IN THE UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

No. 92-3313

WILLIAM L. MANION, MD,
Plaintiff-Appellee

vs.

GEORGE EVANS, MD,
Defendant

LIMA MEMORIAL HOSPITAL & GREGORY TURNER,
Defendants-Appellants

BRIEF AMICI CURIAE OF THE AMERICAN MEDICAL ASSOCIATION, CALIFORNIA MEDICAL ASSOCIATION, and OHIO STATE MEDICAL ASSOCIATION NEUTRAL POSITION - FOR THE COURT'S INFORMATION

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

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INTEREST OF AMICI CURIAE

The American Medical Association ("AMA") is a private, voluntary non-profit organization of physicians. The AMA was founded in 1847 to promote the science and art of medicine and the improvement of the public health. Its membership exceeds 285,000 physicians and medical students.

The California Medical Association ("CMA") is a non-profit, incorporated professional association of approximately 33,000 physicians practicing in the State of California. The Association's primary purposes are ". . . to promote the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession." CMA and its members share the objective of promoting effective and efficient health care for the people of California and the nation.

The Ohio State Medical Association ("OSMA") is a non-profit professional association of approximately 20,000 physicians, residents and students in the State of Ohio. OSMA's membership includes most of the Ohio physicians who are engaged in the private practice of medicine, in all specialties. OSMA's purposes are to improve the public health through education, encourage interchange of ideas among members, and maintain and advance the standards of medical practice by requiring members to adhere to the concepts of professional ethics.

Amici, as well as medical associations across the country, were integrally involved in the process of enacting the Health Care Quality Improvement Act

("HCQIA", 42 U.S.C. § 11101 *et seq.*).[1] Although we supported HCQIA's goal of protecting patients by establishing a centralized databank reporting scheme, we had many concerns regarding other aspects of the Act. Primary among them were two things: First, we were concerned that there be an immunity provided to physicians who participate in legitimate peer review activities, in order to protect them from the time and expense associated with defending against unfounded lawsuits, particularly those based upon the federal antitrust laws. Second, we believed there should be safeguards in the statute in order to guard against peer review abuse. Thus, we were in favor of the four statutory conditions to the HCQIA immunity, which provide that peer review must be conducted reasonably and fairly in order for the peer reviewers to qualify for immunity protection. As it currently exists, HCQIA represents a just balance between these competing concerns. If this balance is to be preserved, however, it is crucial that courts across the nation interpret this statute in a manner which gives proper effect to the Congressional intent which underlies it. Accordingly, we provide this discussion of the HCQIA immunity to assist the Court in determining the issues before it.

We wish to emphasize that we have not reviewed the record in this case and we take no position as to the underlying merits of this specific dispute. Rather, we seek only to address the Congressional intent underlying HCQIA, the legal issues

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[1] Note that throughout this brief Amici AMA, CMA and OSMA are referred to as "*Amici*" or as "we". This is to be distinguished from references to the American Hospital Association et al., who appears as *Amici* for Defendants and who are herein referred to as "*Amici* AHA et al."

respecting application of the immunity and procedural matters related to summary judgment.

SUMMARY OF ARGUMENT

Amici begin by pointing out the legislative intent underlying HCQIA. We point out that HCQIA's comprehensive statutory scheme provides protection to the public health, to peer reviewers, and to physicians who are the subject of peer review. Thus, in addition to requiring reporting of adverse actions to a central data bank, it provides immunity protection for peer reviewers, but conditions that protection on the provision of reasonable and fair peer review procedures.

We next point out that HCQIA's immunity provides broad protection from almost all federal and state laws and therefore must be construed carefully in order to prevent abuse. We begin by noting that HCQIA's immunity was originally aimed at federal antitrust litigation, not at the full range of legal claims to which it now applies. This was proper as, with increasing frequency, hospitals and physician peer reviewers were the target of federal antitrust claims by disaffected physicians hoping to reap concessions and treble damages from pursuit of this litigation. In our view, the federal antitrust laws do not provide the appropriate paradigm for the resolution of peer review disputes. We point out that vigorous medical staff peer review activities are not only essential to the promotion of quality care, but are also mandated by state and federal law. Moreover, the peer review process contains unique characteristics which set it apart from other

commercial contexts. In addition, a literal application of the language of the antitrust laws may deem adverse peer review determinations to be anticompetitive by their very nature. Although we believe the application of federal antitrust principles to be inappropriate in peer review cases, we acknowledge, however, that courts around the country have permitted such antitrust actions to go forward. For this reason, HCQIA's immunity is necessary if robust peer review is to survive.

We next point out that, in order to prevent abuse in the peer review process, and because HCQIA's immunity is extremely broad (extending well beyond the antitrust laws to almost all federal and state laws), Congress provided important conditions for the immunity. The immunity is applicable only where peer reviewers have acted reasonably and provided fair peer review procedures, in accordance with four express statutory conditions.

We also note that Congress intended applicability of the immunity to be decided expeditiously wherever possible. In the view of *Amici*, it is probable that this issue may be resolved as a matter of law by the judge early in the proceedings in many cases, generally upon a defendant's motion for summary judgment. While the question of whether HCQIA's immunity applies is initially a question of law for the judge to decide, however, where plaintiff introduces sufficient evidence in rebuttal, ultimately it is a question of fact for the jury. We point out that, absent express statutory authorization, the judge should not act as the ultimate factfinder.

We next discuss why this interpretation is both consistent with Congressional intent and federal law and procedure in the "new era" of federal summary adjudication. We discuss burdens of proof and the effect of the presumption, noting that, on a motion for summary judgment, defendants may simply rest on the presumption that they have met the objective conditions for HCQIA's immunity and the entire burden is on plaintiff to produce significant probative evidence in rebuttal. To survive a defendant's motion for summary judgment, plaintiff must produce sufficient evidence for the judge to determine that a reasonable jury could find in favor of plaintiff, by a preponderance of the evidence, that defendants did not meet the four statutory conditions for the immunity. We note further that, if plaintiff produces such rebuttal evidence, then the issue of immunity protection must go to the jury as part of the full trial. Defendants may still prevail on the immunity, if the jury finds that they indeed acted reasonably and fairly in the peer review process (i.e. that they met the statutory conditions).

Finally, we argue that, while the immunities are supported by similar public policy considerations, application of HCQIA's qualified immunity is wholly different from application of the qualified immunity afforded to public officials. This is because the public official immunity is a question of common law, which turns almost exclusively on whether the public official had adequate notice and knowledge of "clearly established laws" against which to measure his or her own performance. By contrast, HCQIA's immunity is statutory in nature. The four

objective immunity conditions are clear and provide the only standard against which peer review performance is to be measured.

ARGUMENT

I. HCQIA'S COMPREHENSIVE STATUTORY SCHEME PROVIDES PROTECTION TO THE PUBLIC HEALTH, TO PEER REVIEWERS, AND TO PHYSICIANS WHO ARE THE SUBJECT OF PEER REVIEW.

As is reflected in the legislative history and indeed in the legislative findings contained in the Act itself, in enacting the Health Care Quality Improvement Act ("HCQIA", 42 U.S.C. § 11101 *et seq.*), Congress recognized and sought to protect a number of important, but potentially competing, interests. First, Congress recognized the national need to restrict incompetent physicians from moving from state to state without the possibility of ready discovery by others of the physician's previous incompetent performance. § 11101(2). Second, Congress realized that this problem could be remedied through effective professional peer review and reporting of adverse peer review actions to a central data bank which would be accessible to hospitals, medical staffs and other health care entities in all states. §§ 11101(1),(3); 11131 *et seq.* Third, Congress realized that physicians were often hesitant to participate fully in such professional peer review activities, out of a fear of being subjected to lengthy, costly retaliatory legal proceedings. § 11101(4). In order to remedy this concern, Congress recognized the need to provide some form of immunity from damages liability to such physicians. § 11101(5). Finally, Congress recognized the potential for peer

review abuse, in light of the legal protection, and therefore conditioned applicability of the immunity on the provision of reasonable decisions following fair procedures to physicians who are the subject of professional review.[2]

II. AS HCQIA'S IMMUNITY PROVIDES SWEEPING PROTECTION FROM ALMOST ALL FEDERAL AND STATE LAWS, IT MUST BE CONSTRUED CAREFULLY, IN ORDER TO PREVENT PEER REVIEW ABUSE.

Although most of the comment regarding HCQIA's immunity is in relation to the federal antitrust laws, it must be remembered that HCQIA's immunity provides sweeping protection not only from potential federal antitrust liability, but also from potential liability under most other federal and state laws.[3] Therefore, in order to realize the Congressional intent to protect physicians who are the subject of peer review from possible abuse, the courts must carefully construe the immunity protection to ensure that it is properly applied. In this section, *Amici* discuss the importance of the immunity, particularly insofar as it relates to federal antitrust law. We also point out, however, that because of its broad applicability, the immunity question must be carefully scrutinized to ensure that abusive situations are not improperly shielded from review.

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[2] § 11112(a); *see generally* 42 U.S.C. § 11101 *et seq.* *See also* H.R. Rep. No. 99-903, 99th Cong., 2d Sess. 12 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6384, *et seq.* *See generally* Scott, Charity, *Medical Peer Review, Antitrust, and the Effect of Statutory Reform,* 50 Maryland Law Rev., 316-407 (1991).

