diversified pool to serve in a "black box."

Whenever any error or complication is reported, it could be submitted anonymously, i.e. without the patient's name, the physician's name, the hospital's name, the city or state, to an odd number (7 to 11) licensed individuals who will also remain anonymous to the patient, physician and hospital. This anonymity will assure an unbiased, impartial

opinion, void of any possible conflict of interest. Such an approach also eliminates any concern of "immunity," as the identity of those individuals will never be known.

A "black box" method of investigation should combine multiple disciplines, i.e. physicians, pharmacists, nurses, administrators, medical device manufacturers, laboratory technicians, etc., because errors and complications in the health care sector can result from various sources in a hospital, a laboratory, a pharmacy, a doctor's office, etc. "It's the system stupid," as R.M. Wachter, M.D. and K.W. Shojania, M.D. point out in *Internal Bleeding – the truth behind America's terrifying epidemic of medical mistakes*.[3]

Such a "black box" could be consulted in lieu of "experts" by state medical boards investigations, hospitals' peer review, medical malpractice cases, Medicare investigations, etc., since their "experts" are at times the weak link or "Achilles tendon" of the system.

Such a "black box" could also prevent future errors and complications because the opinions of each member of such a "black box" would be reviewed and a physician, a pharmacist, a nurse, or an administrator whose professional opinion may fall below the acceptable standard of practice could be identified and educated in such a proactive "two way" analysis. Isn't the whole purpose of peer review to learn from our colleagues' mistakes so that we can reduce errors and complications in our industry by not repeating them.

Such a "black box" participation should be mandatory as a part of maintaining and renewing the licenses' of physicians, nurses, pharmacists, hospitals, etc., in the same way that participation in peer review is mandatory under the bylaws of hospitals for physicians in order to maintain their "active" status. We could save the taxpayer a lot of money by merging all state boards - medical, nursing, pharmacists, tissue bank, laboratory, hospitals -, into a single state and federal oversight agencies. Thus, their investigative capabilities would be merged into one single comprehensive unit, much like our multiple intelligence agencies are coordinated through the "Homeland Security" Department. This is the only way to achieve a uniform quality control across the country. See articles in the Washington Post by CW Thompson regarding the disparate effectiveness of various state medical boards [4]

Such a multidisciplinary system will easily overcome the multiple deficiencies due to limited "jurisdiction" presently encountered by the existing agencies. Currently, an investigation by a state medical board can find wrongdoing by a hospital, yet cannot act upon such finding because it has no jurisdiction over hospitals.

On the other hand, the DHHS (county, state or federal agencies) cannot act based on a medical state board investigation. It has to proceed with its own investigation that may be limited by its own restrictions of "jurisdiction."

This "black box" comes very cheap. The physicians could be paid the same as members of a jury in courts where physicians and nurses usually do not serve because the time required to serve on a jury could adversely impact their patients' care. As a

reward, participation in the "black box" would provide the participants CME credit, with AMA or specialty organizations such as ACOG-cognates. It would pay for itself through the existing licensing fees paid by physicians, nurses, pharmacists, hospitals and taxpayers.

Since Kip Viscusi, an economist at Harvard University, estimates the value of a human life to be worth between 4 to 9 million dollars in the U.S. , every life saved represents a savings of 4 to 9 million dollars to the US economy.[5]

In July 2004, the HealthGrades study, "Patient Safety in American Hospitals,"[6] demonstrated the devastating effects of errors and complications in the health care industry and established the loss of 600,000 human lives every three years. That represents 2.4 trillion to 5.4 trillion dollars wiped out of the U.S. economy every three years, or 800 billion dollars to 1.8 trillion dollars every year, as 200,000 humans, i.e. taxpayers, consumers, productive people …., disappear from our society annually.

In 2002, our national health care cost was $1.6 trillion (about 15% of the Gross Domestic Product (GDP). If one considers the additional economic impact of health care errors and complications, the total health care cost may actually be about 30% of the United States' GDP. Accordingly, there is no reason for the taxpayer to continue to waste public funds for obsolete and ineffective layers of organizations and agencies that are not capable of fulfilling their mission even if they wanted to.
This was convincingly illustrated by whistleblower Charles Rosen, M.D., who stated in a 7/25/2003 Street.com article that he observed at his hospital a "deliberate attempt at cover-up for financial reasons" and wondered why no agency was intervening after he reported the source of the unusually high infectious rate at his facility.[7] No wonder patients are afraid of hospitals. See the *Wall Street Journal,* 9/11/2003, article by Laura Landro, "How to keep the Hospital from Making you Sicker."[8] That's why alternative medicine is so popular.

