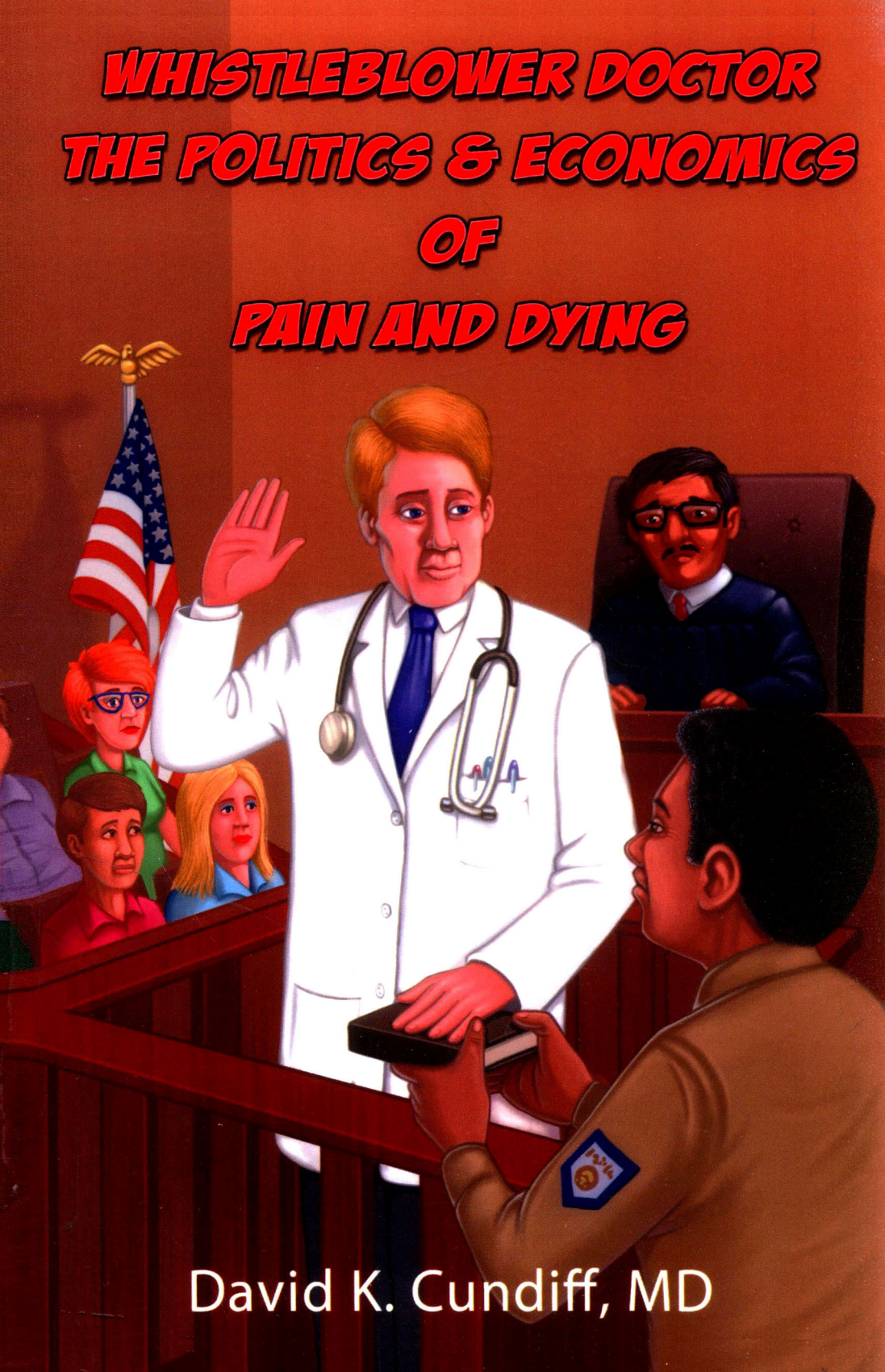
WHISTLEBLOWER DOCTOR
THE POLITICS & ECONOMICS OF PAIN AND DYING



David K. Cundiff, MD

Whistleblower Doctor

The Politics and Economics Of Pain and Dying

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- You are encouraged to confirm information with other sources and confer with your doctor with regard to information contained in this book.

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DEDICATED

with much respect
to

To the patients and staff of the LA County + USC Medical Center, who deserve to receive and deliver the best possible medical care.

Executive Summary

A one-month experience of working in three hospices in England convinced me to focus my medical career on alleviating pain and suffering of terminally ill cancer patients. After finishing my fellowship training in hematology and medical oncology (cancer) at the University of California San Diego Medical Center, I resolved to find a way of integrating hospice principles and philosophy with my practice of cancer medicine.