[3] HCQIA does not provide immunity from damages under any law of the United States or any state relating to civil rights, nor does it prevent the United States or any attorney general of a state from bringing an action, including an action under Section 4C of the Clayton Act, 15 U.S.C. 15C, where the action would otherwise be authorized. (42 U.S.C. § 11111(a)(1)(D)).

A. HCQIA's Immunity Was Originally and Properly Aimed at Federal Antitrust Litigation.

It is clear from the legislative findings and history of HCQIA that the provision of the qualified immunity under HCQIA derived from a Congressional desire to protect physicians who engage in proper peer review activities from the costs of defending (and the potential treble damage liability resulting from) federal antitrust lawsuits.[4]

Congressional focus on providing protection from unfounded antitrust lawsuits was both appropriate and necessary. It would be grossly unfair to subject peer reviewers who have acted reasonably to the time and expense burdens inherent in defending against an antitrust lawsuit. Moreover, the federal antitrust laws simply do not provide the appropriate paradigm for peer review cases. Peer review is not a commercial activity. Rather, it is a unique professional activity comprised of an ongoing program carried out by individuals, to maintain and improve the quality of health care services. As a process, peer review, of necessity, involves concerted action in developing and applying practice standards, rendering medical staff privilege determinations, and ultimately, if educational efforts fail, engaging in disciplinary action. By definition, physicians can only be "peer reviewed" by their peers, that is, by other physicians. Nonphysicians possess neither the necessary license nor the qualifications to

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[4] *See* 42 U.S.C. § 11101(4) ("the threat of private money damage liability under federal laws, including treble damage liability under federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review"). *See also* 132 Cong. Rec. H9960 (Daily Edition, Oct. 14, 1986) ("the committee report accompanying HR 5540, rested the damage immunity provision almost exclusively on the treble damage remedy available under the Federal antitrust law").

render professional opinions concerning a physician's competency. Moreover, it is often necessary to obtain input from physicians in the same specialty to determine whether a particular practice was appropriate, given specific medical circumstances. As a result, often at least some of the physicians who participate in the peer review of a fellow medical staff member will be competitors. Nonetheless, peer review provides the only reasonable means of protecting patients from incompetent practitioners. Indeed, unlike commercial transactions involving abuses of economic power which historically have raised antitrust concerns, peer review is required by both the law and the ethical principles of medical practice. *See* discussion below.

Despite the fact that these collective activities are an essential mechanism for assuring quality of patient care through objective, candid, and sometimes critical evaluations, adverse medical staff peer review determinations have increasingly resulted in federal antitrust lawsuits on the theory that the peer review participants, among others, conspired to restrain trade with respect to the practice of the physician being reviewed. As is discussed in more detail below and as Congress recognized in passing the HCQIA, the antitrust laws do not provide an appropriate standard for assessing peer review activities.

1. Vigorous Medical Staff Peer Review Activities are Essential to the Promotion of Quality Care.

    a. Peer Review Provides the Optimal Method of Maintaining and Improving the Quality of Patient Care Provided in a Health Facility.

To provide quality patient care, health care services must be regularly monitored and evaluated. A comprehensive quality review process is critical to the resolution of ongoing problems, as well as to the identification of opportunities to improve patient care. Protocols and procedures must be continually analyzed and revised to reflect new information and technologies. The clinical performance of physicians and other health care providers must be repeatedly assessed so that substandard performance and impaired or incompetent individuals may be identified before patients are seriously injured.

To be effective, this monitoring function must be performed by individuals who have both the expertise necessary to conduct these quality assurance activities and the ability to implement any indicated changes. An effective peer review system provides the optimal solution. Medical staff members have both the expertise and familiarity with the facility and the physicians and other health care providers involved to conduct effective peer review. Members of the medical staff are responsible for possessing, securing, and implementing the professional expertise necessary to assure the delivery of quality care. These are the members who develop and enforce the patient care standards, policies and protocols, and perform the peer review functions necessary to assure the quality of inpatient care. The full participation of these members is critical; without them the entire system would grind to a halt.

Moreover, the peer review system does much more than maintain "competent" medical standards; it strives for quality. A physician's basic

competency to practice medicine is a matter for a state's medical licensing board which decides whether to revoke or grant a physician's license. While the issue of competency is also properly within a medical staff's domain, medical staffs can discipline a physician, or otherwise revoke his or her privileges under substantially less egregious circumstances than those which warrant licensure revocation.[5]

Thus, if performed in good faith following fair procedures, the peer review process increases the likelihood that only qualified physicians obtain and maintain medical staff membership and appropriate clinical privileges in a hospital which serves the community where the physician's patients reside. From the perspective of the community, effective peer review provides the best assurance of optimal medical care.

b. State and Federal Law Mandate Peer Review and Provide Necessary Protections.

(i) State Peer Review.

Recognizing the fact that medical staff peer review is the central patient protection mechanism in hospitals, virtually every state requires that medical staffs perform a host of quality assurance functions. These peer review activities cover two major areas: (1) patient care review (the ongoing review of the quality of patient care provided throughout the hospital) and (2) credentialing (the process of reviewing the initial and ongoing competence of every physician and other health

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[5] Moreover, medical staffs have the ability to act more quickly than the medical board in cases posing a serious threat of harm to patients. *See generally* Bonner v. Sisters of Providence, 194 Cal. App. 3d 437 (1987) (medical board proceedings and medical staff disciplinary proceedings do not serve the same goal).

care provider who practices in the hospital). These obligations are imposed not only by statute[6], but also by a common law direct duty to patients on the part of the hospital, to ensure medical staff members' competency through careful selection and review.[7]

State legislatures throughout the country have recognized the importance of medical staff quality assurance activity by enacting the appropriate immunities and privileges necessary to ensure that medical staff members continue to perform critical peer review functions, including reporting adverse determinations, without undue fear of liability.[8] In California, for example, the legislature has addressed this problem by enacting a number of statutes specifically protecting members of medical staffs engaged in quality assurance activities.[9] Other states, similarly, have enacted a host of laws designed to protect the peer review process.[10]

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[6] For a state by state analysis of laws concerning medical staff issues, *see* Hospital Law Manual, Attorney's Volume IIB, Medical Staff, at 96(6)-138 (1983).

[7] *See* Elam v. College Park Hosp., 132 Cal. App. 3d 332 (1982), Darling v. Charleston Community Hosp., 33 Ill. 2d 326, 211 N.E.2d 253 (1965), Bing v. Thunig, 2 N.Y.2d 656, 163 N.Y.S.2d 3, 143 N.E.2d 3 (1957), and Johnson v. Misericordia Community Hosp., 99 Wis. 2d 708, 301 N.W.2d 156 (1981).

[8] *See generally "The Legal Liability of Peer Review Participants for Revocation of Hospital Staff Privileges"* 28 Drake Law Review 692 (1978).

[9] *See e.g.* Ohio Rev.Code § 2305.24 (providing for confidentiality of information furnished by physicians to Quality Assurance Committees), § 2305.25 (A) (providing an immunity from liability for any actions of persons on a hospital's Quality Assurance Committee), § 2305.251 (providing that proceedings and records of Quality Assurance Committees shall not be subject to discovery; also, providing that members of such committees may not be compelled to testify in Civil actions on evidence or other matters presented during the proceedings or on findings of the committee); Cal. Civil Code Section 43.7 (providing a conditional immunity for actions taken by members of medical staff committees engaged in quality assurance activities); Cal. Civil Code Section 43.8 (providing an absolute immunity for those who communicate information to medical staff committees "intended to aid in the evaluation of the qualifications, fitness, character or insurability of the practitioner of the healing arts"); Cal. Civil Code Section 47 Subdivision 2 (providing an absolute privilege for any "publication or broadcast" made "in the initiation or course of . . . proceedings authorized by laws and reviewable" by writ of mandate, including medical staff disciplinary hearings); Evidence Code Section 1157 (providing broad protection for the

The existence of these protections clearly demonstrate recognition of the importance of medical staff quality assurance activity and the state legislatures' intentions to take those steps necessary to insure that medical staffs continue to perform these functions without undue interference. In upholding these protections, Courts around the country have recognized their underlying public policy rationale (*see e.g.* Matchett v. Superior Court, 40 Cal. App. 3d 623 (1974) (effective peer review requires free and open discussions which can only take place in a protected environment).

(ii) Federal Peer Review.

Generally speaking, the peer review activities imposed by state law are also required by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), the non-profit association which accredits hospitals nationwide. *See* Joint Commission, Accreditation Manual for Hospitals, Chapter on Medical Staff, (1992). Peer review activities are additionally mandated by Congress as a condition for payment under the Medicare and Medicaid programs (*see* 42 U.S.C. § 1395x(k)(r)(s); 42 U.S.C. § 1396a(a)(19)(26)). Notably, Joint

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confidentiality of the proceedings and records of medical staff committees by insulating them from discovery); Cal. Civil Code Section 43.97 affording a conditional immunity from damages (except economic damages) for all persons and organizations involved, for any disciplinary action which is reported to the Medical Board of California pursuant to Business & Professions Code Section 805); and Business & Professions Code Section 805(d) providing that no person shall incur any civil or criminal liability as the result of making any report required by that provision. The latter provision "underscores the legislature's patent intent that hospital and medical personnel who file BMQA (effective January 1, 1990, renamed the Medical Board of California (MBC)) disciplinary reports be free from the prospect of having to defend themselves in court as the result of any statements contained therein." *See* Dorn v. Mendelzon, 196 Cal. App. 3d 933, 941 (1987).