Once the "black box" is operational, it will markedly reduce the number of litigations by patients and their families, victims of errors and complications, and decrease professional liability premiums. (See Figures 1 and 2, The "Big Picture")

The "black box" could assist justice, as the legal system and courts in general are intimidated by any intervention in the medical field. Judges feel they lack the necessary expertise and thus fear allowing a potentially bad physician to return to medical practice. In the name of "public interest," judges prefer to err against the physician, even when the allegations are clearly silly, and thus assume the presumption of correctness of the process of hospitals' "hearings". Hospital attorneys have for many years very skillfully abused these shortcomings by courts all over the country.

Judges are also mindful not to overburden an already costly health care system. They do not realize that by protecting hospitals' administrators and their boards, the runaway health care costs will never stop growing because errors and complications are a great source of revenues for them. In USA Today, Lucian Leape and his researchers stated on 5/18/2004.[9], "We have to turn the heat up on the hospitals…." as "…there's no

economic incentive for hospital's to reduce errors because they make more money by treating the resulting problems." See also Professor Leape's *JAMA* article. [10]

So far, federal prosecutors have not been able to compel any significant change in the conduct of the management of hospitals despite several multi-billion dollar settlements by the U.S. Department of Justice vs. NME, HCA, Tenet and others, as these administrators (CEOs, COOs, etc.) continue their devastating practices under their corporate umbrellas, following those settlements.

If we genuinely want America to be competitive and have a healthy workforce, we need to reduce the individual, corporate, insurance and government financial health care burden by establishing, as quickly as possible, a meaningful, credible, cost effective and reliable quality control for the health care industry. We need not forget that as our population's age grows, its health care needs and costs will continue to rise, yet we have some of the finest physicians, nurses, pharmacists, etc. in the world and we have the most advanced technology available to us. Thus, we cannot allow this organized sabotage to persist and undermine the quality of the delivery of medical care in our country.

When Congress passed the HCQIA, it failed to establish a HCQIA- Agency to assure the mission and intent of Congress because it depended on a "licentiates"-driven peer review reinforced by legislatures in Business and Professional Codes of California and other states. Alas, that wishful thinking rarely materialized.

We have to learn from the experience of years of repeated failures. As observed in "Clinical Peer Review or Competitive Hatchet Job" by William W. Parmley, MD,[11] too often the physician members of the "old boys network" abuse peer review as a tool to protect each other by covering up acts of negligence or to eliminate their competitors.[12]

Peer review, controlled by hospital administrators' greed and economic interests, has totally failed to achieve the quality control that Congress and California's legislature assigned to it., Hospital administrators are the "gate keepers" who control which medical records are submitted to the peer and chart review committees and which physicians escape scrutiny. Hence, they cover up the wrongdoings of those physicians who represent significant revenues in order to secure their stream of profits. See "Rape of the Medical Peer Review Process By Tenet Healthsystem." [13] That's what happens in many hospitals. See *Critical Condition – how US healthcare became big business and bad medicine* by Donald L. Bartlett and James B. Steele[14] and the outstanding "Cost of Courage" series in the *Pittsburgh Post-Gazette* by Steve Twedt, a comprehensive investigation of systematic failures of peer-review nationwide, published 10/26/2003 to 10/29/2003. [15, 16]

It is said that, "Internists know everything but see nothing, Surgeons see everything but know nothing, and Pathologists know everything and see everything but, too late. " By the time the FBI raided "Redding," they "knew and saw everything, but too late" for the victims and people who died as a consequence of unnecessary and non-indicated cardiovascular surgeries performed at that facility. See "Unhealthy Diagnosis," 60 Minutes, CBS, July 25, 2003. [17]

The matter of quality control in the health care industry cannot be limited to the agenda of a single party, Republican or Democrat. Nor is it a political ideology, i.e. capitalism or socialism. It can only be achieved by taking into consideration humans' natural limitations, e.g. egos, bias, partiality, conflicts of interests (economic or other), discriminatory, arbitrary, capricious or malicious conducts. The "black box" circumvents all of the above human shortcomings. No laws passed by Congress or any legislature can change nature's own biological, sociological, and psychological laws, i.e. the organic human deficiencies.