I worked at the Los Angeles County Department of Health Services (LAC-DHS) from 1979–1998, including nine years of directing the Pain and Palliative Care Service at the Los Angeles County+University of Southern California Medical Center (LAC+USC Medical Center). By the early 1990s, the Pain and Palliative Care Service (the Service) had become very popular with the patients, housestaff, nurses, social workers, and other caregivers. Overworked residents and nurses saw that we alleviated pain of their patients while reducing work for the hospital caregivers. We provided their patients with outpatient hospice follow-up and 24-hour/seven-day phone availability that prevented many readmissions for uncontrolled symptoms. In addition, we educated the doctors and nurses in pain management and palliative care techniques.

Unfortunately, for the financial bottom line of the hospital, the better the Service controlled pain and distressing symptoms the more money the hospital lost. Our success in controlling pain and providing comfort to over 400 terminally ill patients led to an estimated 4,000 fewer reimbursable inpatient days in 1994, saving the taxpayer over $9 million in Medi-Cal spending. (California's Medicaid program) However, LAC-DHS management did not appreciate the savings to taxpayers by the Service, since our efficient and effective outpatient care reduced the Medical Center's revenue by the same $9 million.

By the time cancer and AIDS patients reached the end stages of their diseases, they almost all had Medi-Cal insurance. Consequently, prolonged hospitalizations for terminally ill cancer and AIDS patients served as a "cash cow" for the LAC+USC Medical Center. This population comprised less than 1% of patients treated, but yielded as much as 15% of the $700 million Medi-Cal yearly revenue for the Medical Center. Since Medi-Cal paid a high all-inclusive daily fee for

acute hospital care and little for outpatient treatment, the LAC+USC Medical Center needed a high inpatient census to maximize government reimbursement for services. This discouraged appropriate outpatient pain management and palliative care for terminally ill cancer and AIDS patients.

As the Service had an increasingly adverse effect on inpatient census, management became more and more hostile to me. They reassigned me to additional duties, took away two federal grants for improving the evaluation and treatment of pain, did not permit me to apply for other outside funds to improve pain management, and failed to allocate resources to keep up with the volume of work.

Financial Crisis Hits LAC-DHS

In the summer of 1995, the LAC-DHS faced the largest budget shortfall in its history—$655 million deficit out of an operating budget of $2.3 billion. To resolve the budget crisis, the Los Angeles County Chief Administrative Officer's proposed budget to the Board of Supervisors for 1995–96 included the closure of the LAC+USC Medical Center. After all of the politicians and County Administrators completed their negotiations over the crisis, the LAC+USC Medical Center was saved, but employees and services of the LAC-DHS were downsized by nearly 15%. Under the cover of this crisis, the LAC-USC Medical Center management closed the Pain and Palliative Care Service and transferred me to attending in internal medicine inpatient wards and outpatient clinics.

In conjunction with the LAC-DHS downsizing of personnel and services in September 1995, management negotiated a $1.2 billion five-year Health Department bailout from President Clinton to save the LA County Government from threatened bankruptcy. The strings attached to the bailout included reengineering the LAC-DHS to shift considerable resources from inpatient care to out-of-hospital services. I rejoiced that, finally, financial sanity would come to the LAC-DHS and that pain management and palliative care would have to be recognized as a necessary component to comprehensive care, requiring significant resources.

Inexplicably, the federal Medicaid bureaucracy increased rather than decreased our inpatient reimbursement rate and did not increase funding for outpatient services. I had hoped for a comprehensive

change in the system of funding the LAC-DHS to per patient (capitated) reimbursement or another system that encouraged outpatient care. Paradoxically, complying with the conditions of the federal bailout by shifting resources from inpatient to outpatient care would have severely reduced revenues to the LAC-DHS. Consequently, resources were never shifted.

Challenging the LA County+USC Medical Center $900 Million Replacement Project

After averting the Medical Center closure by receiving the federal bailout in 1995 and securing an outrageous daily fee rate for Medi-Cal inpatients ($3,800 per day), LAC-DHS management next set its sights on replacing the aging Medical Center with as large a hospital as possible. The more beds in the new hospital, the more of the 8,300 LAC+USC Medical Center employees would salvage their jobs. This increased ongoing census-raising strategies that precluded an effective pain and palliative care service designed to help terminally ill patients remain comfortably at home rather than in acute-care hospital beds.

