President's Page

Cur Vexatum[1]

By Kenneth Y. Pauker, M.D., President

The CSA cares about the opt-out because our ethical obligation is to protect patients—not only our current patients, but also generations yet to come—by placing their interests foremost.

Justice on Trial

The opt-out lawsuit in California, *CSA and CMA v. Schwarzenneger,*[2,3] is entering a new and critical stage. We, who were plaintiffs in the Superior Court, morphed into appellants before the California Court of Appeal, wherein again, unfortunately and outrageously, we unjustifiably did not prevail. The unanimous decision by the three-judge panel was handed down on March 15, 2012, and becomes final after 30 days. Immediately thereafter, there is a ten-day window in which a petition for review by the California Supreme Court can be filed.

Justice, and only justice, you shall pursue…

Deuteronomy 16:20

Perspectives on Filing a Petition for Review

A review by the California Supreme Court is by no means automatic, or even very likely. Overall, the Supreme Court accepts a mere 3 percent of cases presented to it. This rises to 10 percent if it is a published opinion, which is the case for our lawsuit. However, this case presents important and complex issues that have never been adjudicated at a Supreme Court level in any state, and which may have far-reaching implications for medical care not only in California, but nationally as well. Thus, the probability of the court accepting our request for review may be as high as 40 to 50 percent.

The significance of our litigation is that it stands at the cutting edge of a controversial and as yet poorly addressed national health care issue. Simply stated, the debate is over whether physician supervision of advanced practice nurses (and other allied health care practitioners) should be preserved. How is the imperative—like that pontificated *without* an evidence base by the Institute of Medicine—that "nurses should practice to the full extent of their education and training" (with its intention of advancing nurses' scope of practice) to be balanced against protecting the safety of the public from potential degradation

in the quality of care rendered by practitioners who are less educated and trained than are physicians? How is *"the full extent"* defined and who is the definer? Is it ethical to force such an upheaval of our health care system without evidence supporting and moreover justifying doing so? Do the benefits of such a change outweigh its risks? How is this question to be answered—and by whom? The crux here is how one measures both the economic costs to society and the quality of health care for our citizenry, and then weighs—with imperfect information and under conditions of uncertainty—one against the other.

Ultimately this is a societal decision, but for now the courts are the proxy decision-makers. At the Supreme Court level, the justices often decide cases not merely based upon narrow questions of semantics, but rather by analyzing issues within a broader context. As practicing physicians, we value, promote, and appreciate logic and science and evidence. Yes, we are horrified by the fact that single-minded self-interest groups like the American Association of Nurse Anesthetists disingenuously employ faulty reasoning to mislead the public as they persist in their campaign to validate independent practice by nurse anesthetists and pervert what physicians have, for millennia, steadfastly held as our ethical creed—to place patients' interests foremost.

If this case were not accepted for review, then that would put the lid on litigation for the CSA at this time, but by no means would this signal the end of litigation in this pressure-cooker arena. The impetus to pursue justice will intensify and continue to demand action, be it in the courts or through the legislative process.

Making the Decision to Proceed

Our various options and strategies were discussed and debated at the March meetings of CSA's Legislative and Practice Affairs Division and Board of Directors. The CSA Executive Committee (EC) then assembled an "army" of legal experts—our lead appellate attorney, Curtis Cole; CMA counsel Long Do; our CSA lobbyists, the Barnabys; CSA counsel from the Superior Court lawsuit Tom French; ASA attorneys from its Governmental Affairs Office, Ron Szabat and Lisa Albany—plus the ASA Vice President of Professional Affairs, Norm Cohen, to join in the deliberations on how best to proceed.

The EC was understandably concerned that there be a substantive change in our approach, lest we suffer from "déjà vu all over again." Both the superior and appellate courts have declined to declare that Schwarzenegger's opt-out decision constitutes an abuse of discretion. In effect, they ceded to him a wide berth to declare what California law is, based upon his abiding formulaically by the letter, *but certainly not* the intent/spirit of federal regulations. Both courts found the absence of the word "supervise" in the California Nurse Practice Act to be

dispositive—meaning being decisive for the resolution of the case—rather than considering the entire body of California laws and regulations as they apply to this issue. This is a systematic failing of the courts. Many sections of the applicable codes, written over many years and never revised into a coherent whole, are peppered with the specific phrases "order by" and "under the direction of," and this language has been understood by legislators, the California Attorney General, and the California Legislative Counsel (the attorney who represents individual California legislators when they request it) to denote supervision for many decades.