[10] *See* note **Error! Bookmark not defined.**, *supra.*

Commission accreditation is deemed to be *prima facie* compliance with these federal requirements. 42 U.S.C. § 1395x(e). *See also* 42 C.F.R. § 482.22 (requiring that a hospital have "an organized medical staff that operates under bylaws approved by the governing body, and is responsible for the quality of medical care provided to patients by the hospital.")

Congress has further demonstrated the importance of medical staff activities by requiring that Professional Review Organizations designated by the Medicare program to review the medical care provided to beneficiaries offer to consult with the medical staff of each hospital regarding the organization's review of hospital services for which Medicare payment may be made. 42 U.S.C. § 1320c-3(a)(6)(A); 42 U.S.C. § 1320c-5(c). Finally, in enacting HCQIA in 1986, Congress largely replicated the comprehensive statutory peer review scheme, adopted by California and other states, by mandating the reporting of physicians who have suffered adverse disciplinary actions and providing broad immunity from damages for all individuals and entities involved in reasonable professional review activities.

c. Both Federal and State Law Protect Incorrect Decisions as Long as Those Decisions Reflect a Reasoned Decision for the Purpose of Furthering Quality Patient Care Following a Careful Review of the Facts.

In order to be eligible for the protections afforded by state and federal law, peer review determinations do not need to be correct, they need only be reasoned

decisions following a fair process.[11] This is because medicine is an inexact science and qualified physicians often differ in their treatment methods. Depending upon the particular facts of the case, physicians may occasionally be subjected to erroneous medical staff determinations, even though those conducting the review have acted in good faith. Both the federal and state governments have concluded that the competing interests supporting peer review and obtaining redress from good faith, but erroneous, peer review determinations weigh in favor of the public policy supporting the protections for peer review. For that reason, neither state nor federal law requires that the underlying peer review decision be correct. Such a requirement would only serve to discourage effective peer review and undermine the very purpose of the broad statutory immunities.

2. The Public Interest in Receiving Quality Care Through Effective Peer Review Renders Application of the Federal Antitrust Laws Problematic.

a. The Peer Review Process Has Unique Characteristics Which Sets It Apart From Other Commercial Contexts.

As a system which maintains and encourages quality health care, patients (the consumers) are the direct beneficiaries of the peer review process. However, due to a number of unique factors, peer review cannot be judged by conventional antitrust analysis. First, patients are generally unlearned in the medical sciences, and therefore, have "an abject dependence upon and trust" in their physicians for

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[11] *See e.g.* Bonner v. Sisters of Providence Corp. (1987) 194 Cal.App.3d 437 (subsequent "vindication" by medical board, which chose to take no action against a physician who had been disciplined, does not invalidate a medical staff decision which was supported by uncontested substantial expert evidence).

the information upon which they rely during the "decisional process." Cobbs v. Grant, 8 Cal. 3d 229, 242 (1972). Unlike consumers in most "commercial" contexts, patients generally do not have the requisite sophistication to select their "product", that is, physicians, on the basis of quality. This "buyer ignorance" renders the medical "market" imperfect.

Moreover, unlike most cases of "buyer ignorance", the market imperfection is not cured through information. Due to the rapidly increasing complexity of the practice of medicine, there is no information readily available to patients which enables them to assess the quality of care offered by different physicians. This lack of information further compounds the imperfect market for health care services.

Also making health care unlike the usual commercial context is the fact that a patient's selection of a physician is generally not based upon price considerations, because insurance is usually available. *See* Robinson v. Magovern, 521 F. Supp. 842 (W.D. Pa. 1981), *aff'd*; 688 F.2d 824 (3d Cir.), *cert. denied;* 459 U.S. 971 (1982) (stating "as we observed earlier, the third-party payor system generally insulates the consumer-patients from price considerations; this sharply contrasts with the commercial world, in which price often is the determinative factor for the buyer.") Thus, neither price nor quality is a competitive variable for the average medical care consumer.

If physician services were comparable to services offered in the ordinary commercial context (which they are not), purchasers would generally be able to

assess accurately the degree of quality offered by the different suppliers and price would be a competitive variable. Under this scenario, patients would be able to balance cost and quality tradeoffs in making their determinations and peer review might not be as critically important because the marketplace would force a "competitive" level of quality. This scenario does not and cannot exist in our current health care system. In any event, we question whether a purely market driven system would result in a more efficient and proactive system for enhancing quality medical care. Rather, *Amici* contend that unnecessary or poor quality health care products and services will not and cannot be eliminated through normal marketplace activity, a process which the antitrust laws assume. Peer review is essential since it maximizes the ability of an inherently imperfect marketplace to provide quality care. Peer review assumes that patients should not have to be injured repeatedly by incompetent practitioners while the marketplace works, assuming that it works at all where there are such barriers to information.

Finally, as is discussed above, not only is peer review in the public interest, it is required. It is unconscionable to subject physicians who perform peer review activities reasonably to lengthy, expensive antitrust lawsuits for legitimate activities which are not only ethical, but mandated by state and federal laws.

b. Despite the Fact That Peer Review is Both Required by Law and Necessary, the Antitrust Laws May Deem Adverse Peer Review Determinations "Anticompetitive".

Broadly construed, Section 1 of the Sherman Act would reach all adverse peer review determinations. Both substantive elements required by Section 1 arguably are met. The "contract, combination or conspiracy" element can be satisfied by the very nature of peer review - which involves a collective decision made by competing individuals otherwise acting independently.[12] The "unreasonable restraint of trade" element of Section 1, similarly, may appear to be satisfied because an adverse peer review determination necessarily results in a restraint of trade, that is, the exclusion of an individual from at least a segment of the marketplace. For these reasons, medical staff peer review activity, which otherwise would not be suspect as it does not involve conduct which traditionally has been condemned by the antitrust laws (e.g. boycotting activities) has, like the traditionally condemned activities, resulted in massive antitrust lawsuits against physicians and hospitals alike. This has been true even when the activity was undertaken in good faith following proper procedures.

In sum, although we believe that the federal antitrust statutes do not provide the appropriate paradigm for litigation of peer review cases, these laws may apply on their face, and the courts have no choice but to entertain these cases. Indeed, more such cases may be predicted for the future in light of two recent Supreme

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[12] Depending on the economic realities of a particular case, a court may conclude that the "intra-corporate conspiracy" exception precludes a finding of conspiracy. *See* Weiss v. York Hospital, 745 F.2d 786, 814 (3rd Cir. 1984) *cert. den.* 470 U.S. 1060 (1985) (hospitals incapable of conspiring with their medical staffs). *But see* Oltz v. St. Peters Comm. Hosp. 861 F.2d 1440 (9th Cir. 1988) (physician anesthesiologists may have independent stake in excluding nurse anesthetist services), Bolt v. Hallifax, 891 F.2d 810 (11th Cir) *cert. den.* 110 S.Ct. 1960 (1990) (hospitals and medical staff members can conspire).

Court cases which have largely disposed of two defenses which had typically been raised (i.e. that defendants were protected from liability under the "state action" immunity and that there was no federal court jurisdiction because of an insufficient nexus with interstate commerce).[13] Even before these Supreme Court decisions, in providing immunity as part of HCQIA in 1986, Congress recognized that broadly immunizing properly conducted peer review activities was necessary since the reporting system required under the legislation would "most likely increase the volume of such [antitrust] suits." HR Rep. No. 99-903, 99th Cong. 2d Sess. 21, reprinted in 1986 U.S. Code Cong. & Admin. News 6384, 6391.

B. Recognizing That HCQIA's Extremely Broad Immunity Could Foster Peer Review Abuse, Congress Provided Important Conditions For the Immunity.

As the above discussion demonstrates, Congress was primarily and properly concerned with protecting good faith peer reviewers from the threat of extended litigation and potential liability under the federal antitrust laws. However, the immunity goes far beyond the antitrust laws, extending to protect peer reviewers from liability under most other federal and state laws, with few exceptions.[14] In this regard, HCQIA's immunity also extends to state law tort

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[13] *See* Patrick v. Burget, 486 U.S. 94, 108 S.Ct. 1658 (1988)(holding the state action doctrine inapplicable because "active supervision" prong of the test not met where neither the State Health Division, the State Board of Medical Examiners, or the State judiciary reviewed private peer review decisions), Summit Health Ltd. v. Pinhas, 114 L.Ed.2d 366, 111 S.Ct. 1842 (1991) (holding that interstate commerce requirement of antitrust jurisdiction was satisfied by allegations that the hospital, its owner, and the medical staff conspired to exclude a duly licensed and practicing physician from the market for ophthalmological services, where the parent company and hospital were unquestionably engaged in interstate commerce, and ophthalmological services were provided to out-of-state patients.)