Policies and procedures throughout the Medical Center encouraged unnecessary hospitalizations and encouraged more days in hospital than needed for those admitted appropriately. Major deficiencies in primary care services in affiliated clinics and comprehensive health care centers paid off financially with more emergency admissions to the hospital. As had long been the case at LAC-DHS hospitals, admitted patients could wait days or weeks for surgery, diagnostic studies, or specialty medical procedures. Nearly everyone believed that the long waits were due to underfunding of the LAC-DHS. In reality, the LAC-DHS depended on long waits of Medi-Cal patients to increase revenue. Inefficiency paid well while efficiency was financially punished.

In a highly contentious meeting in November 1997, the LA County Board of Supervisors approved a 600-bed replacement hospital instead of the management-supported proposal of 750 beds. This meant that up to 4,000 jobs would be lost at the Medical Center.

Later that month I published an editorial in the *LA Times*, advocating that the LAC-DHS lease acute-care hospital beds from private hospitals or buy existing hospitals instead of spending $900 million on a replacement hospital. Since LA County had about 20,000

acute-care licensed beds, of which only about 10,000 were filled in an average day, I argued that a replacement hospital of any size would waste taxpayers' money. Instead, I recommended immediately switching to per patient (capitated) reimbursement from Medi-Cal, reorganizing the LAC-DHS as a health maintenance organization, and leasing or buying the necessary acute-care beds from the private sector. Then, we could effectively compete with the rest of the LA community health care providers by making efficient use of hospital beds and shifting more resources to out-of-hospital care, such as hospice. With capitated reimbursement, we would no longer be financially dependent on institutionalized inefficiency and waste driven by the dysfunctional funding system.

Management responded to my editorial with resounding silence. Despite the fact that I claimed that the Health Department fostered dysfunctional policies and procedures that purposefully raised the census solely to increase reimbursement, no one issued a verbal or written rebuttal.

In February 1998, I audited my inpatient medical service, carefully documenting the unnecessary patient days in hospital. Applying my findings to the census figures of the LAC+USC Medical Center, I calculated that the average inpatient census should have been about 480 patients rather than the actual 860 (44% of days unnecessary). In March 1998, I sent the results of this audit and my suggestions for re-engineering the LAC-DHS to the federal and California State Medicaid offices and to 11 legislators. Only the California State Medi-Cal office replied to the conclusion from my audit that the Medical Center was defrauding Medi-Cal out of over $200 million per year by institutionalized inefficiencies. They did nothing to investigate.

Chief among these strategies to raise the inpatient census was inadequate pain management and palliative care services, accounting for 28% of the unnecessary inpatient days in my audit.

Complaints about Poor Treatment of 83 Patients

After the Pain and Palliative Care Service closed in September 1995, I assumed full-time duties as an attending physician on the general medicine wards and in the outpatient clinics. In those roles I found numerous instances of poor pain and symptom management of

cancer and AIDS patients. Over five years I submitted 83 incident reports to the LAC+USC Quality Assurance Committee, mostly about patients suffering poor pain management. I also formally submitted these cases as patient care complaints to the Medical Board of California. The Medical Center QA Committee did not acknowledge receipt of the complaints. The Medical Board responded that the patients and/or patients' families would have to submit the complaints rather than a physician that was aware of the substandard care. Unfortunately, all the patients were dead and I had no access to the charts at that point to contact the families.

Fired and Medical License Revoked

Four days after I sent the results of my inpatient service audit to Medicaid administrators in Washington, DC and Sacramento and several legislators, my supervisor placed me on paid administrative leave. Seven months later management fired me supposedly for my clinical decision (a judgment call) to stop the drug Coumadin (generic name: warfarin, a blood thinner) in an alcoholic patient with a leg clot (deep venous thrombosis or DVT). He had a very high bleeding risk. The patient later died of a clot in his lung. I had no previous malpractice judgments or disciplinary actions in 25 years of practice.

In a Civil Service Hearing, I lost my case to be reinstated in my job. Subsequently, the California Superior Court denied my appeal. Finally, I faced a California State Medical Board hearing for my medical license.

I defended my judgment to stop the Coumadin in my patient by pointing out that Coumadin is contraindicated in alcoholic patients because of the bleeding risk. My medical resident on the case diagnosed alcoholism by documenting in the chart that the patient reported drinking a six-pack of beer per day for 20 years. Neither the Deputy Attorney General nor the judge disputed that alcoholism is a contraindication for using Coumadin for deep venous thrombosis. The decision in the case hung on whether the patient was an alcoholic.