Moreover, legislative *intent* appears not to have been given any weight by the courts in their deliberations. The historical fact is that in the past there were some legislators who unsuccessfully pursued scope-of-practice enhancements for nurses, *failing three times* to remove physician supervision imperatives. Presiding Justice Ignazio Ruvolo of the First Appellate District, Division Two, California Court of Appeal, who declared that these failures could not be used as evidence of legislative intent, imperiously dismissed this important portion of legislative history! This is turning logic on its head: if three failed attempts to pass enabling legislation cannot be used to establish intent to keep supervision intact, then neither should it be used to facilitate independent practice. How can the opt-out be consistent with California law, given that the law is, at best, unclear or even equivocal? Constitutionally, the courts are *not* to write the law, but only to *interpret* it. Both court decisions suggested that we might better turn to the legislature to remedy what amounts to an egregious disregard of the potential serious adverse consequences to the health of the citizens of California.

The EC carefully deliberated upon our options, ranging from passive abject surrender and then moving on to deal with the consequences of a "brave new world," to continued vigorous pursuit of what we believe to constitute our ethical obligation to pursue justice for our patients and our profession. This includes the necessity of refining our tactical approach and substantive arguments for the next higher judicial level. Also taken into account was CMA's offer to share the costs of the petition for review, as well as the likelihood of financial support from other sources, including the ASA, should the Supreme Court accept this case. The potential state and national consequences of not proceeding weighed heavily in our conversations. Ultimately, the EC decided unanimously to authorize our legal team to write a petition for review by the Supreme Court and, if it is granted, to litigate our case to its ultimate resolution.

Process, Arguments, and Issues

Part of what persuaded the EC was that the *process* of how the appellate decision was reached was flawed in several major areas. It certainly was disappointing

that many of our *arguments* were totally ignored by the appellate court, even though it is not obliged to respond to all, or even any, of our logic or theory! The appellate court was, however, absolutely obliged to address *issues* of substance brought before it. Our *arguments* and theory are our side's perspective and interpretation of the facts of the case. The *issues* are the legal questions and conundrums that are raised in a legitimate manner by either side, and the appellate court must address and decide these.

The overriding issue (and the subsidiary aspects of this one issue) brought forth by us as plaintiffs at the Superior Court level, and thereby appropriate for consideration by the appellate court in this matter, was whether Schwarzenegger's opt-out was consistent with California law. Why or why not? Issues of public safety, economics, access, quality, or even whether he legitimately followed the other requirements of the federal opt-out regulations were not and cannot, according to the rules of the appellate process, now be part of the case. The Intervener, the California Association of Nurse Anesthetists (CANA), has tried to add many new issues for the courts to consider, and has pushed to make this case about economics, which it is not. Nonetheless, for the appellate court not to comment upon and decide legitimate issues is a *defect* in the substance of the appellate decision. A higher court should address this defect.

The first serious and problematic flaw with the appellate decision is that it ignores the disingenuously camouflaged illegal process whereby CANA, aided and abetted by Schwarzenegger and the courts, was able to expand the scope of practice of nurse anesthetists through the vehicle of "underground regulation." Their process disregards the legal requirement to adhere to the Administrative Procedure Act, and therefore is illegitimate and illegal under California law.

Second, the appellate decision mistakenly and misleadingly minimizes the physician supervision issue to one of pure economics, an argument once again disingenuously proffered by the CANA attorney and manipulated to their advantage. Contrary to his assertion, nowhere in the federal regulation on opting out is there any mention of payment for services. The presumption always has been, although not stated explicitly, that *supervision*, an integral part of the Medicare regulations since their inception, was required as a matter of patient safety and physician responsibility. Making the decision primarily on economics fails to clarify whether the opt-out is consistent with California law, and thereby hinges on an extraneous and erroneous argument made by CANA. This taints the legitimacy of the appellate decision, which should be overturned.