[14] *See* note **Error! Bookmark not defined.**, *supra.*

claims, claims which *should* apply in cases where the peer review system has been used for improper purposes such as retaliation or exclusion of qualified competitors.

In providing this broad immunity, Congress was mindful of the potential for abuse in the peer review process. Thus, in developing the four conditions for the immunity protection which have been incorporated into HCQIA, Congressional leaders sought to assure the public that the HCQIA immunity was not intended to protect such abuses. As Congressman Waxman, a principal sponsor of the bill, stated during Congressional hearings:

> I want to make it clear, however, that we fully agree that we *cannot* tolerate abuses of the peer review system, and that HR 5540 was never intended to protect any such abuses.
>
> This is true whether the concern is with anti-competitive activities, with actions based on race, or any other prejudicial or discriminatory factors. We have emphasized this throughout our discussions of this bill within the Energy and Commerce Committee and with the staff of the judiciary committee.
>
> To reiterate: *nothing* in HR 5540, as currently drafted, would protect the type of abuse that I have referred to.[15]

Abuses to which Congressman Waxman and others referred included, among others, (1) discrimination against doctors based upon race, age, or sex, (2) harassment of physicians who engage in "whistleblower" activities for the benefit of their patients and the public, and (3) victimization of doctors based upon anti-

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[15] Hearings on HR 5540 before the Subcommittee on Civil and Constitutional Rights of the House Committee on the Judiciary, 99th Cong., 2d Sess. 52 (1986) [hereafter hearings on HR 5540], at 47 (emphasis in original).

competitive business practices.[16] Indeed, it is somewhat ironic that, although HCQIA was in part enacted out of concerns raised by the federal antitrust case of Patrick v. Burget, it is clear that the anti-competitive activity evident in that case would not have been shielded by HCQIA's immunity protection.[17]

Rather, in order to qualify for the immunity, medical staffs and peer reviewers must have taken a "professional review action" (as defined in the Act and relating exclusively to professional competence or conduct):

(1) In the reasonable belief that the action was in the furtherance of quality health care,

(2) After a reasonable effort to obtain the facts of the matter,

(3) After adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and

(4) In the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

To underscore its commitment to effective peer review, Congress provided that defendants shall be *presumed* to have met the preceding standards. However, to underscore its equally important determination to prevent peer review abuse,

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[16] *Id.* at 49. *See also* Hearings on HR 5110, at 192 where Representative Wyden stated: "There is one thing this bill will not do. It will not shield doctors from liability for what are truly anticompetitive business practices. The only protected activities are those dealing with the professional behavior and competence of individual practitioners." Other kinds of peer review abuse include discrimination against physicians based upon certain factors which are unrelated to patient care, such as patient mix.

[17] 486 U.S. 94 (1988) (upholding multi-million dollar damage liability against medical staff peer reviewers for violation of the Sherman Act). *See* 132 Cong. Rec. H11, 590 (Daily Ed. Oct. 17, 1986) ("bad faith peer review activities permitted by the Patrick case could never obtain immunity under HR 5540").

Congress expressly provided that a plaintiff may rebut the presumption, by a preponderance of the evidence (42 U.S.C. § 11112(a)).

In addressing a plaintiff's claim to have rebutted the qualified immunity, courts around the country are just beginning to address the following underlying procedural issues:

1. When in the proceedings is the ultimate decision regarding applicability of the immunity to be made?

2. Who shall make this determination - judge or jury?

3. What kind and amount of evidence will suffice to rebut the presumption that defendants have met the conditions for the immunity?[18]

These issues are further discussed below.

III. WHILE CONGRESS INTENDED APPLICABILITY OF THE IMMUNITY TO BE DECIDED EXPEDITIOUSLY, WHERE POSSIBLE, IT DID NOT INTEND JUDGES TO USURP THE JURY'S FUNCTION.

There is general agreement among litigants, courts and commentators alike that, in keeping with the Congressional purpose to shield peer reviewers who act reasonably from costly extended litigation and potential liability, the initial determination of whether plaintiff may rebut the presumption that defendants have met the conditions for the immunity should be made as early in the proceedings as

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[18] Cases currently being litigated include Austin v. McNamara, 731 F.Supp. 934 (C.D. Cal. 1990) (granting summary judgment to defendant hospital and peer reviewers based upon HCQIA's immunity) (on appeal to the Ninth Circuit). Fobbs v. Holy Cross Health System Corps., 1992 Trade Cases (CCH) ¶ 69,767 (E.D.Cal. March 17, 1992) (granting summary judgment to defendants based on HCQIA immunity) (on appeal to the 9th Circuit); Decker v. IHC Hospitals (denying defendant's Motion to Dismiss) (on appeal to the 10th Circuit) (Civ. No. 91-4160, 91-4161).

possible.[19] Commentators suggest that it is unlikely Congress intended the issue to be resolved as early as upon a motion to dismiss on the pleadings under F.R.C.P. Rule 12(b)(6). This is because, as the Act expressly permits plaintiff to rebut the presumption in defendants' favor by a "preponderance of the evidence", plaintiff must be afforded the opportunity to obtain sufficient rebuttal evidence through discovery, before the immunity determination is made.[20] We agree that an initial determination of the immunity issue is more appropriate upon defendant's motion for summary judgment under F.R.C.P. Rule 56.

IV. THE QUESTION OF WHETHER HCQIA'S IMMUNITY APPLIES IS INITIALLY A QUESTION OF LAW FOR THE JUDGE TO DECIDE, BUT WHERE PLAINTIFF INTRODUCES SUFFICIENT EVIDENCE IN REBUTTAL, ULTIMATELY IT IS A QUESTION OF FACT FOR THE JURY.

A. Absent Express Statutory Authorization, the Judge Should Not Act as the Ultimate Factfinder With Respect to HCQIA's Immunity.

Defendants, as well as the American Hospital Association et al. (who appear as *Amici* in Support of Defendants, hereafter "*Amici* AHA et al."), suggest that determination of whether HCQIA's immunity applies to protect defendants in a peer review action is strictly a question of law to be determined solely by the

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[19] *See e.g.* HR Report No. 903, 99th Cong., 2d Sess. 3 (1985) (noting House Committee's intention that the immunity provisions "allow defendants to file motions to resolve the issue of immunity is as expeditious a manner as possible").

[20] *See generally* Scott, Charity "HCQIA's Grant of Immunity: Panacea or Pandora's Box?" Hospital Law Newsletter, Vol. 9, No. 3, Jan. 1992. This article, which is attached as Exhibit A for the Court's convenience, provides a cogent summary of the key points made in Professor Scott's exhaustive recent analysis of the application of HCQIA's immunity in peer review litigation. *See* Scott, Charity *Medical Peer Review, Antitrust, and the Effect of Statutory Reform*, 50 Maryland L.Rev. 316 (1991).

judge [Defendant's Brief, pp. 13, 17; AHA Brf., pp. 7, 23 *et seq.*]. This contention is wholly without merit. Although it should be rare, occasionally plaintiff will produce sufficient evidence to create a genuine and material issue of fact regarding whether defendants met the statutory conditions for the immunity. Defendants' position would require judges to weigh the evidence and determine the facts. Nowhere in the HCQIA did Congress expressly authorize a judge to act as the ultimate factfinder in determining applicability of the immunity protection. Moreover, while it is clear from the record that Congress intended the immunity question to be decided expeditiously if possible, there is no evidence that Congress intended the judge to serve as the ultimate factfinder in this regard.

Contrary to Defendants' suggestions, the Congressional Record does not support the conclusion that judges should decide this question in all cases. The statement cited by defendants in support of their argument in this regard does not support this interpretation. That statement provides only that a judge may make this determination, not that a judge must make it:

> The Committee intends that these provisions allow defendants to file motions to resolve the issue of immunity in as expeditious a manner as possible. The provisions **would allow** a court to make a determination that the defendant has or has not met the standards specified in Section 102(a) [42 U.S.C. § 11112(a)]. The Committee intends that the court could so rule even though other issues in the case remain to be resolved. [HR Rep. No. 99-903, 99th Cong., 2d

Sess. 12, *reprinted in* 1986 U.S. Code Cong. & Admin. News 63940.]

Clearly, Congress intended judges to apply the immunity only where they should do so under ordinary summary judgment analysis: when no reasonable jury could conclude that the immunity standards had not been met. Representative Waxman, the primary sponsor of HCQIA, expressly contemplated involvement of the jury when the facts precluded resolution of the case by summary judgment. In explaining the decision to change the standard of proof for rebuttal of the immunity from one which would have required "clear and convincing" evidence to the more traditional "preponderance of the evidence" standard, Congressman Waxman stated that it was believed that the clear and convincing standard might be "too complex in the mind of the juries" 132 Cong. Rec. H11590-591 (daily ed. Oct. 17, 1986, emphasis added).