The Deputy Attorney General responded by bringing the patient's daughter to the stand in court as a surprise witness to testify not only about her account of the events of her father's illness but also as a quasi expert witness. She worked as a substance abuse counselor. She said that her father did not drink "cans of beer" but "quart

bottles of Colt 45 Malt Liquor"—not more than two quarts of malt liquor per day on weekends. She testified that she had never seen her father drunk and that he was not an alcoholic. The district attorney brought no other substance abuse expert witnesses to challenge the diagnosis of alcoholism documented in the chart by my medical resident who, under cross examination, stood firmly by the accuracy of her medical history.

Referring to the daughter's testimony, Administrative Law Judge H. Stuart Waxman wrote in his decision to revoke my medical license, ". . . (The patient) drank less than two quarts of malt liquor per day on weekends. (The evidence did not disclose his drinking customs during his workweek.)" Rejecting my defense that it would have been malpractice for me to continue the Coumadin in an alcoholic, Judge Waxman ruled that I should have continued the Coumadin.

He would not allow into evidence the results of a survey of internists and anticoagulation experts done by my expert witness, Dr. Matthew Conolly, UCLA Professor of Medicine, and me that showed a remarkable variation of medical opinion about the best management of the case. After hearing my testimony on the lack of scientific evidence supporting anticoagulant treatment of deep venous thrombosis, Judge Waxman asked me that were I to treat another patient with identical circumstances, would I again stop the Coumadin. I said, "Yes."

In his decision on my case, Judge Waxman wrote:

> ". . . Respondent is now even more convinced than he was in 1998 that he made the correct decision in discontinuing the anticoagulant medication he had been approving for (patient) BR, and he made it very clear at the administrative hearing that, if faced with the same situation today, he would make the exact same decision. Respondent is entitled to that opinion. However, he is not entitled to foist that opinion on an unsuspecting public, more than 2,000,000 of whom suffer DVT annually. Those popliteal DVT patients who may be treated by Respondent in the future are now at even greater risk of pulmonary embolism than before because of Respondent's ongoing belief that the

> standard treatment for the condition, accepted by the vast majority of the medical profession, is nothing more than "dogma." No probationary order can adequately address and prevent that risk to the public. That risk to the public is too great to permit Respondent's continued practice of medicine."

After I lost my medical license over this case, the patient's daughter brought a wrongful death civil suit against me and LA County, which the County administration settled, over my objections, for $175,000. In a deposition of the patient's daughter before the settlement, my attorney showed her a 40-ounce magnum of Colt 45 Malt Liquor, asking if this was her father's preferred drink. After she said it was, she acknowledged her error in calling it a quart (32 ounces). Two magnums of malt liquor are equivalent in alcohol to eight 12-ounce cans of beer. Only an alcoholic with a high tolerance could consume this much in a day and not appear drunk.

Discovering that Anticoagulation Increases Deaths Overall

This DVT case led me to research the evidence-basis for warfarin (Coumadin) and other anticoagulants for treating clots in the leg and lung veins (DVTs and pulmonary emboli or PE, together called venous thromboembolism or VTE). To my great surprise, I found all the published studies supporting anticoagulants for DVT and PE to be flawed. In court, my expert witness, Dr. Conolly, and I testified about a particular randomized controlled clinical trial comparing standard anticoagulants (heparin and warfarin) to phenylbutazone (an anti-inflammatory drug). The prosecuting attorney objected to us entering the trial into evidence, and the judge sustained the objection. In malpractice proceedings, you cannot have expert witnesses debate the evidence-basis of a medical test or treatment. All that matters is the prevailing opinion of the medical establishment.

I have subsequently published a number of articles in peer-reviewed medical journals showing that anticoagulants increase rather than decrease mortality for deep venous thrombosis. I found that 28 other medical indications for anticoagulants to be likewise based on scientific errors and biases of drug company-funded investigators. None of these challenges to "standard" anticoagulant treatment has

been rebutted by any anticoagulation expert in academia or government.

Worldwide, at least 100,000 people bleed to death from anticoagulants or die of rebound clotting after stopping anticoagulants each year. My quest is to stop this doctor-caused epidemic.

Stonewalling of U.S. Department of Health Services Health Regulators

In August 2010, my sixth major review article challenging the effectiveness and safety of anticoagulation was published by a BioMed Central Journal. (http://www.tbiomed.com/content/7/1/31) The article entitled, "Diet for prophylaxis and treatment of venous thromboembolism?", reviewed the data on anticoagulation drugs for prophylaxis and treatment of VTE and found that they cause about 40,000 deaths per year worldwide of which about 20,000 occur in the U.S. The article went on to recommend either withdrawing the FDA approval of anticoagulants for VTE or funding randomized controlled clinical trials to compare a low VTE risk diet (mostly plant-based foods) with standard anticoagulation for VTE.