The third problem that needs to be addressed is that the court's opinion focuses on its determination that the word "supervision" is not in the Nurse

Practice Act (section 2725 b), and further, that the word "order" does not imply supervision. In actual fact, the word "supervise" does specifically appear in the regulations of the Department of Public Health concerning trauma patients, and this issue was another key matter not considered by the courts. The ostensible omission in the Nurse Practice Act is a defect that must be addressed. California statute and regulation in this area have not been revised for almost 40 years, and hence are not consonant with the complexities of modern medicine. Indeed, they do not serve public safety. As ASA Director Dr. Mark Singleton so eloquently explains:

> *In the days when giving an anesthetic meant dropping ether onto a gauze mask and measuring and recording vital signs, that might have been adequate, but "giving anesthesia" now has become one of the most complex activities in medical practice. Even in other critical care settings where highly skilled and experienced registered nurses provide complex patient care involving autonomous judgments, there are protocols to follow and the ultimate responsibility and oversight rests with a physician.*

Yes, nurse anesthetists are registered nurses, and should be held to common-sense rules (and associated limitations) that mandate this "ultimate responsibility and oversight" to the purview of physicians. This responsibility/oversight/supervision/direction is *epitomized* by the level of education and training mandated by society *only for physicians*, which is the justification for why this oversight should remain solely within the province of the profession and practice of medicine and its accompanying ethical responsibilities to society.

Potential Legislative Remedies and Initiatives

Beyond our battle in the courts, the CSA and CMA are contemplating the need for various potential legislative remedies and initiatives:

1. One might attempt to clean up the language of the Nurse Practice Act (section 2725 b) such that nurse anesthetists remain subject to the same physician supervision requirements as are all other advanced practice nurses in California. Instead of the implication of supervision, which is very apparent to us and, as yet, not as clearly obvious to the courts, the actual word "supervision" could be installed, a remedy suggested by both the superior and appellate courts.

2. The CANA counsel made much hay of his opinion that surgeons are not vicariously responsible for the malpractice of nurse anesthetists working with them. Mr. Cole, however, pointed out that there are even *more* court decisions finding that surgeons are in fact vicariously responsible. One might consider introducing legislation making it explicit that surgeons are

insulated from vicarious responsibility in this situation. What would the various parties, including the public, think of such a law?

3. Given known problems with various health care practitioners—and especially registered nurses—diverting drugs, it may be useful to tighten up the rules for dispensing narcotics in California, so that nurse anesthetists cannot employ anesthetics and Category II controlled substances unless they themselves are specifically licensed to do so by the federal Drug Enforcement Administration (DEA). It is notable that the DEA in the past made a somewhat unusual regulatory decision in this regard, holding that nurse anesthetists can dispense drugs under a facility's narcotic number, and without the necessity for their own narcotic control number. Surely this *modus operandi* could and should be tightened up to require individual DEA registration for drug administration in California.

4. "Truth and transparency" legislation, already California law, requires health practitioners to display their licensure on their name badge. As an extension of this philosophy, one might attempt to enact legislation requiring a practitioner administering anesthesia and/or sedation to obtain written informed consent that stipulates whether they are an anesthesiologist, an advanced practice nurse, or other practitioner (registered nurse, or perhaps in the future, an anesthesiologist assistant). A patient would be given the choice of whether to accept that practitioner and proceed with the surgery or procedure, or to choose someone with different credentials. If a physician were desired and none were available at that facility, then the patient could choose to have the surgery/procedure performed where an anesthesiologist could care for him/her.

5. As alluded to in #4, anesthesiologist assistants (AAs) always work within an anesthesia care team and never without supervision. Consideration should be given to initiating an AA training program here in California, and thereafter seeking enabling legislation for their licensure.

Medical Staff Initiatives

Another important strategy beyond the courts and legislature is to urge medical staff at all facilities to require supervision of registered nurses, which, according to federal regulation, is an option in any opt-out state. A curious logical consequence of the appellate decision is that *if* nurse anesthetists are independent practitioners in California and because all registered nurses in California have the same scope of practice, *then* all registered nurses may be unsupervised. Therefore, critical care (ICU) nurses, endoscopy nurses, and even floor nurses could also function unsupervised by a physician. Of course, some medical

staffs would restrict this situation, but it is not difficult to imagine that some facilities might promote this, likely for local economic considerations.