Thus, plaintiffs are correct that Congress anticipated the possibility that the immunity decision would be determined by the jury. Absent an express statutory mandate for the judge to act as factfinder in this regard, there is no basis upon which to argue that the judge should undertake the ultimate factfinding duties normally reserved to the jury. Moreover, there is a significant danger in adopting such an approach. As is well-illustrated by law professor Scott:

> . . . authorizing judicial factfinding on [HCQIA] immunity standards could create a conflict with the jury's factfinding on the underlying claims in an antitrust case. For example, suppose that a judge determined that the defendants were not entitled to immunity because, as a factual matter, they did not meet the reasonable

> belief/reasonable effort standards. Would the judge's factual determination then bind the jury when it considered the defendants' argument, in defending against an antitrust conspiracy claim, that they had a legitimate reason for acting adversely to the plaintiff? (Citation omitted).[21]

Clearly it would serve neither plaintiffs' nor defendants' interests for the judge to act as the ultimate factfinder on the question of HCQIA immunity. Rather, the judge must make an initial determination regarding whether plaintiff has produced evidence sufficient to rebut the presumption in favor of defendants according to the general principles of "new era" summary judgment adjudication, as is further discussed below.[22]

B. Consistent With Congressional Intent and Federal Law and Procedure, the Question of Whether HCQIA's Immunity Applies is Initially a Question of Law for the Judge, But Where Plaintiff Introduces Sufficient Rebuttal Evidence, Ultimately it is Question of Fact for the Jury.

At the time Congress was in the process of enacting HCQIA, Congress correctly assumed that federal courts were applying the so-called "old era" standards for summary adjudication. Under the "old era", whenever a plaintiff introduced "even a suggestion of an issue of fact . . . [this] tended to emasculate summary judgment as an effective procedural device."[23] Under those circumstances, if Congress had merely enacted the conditional HCQIA immunity

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21 Scott, Hospital Law Newsletter, *supra* note **Error! Bookmark not defined.**, at 4.

22 *See e.g.* Anderson v. Liberty Lobby, 477 U.S. 242, 249, 91 L.Ed.2d 202, 106 S.Ct. 2505 (1986) (". . . it is clear enough from our recent cases that at the summary judgment stage, the judge's function is not himself to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial.").

23 Street v. J.C. Bradford & Co., 886 F.2d 1472, 1476 (6th Cir. 1989) Rhg. Den. (1990).

without the special presumption and burden of proof requirements, any adversely affected physician could have merely alleged improper motive on the part of the peer reviewers and hospital and thereby defeated a summary judgment motion by defendants.[24]

Recognizing that this "old era" principle presented the danger of giving plaintiffs a grossly unfair advantage in peer review cases, Congress, in enacting HCQIA's immunity with the presumption and rebuttal standard, sent a clear message to the courts that it intended them to scrutinize closely plaintiffs' evidentiary offering at the summary judgment stage. By adopting a "reasonableness" standard, instead of a merely subjective "good faith" standard, Congress sought to avoid full jury trial proceedings on the sole basis of mere allegations of anticompetitive or other bad motives.[25]

Coincidentally, in 1986, the very year that HCQIA was hotly debated and ultimately passed, the Supreme Court issued rulings in the now famous trilogy of cases which was to significantly change the course of summary judgment adjudication, ushering in a "new era".[26] Under "new era" principles, which Congress could not have anticipated, the judge has considerably greater latitude in

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[24] For a discussion of "new era" summary adjudication principles and the effect of HCQIA's immunity, *see generally* Scott, Charity, *Medical Peer Review, Antitrust, and the Effect of Statutory Reform, supra* note **Error! Bookmark not defined.** at pp. 372 - 403. *See also* Street v. J.C. Bradford & Co., *supra*, note **Error! Bookmark not defined.**.

[25] *See* note **Error! Bookmark not defined.**, *infra*, and accompanying text.

[26] *See* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 106 Sup. Ct. 2505, 91 L.Ed.2d 202 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 106 Sup. Ct. 2548, 91 L.Ed.2d 265 (1986); and Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 106 Sup. Ct. 1348, 89 L.Ed.2d 538 (1986).

granting summary judgment, based upon his or her determination that the plaintiff has failed to produce sufficient probative evidence of a genuine issue of material fact. Thus, even without HCQIA's immunity, the "new era" test for summary judgement is much more protective of peer reviewers than the "old era" test had been. However, the enactment of the immunity with its presumption and rebuttal standard underscores Congress' intent that plaintiff's allegations be carefully scrutinized before defendants' summary judgement motions in peer review cases are denied.

1. Burdens of Proof and Effect of Presumption.

Under general principles of summary adjudication, the moving party (generally the defendants) has the initial burden of either (1) showing that plaintiff has failed to produce evidence supporting one or more of the elements of plaintiff's prima facie case or (2) presenting affirmative evidence that disproves or negates one or more of the elements of plaintiff's claim. Once defendants have met their burden in this respect, the burden of production shifts back to the plaintiff to show a genuine dispute of fact which would require resolution by the jury.[27]

If there were no presumption in favor of defendants, under HCQIA, the defendants would have the burden of showing either that plaintiff failed to produce evidence in support of plaintiff's prima facie case or that defendant did indeed act

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[27] *See generally* Scott, *supra*, note 2, at 376-383.

reasonably and fairly in the peer review process in compliance with the four conditions for the immunity protection.[28] HCQIA's presumption relieves defendants from this burden.[29, 30] In other words, defendants may rest on the immunity presumption provided in the Act and the sole burden will be on the plaintiff, who must establish a *genuine* issue of *material* fact regarding whether or not defendants really did act:

> (1) In the reasonable belief that the action was in the furtherance of quality health care,
>
> (2) After a reasonable effort to obtain the facts of the matter,
>
> (3) After adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and
>
> (4) In the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).[31]

All four of the conditions for the immunity are potentially at issue, for HCQIA requires compliance with all four of them for the immunity to apply. Thus,

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[28] A challenge to plaintiff's *prima facie* case may be (and generally should be) made as early as upon a Motion to Dismiss on the Pleadings. F.R.C.P. 12(b). At the summary judgment stage, defendant may also present a challenge based upon HCQIA's immunity. *See generally* discussion in Section III, above.

[29] This interpretation would appear to accord the presumption its clearly intended effect. *See generally*, Moore's Federal Practice, 2nd Ed., Vol. 10, § 301.02, P. III-14, discussing Federal Rule of Evidence 301 ("Congress, of course is a creative source for presumptions. If it creates both a presumption and states its effect, the presumption should be applied, when appropriate and the effect declared by the statute should be accorded.")

[30] Of course, even if defendants have not met the HCQIA immunity standards they may still argue that the plaintiff has failed to state a claim or support a prima facie case regarding any of plaintiffs claims, including those brought under the antitrust laws. Such arguments should be considered following applicable principles, without regard to HCQIA.

[31] 42 U.S.C. § 11112(a), providing four conditions for HCQIA's qualified immunity, emphasis added. *See also* discussion under Section II.B., above.

plaintiff may defeat defendant's motion by producing sufficient probative evidence which could lead a jury to conclude by a preponderance of the evidence that defendant's failed to meet any one of the conditions.

In sum, the presumption of immunity works to defendants' benefit in two ways. First, at the summary judgment stage of the proceedings, defendants need not produce any evidence to rebut plaintiff's allegations. Rather, defendants need only rest on the HCQIA immunity's presumption that they acted reasonably. The entire pre-trial burden is therefore on plaintiff to present rebuttal evidence which is sufficient to overcome the presumption. Second, by specifying that the presumption may only be overcome by a preponderance of the evidence, HCQIA emphasizes the principle which developed in the "new era" cases, that plaintiffs must offer significant affirmative evidence, well beyond mere allegations, in order to survive defendants' motion, as is further discussed below.

2. Plaintiff's Rebuttal Burden.

By far the hardest question in application of the HCQIA immunity is what amount or kind of evidence will be sufficient at the summary judgment stage of the proceedings to overcome the presumption in favor of defendants. In this regard, the Supreme Court trilogy is most significant. In essence, these cases "breathe new life" into summary adjudication by recognizing that even complex cases may be resolved appropriately by summary judgment and by requiring a

plaintiff to either "put up or shut up" in responding to defendant's motion for summary judgment.[32] As this Court noted in Street v. J.C. Bradford & Co.,

> Further reflection and a review of current court decisions and commentary concerning the effect of the three Supreme Court decisions yields the conclusion that these three decisions establish at least the following principles for the "new era" summary judgment practice:
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> 1. Complex cases are not necessarily inappropriate for summary judgment. (Footnote omitted.)
>
> 2. Cases involving state of mind issues are not necessarily inappropriate for summary judgment. (Footnote omitted.)
>
> 3. The movant must meet the initial burden of showing "the absence of a genuine issue of material fact" as to an essential element of the non-movant's case. (Footnote omitted.)
>
> 4. This burden may be met by pointing out to the court that the respondent, having had sufficient opportunity for discovery, has no evidence to support an essential element of his or her case. (Footnote omitted.)
>
> 5. A court should apply a federal directed verdict standard in ruling on a motion for summary judgment. The inquiry on a summary judgment motion or a directed verdict motion is the same: "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." (Footnote omitted.)
>
> 6. As on federal directed verdict motions, the "scintilla rule" applies, i.e., the respondent must adduce more than a scintilla of evidence to overcome the motion. (Footnote omitted.)
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> 7. The substantive law governing the case will determine what issues of facts are material, and any heightened burden of proof required by the substantive law for an element of the respondent's case, such as proof by clear and convincing

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32 *See generally* Street v. J.C. Bradford & Co., 886 F.2d 1472 1476-1481 (6th Cir. 1989).

evidence, must be satisfied by the respondent. (Footnote omitted.)