I immediately notified leaders at the Food and Drug Administration (FDA) and National Institutes of Health (NIH) by email of the publication of this article and requested their critique. Janet Woodcock, MD, Director of the Center for Drug Research and Evaluation of the FDA, delegated the job of replying to me to Ann Farrell, MD, Acting Director of the FDA Division of Hematology Products. Dr. Farrell was explicit about refusing to go on record with a critique of my paper: "We have reviewed your interesting paper but have no written critique."

My email to Francis Collins, MD, Director of the NIH began

> I am the lead author of an article published in a BioMed Central Journal that provided literature documentation that anticoagulant prophylaxis and treatment for venous thromboembolism (VTE, i.e., DVT and PE) unnecessarily causes about 40,000 bleeding and rebound clotting deaths per year worldwide, about 20,000 of which occur in the U.S. http://www.tbiomed.com/content/7/1/31 . . .

Dr. Collins delegated his reply to me to Susan Shurin, MD, Acting Director National Heart, Lung, and Blood Institute. Dr. Shurin completely avoided any direct response to my data and conclusions of the article and replied in boilerplate bureaucratese:

> The risks and benefits of the prophylactic and therapeutic use of current anticoagulation therapies are well recognized. Therefore, the NHLBI actively supports basic, translational, and clinical research on safer and more effective therapeutic options for VTE. . . .

Despite multiple attempts by me and others to have FDA and NIH scientists and drug regulators critique the data and conclusions of this article of any of my other five published peer-reviewed medical journal articles showing that anticoagulants do catastrophic harm to people, they continue to stonewall with no public, transparent, detailed analysis of my data and conclusions.

Medical License Reinstatement Hearing in LA County Superior Court

On May 27, 2011, I will appear before Judge James Chalfant in Los Angeles County Superior Court to appeal for the reinstatement of my medical license. Deputy Attorney General Klint McKay's brief in opposition to my license reinstatement maintains that I am a risk to patients because of my opinion that anticoagulant drugs do harm in patients with deep venous thrombosis.

My reply brief concludes:

> Petitioner's medical judgment that anticoagulants for VTE treatment increase the risk of death has not been rebutted in six peer-reviewed medical articles published from 2004–2010. That anticoagulants cause catastrophic harm to patients has not been rebutted by the FDA or NIH leaders in charge of regulating these drugs. The burden is on Respondent to produce declarations by authoritative physicians that are expert in anticoagulation medicine to address

Petitioner's medical judgment in 2011 that anticoagulant medication for treatment of VTE does harm to patients. Failing that, Respondent should reinstate Petitioner's medical license.

Conclusion

By relating my 19-year saga in the LAC-DHS, I hope to focus attention on issues that are much more important than my case for medical license reinstatement:

1. My hostile work environment and job termination resulted from perverse financial incentives in the Medicaid program that rewarded hospitalization and discouraged outpatient hospice care. This increased pain and suffering and impaired training of health care providers, compounding the other barriers to effective and compassionate palliative care of the dying.
2. Anticoagulation drugs for VTE prophylaxis and treatment doesn't work and causes about 40,000 deaths per year worldwide. Drug company financial clout has exerted its influence on academic researchers, medical journal editors, government regulators, and the medical media to foster this ineffective, dangerous, and expensive practice.
3. For many other medical indications where anticoagulation is used according to clinical practice guidelines as the standard of care, it is not evidence-based to work and, in fact, may be evidence-based to increase complications and death.
4. "Sham peer-review," as in my case, has become an increasing problem that stifles health care innovation, efficiency, and quality of care improvement. Whistleblowing physicians who point out deficiencies in health care and expert physicians who pose competitive threats to local medical establishments may be targeted for retaliation like I was. Resolving the current medico-legal mess regarding physician malpractice requires a comprehensive overall of the tort system in health care.

More broadly, health care in the U.S. is in crisis with decreasing access and quality while costs escalate. We will never be able to

control medical costs and provide universal access to quality medical care until we stop paying for tests and treatments that don't work such as anticoagulation drugs for prophylaxis and treatment of VTE. My saga relates to the need for a wide-based restructuring of health care to get the financial incentives right. If we properly reward good, efficient, compassionate care rather than ineffective medical interventions, quality will go up and costs will come down.

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* This book is documented with 422 appendices and 44 exhibits totaling over 2,000 pages. To access any appendix or exhibit online, go to http://TheHealthEconomy.com/WD/Appendices.htm and click on the appropriate appendix or exhibit.