Threats by the Federal Trade Commission and PPACA

Moreover, we should all have a real concern about what has emerged as a disturbing national trend, wherein the Federal Trade Commission has opined that limiting the scope of practice of allied health practitioners by some medical boards, because these boards declare certain acts and procedures to be the practice of medicine, may possibly constitute antitrust violations! Furthermore, the antidiscrimination provisions in the federal Patient Protection and Affordable Care Act (PPACA), unless the United States Supreme Court invalidates the law, raise the specter of federal civil rights investigations or civil lawsuits, should some classes of health care practitioners feel discriminated against with respect to being able to render care for which they claim to be qualified. As noted above, additional litigation as a subsidiary issue within the overriding question of the requirements for supervision may rise through the courts, as this area of law remains unsettled.

Taking It to the Public

Finally, we members of the CSA must redouble our efforts to communicate with our patients and their families and friends, the public, legislators, regulators, and the press about the realities of anesthesia practice. This then is one more prong in our integrated strategy to try to influence and redirect the mounting trajectory of decisions by others concerning how we practice anesthesiology. Some of what we might say could incorporate the following thoughts:

"Ordering" an anesthetic is not the same as ordering a milkshake. We do not "order" intensive care unit nurses to cure a patient in septic shock, but rather *supervise,* even *direct* the details, including diagnostic tests and doses of medications, which by their very nature are integral to the practice of medicine. Lawyers do not "order" paralegals to take charge of litigation. It is for very good reasons that architects *supervise* builders.

When we compare outcomes between various types of anesthetic practitioners, science and logic dictate that we must employ risk adjustment and correct the results for the very different complexities of the cases performed. That is the egregious flaw in the articles appearing in supposedly credible periodicals that purport to show equivalence of outcomes between anesthesiologists and nurse anesthetists in opt-out states. The kinds of cases in those "reports" are very different, as anesthesiologists are more likely to be involved with the care of the more complex and sicker patients. Yet, while gross administrative statistics seemingly show the same mortality rate between the two kinds of practitioners,

nurse anesthetists caring for simpler patients should be expected to have lower mortality rates. That they do *not* speaks volumes. *Administrative* data can distort or disguise many complications and undesired outcomes. *Clinical* data gathered at the point of care is what speaks most persuasively, but there is precious little of it. With the advent of the Anesthesia Quality Institute and the National Anesthesia Clinical Outcomes Registry, our earnest hope is that justice, ethics, reason and safety of patients will prevail.

We care about Ethics because they are fundamental to our professionalism as physicians. We care about Justice because it represents an ideal of fairness aspired to by free people everywhere. As we labor to preserve what is good and noble in the profession we have chosen, we seek, in our tenacious efforts to improve safety, Justice on behalf of our patients. However, Ethics and Justice are subject to interpretation by different people, with diverse perspectives and motivations, in evolving times and changing circumstances. We would like to believe that, ultimately, the Law is sharply defined and dispassionately applied, but it appears that reality may fall short of this hopeful belief in achieving Justice, as to date we have learned as parties to this litigation.

Truth is mighty and will prevail. There is nothing the matter with this, except that it ain't so.

Mark Twain

The CSA has fought this opt-out from its inception, almost three years ago. We are not done with this matter, and we are resolved to do whatever it takes to confront the dumbing down of American medicine.

References

1. From the Latin: "Why should we bother?"
2. This article presumes an understanding of the basic facts of *CSA and CMA v. Schwarzenegger*, and analyzes the current situation of the opt-out litigation at a more advanced level. The possible motivations for why the disgraced former governor executed the opt-out are discussed in the Barnaby article referenced below. For a summary of the basics see:
   - AMA news, Feb. 22, 2010: http://www.ama-assn.org/amednews/2010/02/22/prsa0222.htm
   - CMA/CSA press release, Feb. 1, 2011: http://www.csahq.org/pdf/news/Press_Release_re_Appeal_of_CRNA_decision__1-31-11_.pdf
   - The Barnabys' larger perspective, *CSA Bulletin*, Volume 60, Number 3 (Fall 2011): 30–36: http://www.csahq.org/pdf/bulletin/lpad_60_3.pdf
3. For a complete compendium of all of the briefs in this case, please see http://www.csahq.org/legislative.php (log in to access this area of the CSA website).