8. The respondent cannot rely on the hope that the trier of fact will disbelieve the movant's denial of a disputed fact, but must "present affirmative evidence in order to defeat a properly supported motion for summary judgment." (Footnote omitted.)

9. The trial court no longer has the duty to search the entire record to establish that it is bereft of a genuine issue of material fact. (Footnote omitted.)

10. The trial court has more discretion than in the "old era" in evaluating the respondent's evidence. The respondent must "do more than simply show that there is some metaphysical doubt as to the material facts." (Footnote omitted.) Further "where the record taken as a whole could not lead a rational trier of fact to find" for the respondent, the motion should be granted. (Footnote omitted.) The trial court has at least some discretion to determine whether the respondent's claim is "implausible." (Footnote omitted.) *Id.* pp. 1479-1480.

[Note that we believe that principles 3 and 4 are obviated in a peer review case by HCQIA's presumption in favor of defendants, except to the extent defendants are arguing pursuant to general law that plaintiff has failed to state or support a prima facie case. *See* discussion, above.]

As they are applied in the peer review litigation context, the following extrapolated principles from the Supreme Court trilogy are particularly pertinent:

a. To survive defendant's motion for summary judgment, a plaintiff must produce sufficient affirmative probative evidence.

If one thing is clear from the Supreme Court trilogy, it is that no longer will a mere "scintilla of evidence" presented by a plaintiff in countering defendants' motion for summary judgment be sufficient to defeat that motion. To the contrary,

the Supreme Court has made it crystal clear that "*a party opposing a properly supported motion for summary judgment ''may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial.*''"[33] The Supreme Court also referred to its earlier decision in First National Bank of Arizona v. Cities Service Co., 391 U.S. 253, 290, 20 L.Ed.2d 569, 88 S. Ct. 1575 (1968), where it held that "in the face of the defendant's properly supported motion for summary judgment, the plaintiff could not rest on his allegations of a conspiracy to get to a jury without `any significant probative evidence tending to support the complaint.'" Rather, plaintiff must present evidence to show that there is a "*genuine*" issue of "*material*" fact. Liberty Lobby, *supra*, note **Error! Bookmark not defined.** at 248. With respect to "materiality", the Supreme Court stated that:

> . . . the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted . . . . This materiality inquiry is independent and separate from the question of the incorporation of the evidentiary standard into the summary judgment determination. That is, while the materiality determination rests on the substantive law, it is the substantive law's identification of which facts are critical and which facts are irrelevant that governs. Any proof or evidentiary requirements imposed by the substantive law are not germane to this inquiry, since materiality is only a criterion for categorizing factual disputes in their relation to the legal elements of the claim and not a criterion for evaluating the evidentiary underpinnings of those disputes. (*Id.*, emphasis added.)

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[33] Anderson v. Liberty Lobby, Inc., *supra* note **Error! Bookmark not defined.** at 248, emphasis added.

The court went on to define "genuine" as evidence which would allow a reasonable jury to return a verdict for the non-moving party:

> Our prior decisions may not have uniformly recited this same language in describing genuine factual issues under Rule 56 . . . . As [our prior cases] indicate, there is no issue for trial unless there is sufficient evidence favoring the non-moving party for a jury to return a verdict for that party (citations omitted). If the evidence is merely colorable, (citations omitted) or it is not significantly probative, (citations omitted), summary judgment may be granted. *Id.* at 250.[34]

From this it is clear that, in cases involving HCQIA's immunity, the plaintiff may not succeed in defeating the presumption in favor of defendants by merely *alleging* (1) that defendants acted in bad faith or with unlawful purpose or that defendants are not credible and (2) that, therefore, a jury could find that they had not acted reasonably or provided a fair hearing as is required for immunity protection. Rather, the plaintiff must produce *significant affirmative* evidence which is sufficient for a jury to conclude that one or more of the immunity conditions were not met.

For example, assume *arguendo* that two or more physicians, in positions of leadership within the medical staff, were jealous of or threatened by a competitor (who presented no quality concerns) and wished to drive that physician from the community. To achieve their purpose, the physicians might bring false charges

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[34] *See also* Matsushita Elec. Ind. Co. v. Zenith Radio, 475 U.S. 574, 586-587, 89 L.Ed.2d 538, 106 S. Ct. 1348 ("The issue of fact must be 'genuine'. . . . When the moving party has carried its burden under Rule 56(c), (footnote omitted) its opponent must do more than simply show that there is some metaphysical doubt as to the material facts . . . . Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial' (citation omitted)).

against the competitor, might falsify records and might present perjured testimony in a disciplinary hearing. Because of the falsified records and perjured testimony, on the surface, the record of the investigations and hearings might appear reasonable and fair. If plaintiff merely *alleged* that defendants had conspired against him, had falsified records and had presented perjured testimony, without producing any "hard" evidence on these allegations, plaintiff would be unable to defeat defendants' motion for summary judgment based on HCQIA's immunity. Although perhaps harsh to the plaintiff in this example, this would be the proper result, as it would achieve the Congressional intent underlying the immunity by upholding HCQIA's objective standard and it is consistent with federal summary adjudication principles in the "new era".

However, if plaintiff could produce credible affirmative evidence supporting one or more of the allegations, then a judge might find that a genuine issue of fact arose as to whether the defendants had indeed met all four of the immunity conditions. Accordingly, in the scenario posed above, if plaintiff introduced documentary evidence (in the form of letters or other communications between the parties) which reflected the alleged unlawful purpose or activities, such evidence would be extremely probative of the reasonableness or fairness of defendants' actions. Thus, documentary evidence or witness testimony that defendants had brought false charges (i.e. that they had no quality concerns regarding the accused or that they could not reasonably have had any such concerns) would tend to rebut the presumption that defendants acted "in the

reasonable belief that the action was in the furtherance of quality health care," the first condition necessary for the immunity. 42 U.S.C. § 11112(a)(1). Similarly, documents or witness testimony showing that defendants had falsified records or presented perjured testimony would tend to rebut not only the presumption that defendants met the first immunity condition but also the presumption that they met the other three (i.e. that they acted after a reasonable effort to obtain the facts, after an adequate notice and hearing and in the reasonable belief that the action taken was reasonably warranted). 42 U.S.C. § 11112(a)(2)(3)(4).

In the case of Miller v. Indiana Hospital, for another example, evidence was introduced which tended to show that members of the hospital and administration had expressed concerns about the competitive threat posed by plaintiff and had solicited support within the medical staff in their efforts to prevent plaintiff from hiring good doctors to work at his medical center.[35] Similarly, in Sweeney v. Athens Regional Medical Center, the plaintiff produced evidence of a joint letter, written by the chiefs of departments of obstetrics at two hospitals, stating that a nurse midwife's home birth practice "must be eliminated".[36]

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[35] 843 F.2d 139 (3rd Cir.), *cert. den.* 488 U.S. 870 (1988).

[36] 709 F.Supp. 1563, 1572 (M.D. Ga. 1989) (the court sent the case to the jury because a material question of fact was raised regarding whether defendants' expressed quality concerns were real or rather a ruse designed to hide their anticompetitive purposes). Although HCQIA's immunity does not apply to professional review actions regarding nonphysicians, the kinds of evidence which would defeat summary judgment in peer review cases regarding nonphysicians will often be the same kinds of evidence which would tend to defeat summary judgment in HCQIA peer review cases. *See* Oltz v. St. Peter's Community Hosp., 861 F.2d 1440, 1443 (9th Cir. 1988) (anesthesiologist defendants had prepared report showing impact of nurse anesthetists on anesthesiologists' incomes), Medical Staff of Memorial Medical Center, 110 F.T.C. 541, 544 (1988) (consent decree following F.T.C. allegation that nurse midwives were impeded in obtaining privileges due to concerns that allowing them privileges would create an "economic problem"

The foregoing examples demonstrate evidence which goes beyond mere allegations and which, if when taken together with other evidence could lead a reasonable jury to find that defendants had not acted reasonably or provided a fair hearing, then this could lead a judge to conclude that a genuine issue of material fact had been raised which must be resolved by the jury. Should the judge so conclude, then plaintiff will have met the rebuttal burden.

b. State of mind evidence should be considered if it is material.