The Romans proclaimed a long time ago that, "Errare humanum est," i.e. "To err is human" and the famous maxim, "Primum no nocere," i.e. "First do no harm." Isn't it about time for us to implement this wisdom and common sense? How many more human lives will be victims before we establish a true, effective and reliable quality control of the delivery of the medical care in our country?

Don't we say, "Where there is a will, there is a way"? Isn't that the American way?

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Figure 1.

The "Big Picture"

1. No Peer Review or Sham Peer Review

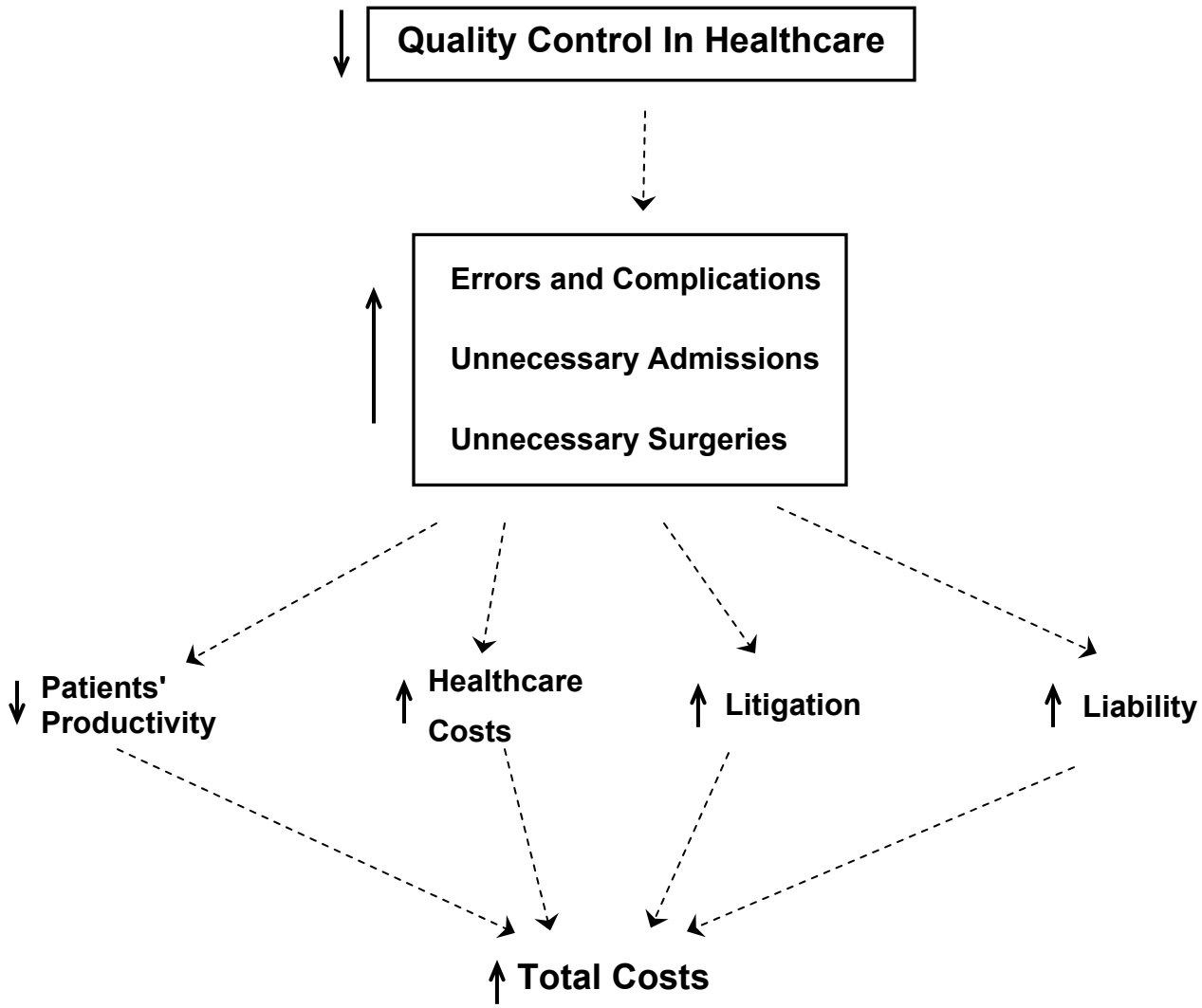

Figure 2.

The "Big Picture"

2. Legitimate Peer Review