In light of the objective nature of HCQIA's presumption which is afforded to defendants in peer review cases, it has been suggested that evidence pointing to a defendant's state of mind, motivation or other subjective qualities is not pertinent to the inquiry of whether defendants meet the conditions for the immunity [*see e.g.* Brf. of *Amici* AHA et al., pp. 16-17, Def. Brf. p. 23]. While we agree that the HCQIA establishes an objective standard and that allegations of a subjective anticompetitive intent will not defeat the immunity if the four objective standards are met, state-of-mind evidence may be relevant to those four standards and should be considered to the extent that it is so relevant. Moreover, under the standards which are clearly articulated by the Supreme Court in Liberty Lobby, *supra*, state-of-mind evidence should be afforded the same attention as any other kind of evidence produced. Thus, in a HCQIA peer review case, the court should

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for obstetricians. There was also evidence (1) that the defendants' alleged quality concerns did not arise until after they had expressed concerns regarding competition and (2) of conflicts of interest and bias in the hearing).

examine the evidence to determine whether it is "material" to the issue of whether defendants acted reasonably under fair procedures in compliance with the four statutory conditions, and whether, when taken together with any other evidence which plaintiff produces, the totality of the evidence points to an issue of fact which is "genuine" (i.e. sufficient evidence such a reasonable jury could find by a preponderance of that defendants had not met one or more of the immunity conditions).[37]

In the peer review context under HCQIA, state-of-mind evidence could be extremely pertinent to the issue of whether defendants did, in fact, act reasonably and fairly in undertaking the professional review action at issue. Revisiting the hypothetical example discussed under subsection a., above, if plaintiff produced copies of letters from one defendant to another showing no quality concerns, while showing defendants' acknowledgement that plaintiff's successful practice was "sending us to the poor house" and agreement to do "whatever it takes to drive [the plaintiff] out of town", such state-of-mind evidence could, either standing alone or taken together with the other evidence plaintiff produces, be sufficient for the judge to find that a reasonable jury could agree with plaintiff that defendants did not meet the conditions for the immunity. Most likely, such evidence would be offered by plaintiff to show that defendants did not "act in the reasonable belief that the [professional review] action was in the furtherance of quality health care

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[37] Liberty Lobby, *supra*, note **Error! Bookmark not defined.** at 248, 249. *See also* discussion under Section III.B.2.a., above.

(the first condition for the immunity). Such evidence was apparently present in the case of Patrick v. Burget, where a jury awarded Dr. Patrick over $600,000, having found that the defendants specifically intended to injure Dr. Patrick or destroy competition.[38]

Thus, state-of-mind evidence should not be rejected as a category in peer review cases under HCQIA. Rather, it should be rejected only if it is immaterial to whether defendants acted reasonably and fairly (in accordance with the four statutory conditions for the immunity) or if, taken together with other evidence presented by plaintiff, the totality of the evidence is not sufficiently probative for a reasonable jury to find by a preponderance of the evidence that defendants had not acted reasonably and fairly in accordance with the statutory conditions.

We emphasize again that, in noting that state-of-mind evidence is to be treated as any other evidence, we do not mean to suggest that *mere allegations* regarding the defendants' state of mind are sufficient to create a genuine issue of material fact. To the contrary, the legislative history of HCQIA indicates that the objective "reasonableness" standard was selected for purposes of the immunity,

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[38] 486 U.S. 94 (1988) (The Supreme Court, in upholding the lower court's ruling by failing to accord the hospital state action immunity protection, noted that the Court of Appeals for the Ninth Circuit which had previously heard the case, characterized the defendant's conduct as "shabby, unprincipled and unprofessional" (*Id.* at 98, n.3, quoting 9th Circuit opinion 800 F.2d 1498 at 1509). The evidence showed, among other things, that (1) defendants had offered Dr. Patrick a partnership in their clinic and had only begun criticizing him when he declined and established a competing practice, (2) that defendants criticized a physician in Dr. Patrick's employ yet immediately offered that physician a position in their clinic when he left Dr. Patrick's practice, (3) that defendants lied to patients regarding Dr. Patrick's availability, and (4) that defendants gave Dr. Patrick inadequate notice of the charges against him and that the hearing committee members were inattentive during the hearing and refused to answer questions as to their personal biases against Patrick.

rather than a "good faith standard" because the latter might lead to the incorrect interpretation that Congress intended that a peer reviewer's subjective good faith be *all that is required* for the immunity.[39] Conversely, a strictly "good faith" standard could give rise to extensive, timely and costly inquiries based upon a plaintiff's assertion that mere allegations of subjective bad faith, standing alone, would be sufficient to rebut the presumption. Clearly, this is not what Congress intended, as is discussed above.[40]

c. In ruling on the applicability of HCQIA's immunity at the summary judgment stage, the

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[39] *See e.g.* Horner, Susan L. *The Health Care Quality Improvement Act of 1986: Its History, Provisions, Applications and Implications*, Am.J.Law & Med., Vol. XVI, No. 4, p. 468 and note 78 and authorities cited therein.

[40] Similarly, in the antitrust context, for example, the Supreme Court has made it clear that although inferences to be drawn from underlying facts must be viewed in the light most favorable to the non-moving party:

antitrust law limits the range of permissible inferences from ambiguous evidence in a § 1 case. Thus in Monsanto Co. v. Spray-Rite Service Corp., 465 U.S. 752, 72 L.Ed.2d 775, 104 S. Ct. 1464 (1984), we held that conduct as consistent with permissible competition as with illegal conspiracy does not, *standing alone*, support an inference of antitrust conspiracy. (Citations omitted.) To survive a motion for summary judgment or for a directed verdict, a plaintiff seeking damages for a violation of a § 1 must present evidence "that tends to exclude the possibility" that the alleged conspirators acted independently. (Citation omitted.) Respondents in this case, in other words, must show that the inference of conspiracy is reasonable in light of the competing inferences of independent action or collusive action that could not have harmed respondents. (Citation omitted.) Matsushita, *supra* note **Error! Bookmark not defined.**, at 588.

Commentors have noted, and we agree, that the Matsushita court was signaling a trend among the federal courts to disfavor antitrust trials where proof of the underlying claims depended solely upon inferences of illegality, in the absence of direct or strong circumstantial evidence, in Section 1 cases. Although the "old era" courts might have allowed a case to go to the jury based strictly upon circumstantial evidence from which the jury might infer a conspiracy, in the "new era" a "plus factor" is needed. This "plus factor" would be comprised of evidence tending to make the inference of unlawful conspiracy stronger than the inference of lawful action. *See* Scott, *Medical Peer Review, Antitrust, and Effect of Statutory Reform, supra* note **Error! Bookmark not defined.** at 342. Moreover, under HCQIA, even direct evidence of anticompetitive motives may not be sufficient for plaintiff to survive summary judgment if there is also credible evidence in the record of legitimate quality concerns. In this event, the judge must determine as a matter of law whether plaintiff's evidence could lead a reasonable jury to find by a preponderance of the evidence that defendant had not met one or more of the immunity conditions (e.g. that defendant did not act in the reasonable belief that the action was in the furtherance of quality care) as is discussed above.

> judge must apply the same standard that would be applied upon a motion for directed verdict at trial.

In Liberty Lobby, the Supreme Court held that a judge must view the evidence presented by a plaintiff in countering defendants' motion for summary judgment, in light of the substantive evidentiary standard of proof that would apply in a trial on the merits. Thus, for example:

> [W]here the First Amendment mandates a "clear and convincing" standard, the trial judge in disposing of a directed verdict should consider whether a reasonable factfinder could conclude, for example, that the plaintiff had shown actual malice with convincing clarity. Liberty Lobby, *supra* note **Error! Bookmark not defined.** at 252.

Similarly:

> [I]f the defendant in a run-of-the-mill civil case moves for summary judgment or for a directed verdict based on the lack of proof of a material fact, the judge must ask himself not whether he thinks the evidence unmistakably favors one side or other, but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented. *Id.*, emphasis added.

Under HCQIA, the judge must therefore review the evidence presented by plaintiff in response to defendant's motion for summary judgment, not to determine whether the evidence unmistakably favors one side or the other, but rather to determine whether a reasonable jury could find that plaintiff had sufficiently rebutted the presumption in favor of defendants (i.e. that a reasonable jury could find that plaintiff had shown by a preponderance of the evidence that defendants had not acted reasonably or fairly under the four statutory conditions necessary for the immunity). 42 U.S.C. § 11112(a).

V. APPLICATION OF THE HCQIA'S QUALIFIED IMMUNITY IS WHOLLY DIFFERENT FROM APPLICATION OF THE QUALIFIED IMMUNITY AFFORDED TO PUBLIC OFFICIALS.

Amici AHA et al. argue that the standard for the application of qualified immunity for public officials at common law should guide the Court in its application of HCQIA immunity. This assertion is incorrect. Although similar public policy concerns underlie both the common law qualified immunity for public officials and the statutory peer review immunity of HCQIA, the specific provisions set forth by Congress in HCQIA clearly determine whether the immunity applies to the conduct of professional review actions.

A. The HCQIA and Public Official Immunities are Supported by Similar Public Policy Considerations.

Amici AHA et al. rightly observe that similar public policy considerations support both the HCQIA and public official immunities. In enacting the HCQIA, Congress sought to encourage peer review by removing the very substantial threat of litigation from participants in peer review processes that are reasonable and fair. Representative Ron Wyden (D.Ore.), in introducing the bill, stated:

> [I]f this country wants physicians to come forward and prevent truly bad doctors from hurting people, there must be legal protection for them from the possibility of multimillion dollar litigation, years in court and financial ruin. That's exactly what the Health Care Quality Improvement Act would provide.

132 Cong. Rec. E735 (daily ed. Mar. 12, 1986) (statement of Rep. Wyden).

Representative Henry Waxman (D. Cal.), one of the sponsors of the HCQIA, clearly delineated the balancing of public policy interests in the Act:

> The purpose of the Federal law is to encourage peer review by assuring adequate protection for all parties-- peer reviewers, witnesses and accused physicians alike. Peer reviewers needed protection against suits under both State and Federal laws, while accused physicians needed guarantees of fair procedures. The Health Care Quality Improvement Act of 1986 itself provides both types of protection.

132 Cong. Rec. E4137 (daily ed. Dec. 11, 1989) (statement of Rep. Waxman).

These public policy considerations are much like those supporting the immunity afforded to government officials as enunciated by the United States Supreme Court in Harlow v. Fitzgerald, 457 U.S. 800, 813-815 (1982). Just as Congress enacted the HCQIA after balancing the interests of the public in receiving quality health care through effective peer review and the interests of physicians in challenging adverse medical staff determinations, the Supreme Court fashioned a qualified immunity for public officials after balancing the interests of individuals seeking enforcement of their rights and the interests of society in protecting government officials' ability to perform their jobs free from unrestrained risks of liability:

> [I]t cannot be disputed seriously that claims frequently run against the innocent as well as the guilty — at a cost not only to the defendant officials, but to society as a whole. These social costs include the expenses of litigation, the diversion of official energy from pressing public issues, and the deterrence of able citizens from acceptance of public office. Finally, there is the danger that fear of being sued will `dampen the ardor of all but the most resolute, or the most irresponsible [public officials], in the unflinching discharge of their duties.'

Id. at 814.

Thus, both the statutory HCQIA immunity for peer review and the common law qualified immunity for public officials rose from a desire to promote activity in the public interest while preserving the rights of those aggrieved by the protected activity. However, it is at this point that the similarity between the two immunities ends.

B. The HCQIA and Public Official Immunities are Applied Under Fundamentally Different Standards.

Amici AHA et al. argue that the HCQIA and public official immunities should be applied in a similar manner. Although *Amici* AHA et al. acknowledge in passing the different focus of these immunities (Br. at 18), the distinction is blurred in their argument. For example, *Amici* AHA et al. assert that "HCQIA's objective standard gives ample room for mistaken judgments by protecting all but the plainly incompetent or those who knowingly violate the law." [Br. of *Amici* AHA et al. at 17.] As described below, this is more accurately a statement of the qualified immunity for public officials, and a fundamental misstatement of the statutory HCQIA immunity for professional review actions.

Qualified immunity for public officials is a creature of common law. The Supreme Court recently described its boundaries:

> We therefore hold that government officials performing discretionary functions, generally are shielded from liability for civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known.

Harlow v. Fitzgerald, 457 U.S. at 818.

The standard announced in Harlow represents an attempt by the Supreme Court to provide government officials with "some form of immunity from suits for damages . . . to shield them from undue interference with their duties and from potentially disabling threats of liability." *Id.* at 806. As this Court recently observed, the doctrine provides an objective test for the appropriate application of qualified immunity to the *unique arena of the behavior of public officials.* Poe v. Haydon, 853 F.2d 418, 423 (6th Cir. 1988) ("exposing government officials to the same legal hazards faced by other citizens may detract from the rule of law instead of contributing to it"). Public official immunity turns on whether the actions in question were lawful or reasonably believed to be so. *Id.* at 423. This deferential standard is both sensible and necessary, given that the issue for public official immunity is whether public officials may be expected to know *all* of the existing laws, including principles of common law as construed by the courts, which may impact their professional duties. As a wide spectrum of laws potentially apply to public officials in carrying out their duties, arguable compliance with any law which is not "clearly established" is all that reasonably may be demanded.[41] In contrast, the issue for HCQIA immunity is whether reviewers have met express

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[41] *See e.g.* Mitchell v. Forsyth, 472 U.S. 511, 526, 86 L.Ed.2d 411, 105 S. Ct. 2806 (finding that the qualified immunity was meant to protect government officials *"in cases where the legal norms the officials are alleged to have violated were not clearly established at the time"). See also* Brandenburg v. Cureton, 882 F.2d 211, 215 (6th Cir. 1989)("in other words, 'the contours of the right must be sufficiently clear that a reasonable official would understand that what he is doing violates that right' [citing Anderson v. Creithton, 483 U.S. 635, 637-39 (1987)] This circuit has noted that the question is whether 'any officer in the defendant's position, measured objectively, would have clearly understood that he was under an affirmative duty to have refrained from such conduct.'[citing Dominque v. Telb, 831 F.2d 673, 676 (6th Cir. 1987)].")

conditions set forth in a distinct, clearly written statute. The Harlow standard does not, and does not purport to, set forth the criteria for the application of a statutory immunity in the entirely different context of professional review actions.

Rather than rely upon common law standards for the application of immunity for professional review actions, Congress set forth the standards for the application of the HCQIA immunity in the statute itself. Thus, HCQIA provides immunity from monetary damages to professional review actions" taken:

> (1) in the reasonable belief that the action was in the furtherance of quality health care;
>
> (2) after a reasonable effort to obtain the facts of the matter;
>
> (3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances; and
>
> (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

42 U.S.C. § 11112.

The Harlow test for the application of qualified immunity for public officials has no place in this statutory scheme. The HCQIA statute provides immunity for professional review actions when the four criteria noted above are met. If they are not met, no immunity applies to the professional review action. The Harlow test, whether a reasonable person would have known of these legal obligations, has no relevance to HCQIA immunity.[42] The HCQIA statute

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[42] The inapplicability of the common law qualified immunity for public officials to professional review actions is aptly demonstrated by the Supreme Court's recent decision in Hunter v. Bryant, 112 S.Ct.

establishes a wholly different scheme for determining whether its immunity provisions apply.

In short, reference by the *Amici* AHA et al. to the qualified immunity for public officials confuses rather than clarifies the issues before the Court. The question whether the HCQIA immunity applies should be resolved by reliance on the language of the statute itself, not by misguided incorporation of the standards of a different, common law immunity.

CONCLUSION

Amici the American Medical Association, the California Medical Association, and the Ohio State Medical Association strongly support resolution of peer review cases as early in the proceedings as possible. Resolution by way of summary judgment in defendants' favor may be appropriate in most cases. Accordingly, where plaintiff's claims are based upon mere allegations or plaintiff has otherwise failed to produce significant probative evidence sufficient to rebut the HCQIA presumption that defendants acted reasonably and fairly in the peer review process (in accordance with the four statutory conditions), plaintiff may not survive defendants' motion for summary judgment. However, in order to protect

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534 (1991), in which the Court held that the actions of two Secret Service agents, in arresting a man they believed posed a threat to the life of the President, were entitled to immunity because, even though mistaken, the actions were undertaken in the reasonable belief that they were lawful. In contrast, HCQIA immunity applies only when the statutory standards are met, regardless of whether the participants in the professional review process believe the standards are met, or even whether the participants are aware of the standards.

against abuse in the peer review process, Congress intended that, where plaintiff has produced evidence sufficient for a jury to find that defendants did not meet the statutory conditions, plaintiff has rebutted the presumption in favor of defendant and the case must proceed to trial.

This standard for review *at the summary judgment stage* does not require plaintiff to "prove" by a preponderance of the evidence that defendants did not act reasonably. There is no authority for the judge to act as the ultimate factfinder in this regard and, indeed, it would pose a danger for the judge to do so. Rather, plaintiff's burden is to raise a genuine issue of material fact regarding whether defendant met any one of the four objective conditions for the immunity. Thus, if the judge finds that the evidence is such that no reasonable jury could find by a preponderance of the evidence that the plaintiff has rebutted the presumption as to a condition for the immunity, then, as a matter of law, the judge must grant summary judgment to the defendant. However, it the judge finds that the evidence presented by plaintiff is such that a reasonable jury could find by a preponderance of the evidence that defendant failed to meet a condition for the immunity, then plaintiff has successfully rebutted the presumption in favor of defendants and the case must proceed to trail. Similarly, if the judge finds that the evidence is such that reasonable minds could differ as to its import, the judge should enter neither a summary judgment nor a directed verdict for defendant. Liberty Lobby, *supra*, note **Error! Bookmark not defined.** at 250. Defendants may still obtain

immunity if the jury concludes, as a matter of fact, that defendants did indeed meet the statutory conditions.

Finally, the qualified immunity for public officials, while supported by a similar public policy rationale as that which supports HCQIA's qualified immunity, is fundamentally different in application. The test for applicability of the qualified public official immunity rests on common law principles regarding whether the actions involved were lawful or reasonably believed to be so in the context of the unique arena wherein public officials function. In contrast, HCQIA provides four express objective statutory conditions, each of which must be met for entitlement to the immunity. It is against these four objective conditions, and only these conditions, that peer reviewers' actions are to be judged. Peer reviewers under HCQIA are already at an advantage vis-a-vis adversely affected physicians, as peer reviewers are entitled to a presumption that they have met the statutory conditions. Given that peer reviewers have the benefit of both clear standards under HCQIA and the presumption in their favor, not only is there no need to afford peer reviewers the same deference as public officials, but it would be unfair to adversely affected physicians to do so.

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