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Editorials

ETHICAL CONFLICTS for Physicians Treating ESRD (KIDNEY FAILURE) Patients

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Managing an end-stage renal disease (ESRD) patient is complex and presents many ethical challenges for the physician. Ownership of dialysis facilities has shifted over the past decade from largely nonprofit organizations to large companies whose shareholders are primarily interested in the profitability of their investments rather than the well-being of the patients being treated. Furthermore, market forces rather than scientific questions that need to be answered now drive much of the research regarding patients with ESRD. These developments have created ethical dilemmas for treating physicians. This editorial describes some of these ethical challenges and expresses the point of view that the doctor-patient relationship and its ethical imperatives are more important than company profit and loss statements.

Few trends could so thoroughly undermine the very foundations of our free society as the acceptance by corporate officials of a social responsibility other than to make as much money for their stockholders as possible.

Milton Friedman, 1962 (Nobel Prize winning economist) (1)

There are nearly 400,000 patients in the United States on chronic dialysis therapy and the incidence of end-stage renal disease (ESRD) is increasing at 8-10% per year. Coincident with the rapid growth in the population requiring renal replacement therapy, there has been a dramatic corporatization of ESRD services. For example, the proprietors of dialysis units have changed over the last two decades from the majority being nonprofit hospital-based or physician-owned facilities to corporate domination of dialysis services (2). The purchase price for corporate entities to buy dialysis units from nonprofits or physicians ranges from $40,000 per patient to as high as $90,000 per patient. Although reimbursement for dialysis treatments has not changed appreciably over the past 25 years, industry must perceive that there is a profit to be made by acquiring these facilities. The dialysis companies claim that profit

margins are meager, yet they continue to acquire dialysis facilities. Perhaps there is economy of scale, perhaps there is the opportunity for vertical integration with sales of products and services within an organization, or perhaps there are new markets globally.

With the change in ownership of dialysis facilities comes the obvious corollary that the major responsibility of the new corporate owners is to shareholders, not to patients or their physicians. Thus in corporate-owned units, guidelines, unit policies, and the practice of patient-oriented medicine are subservient to the goal of making money. This is not necessarily bad, since patient outcomes and satisfaction may be maintained independent of the type of proprietor. If unit policies and practices are acceptable to the owners and physicians, quality can be high. However, the ethical foundation for the doctor is not as it should be—"What is best for the patient?" becomes "What is best for the corporate sponsor"?

Several dialysis corporations employ physicians to run dialysis units. Under these circumstances the physician clearly has two masters, the corporate entity and the patient being treated. There are emerging data that referrals for renal transplantation, the treatment of choice for ESRD, are made less often from for-profit than from not-for-profit dialysis providers (3). In the midst of this serious problem, solutions for which are complex and difficult, the physician should remember that while industry behaves in ways that are responsive to shareholders, the ethical basis underlying medicine relies on the doctor serving as the patient's advocate, not as an advocate for outside interests. When physicians are pressured to behave in ways that they do not consider to be in the best interest of their patient, they clearly should communicate that to the company to see if differences can be resolved. If no resolution is forthcoming, the patient should be so advised in order that he or she may take advantage of mandated grievance policies or third-party peer review for leverage.

Many times epidemiologic data and population statistics such as relative risk are used to anticipate likely outcomes of patients with various comorbid conditions and thus to substitute for individual decisions about individual patients. Patients consult physicians for advice about their case and presume that the physician is acting as their advocate. If there are other motives guiding physician behavior, this should be explicitly revealed to the patient and the patient should be allowed to openly question practices that seem counterintuitive, such as large doses of erythropoietin being given intravenously (with unit profit maximized) rather than subcutaneous dosing, which is equally efficacious. Besarab et al. (4) found using meta-analysis that there was no difference in efficacy and safety between intravenous and subcutaneous erythropoietin. The money savings from using lower doses of subcutaneous erythropoietin was to the primary payer (mostly the federal government). However, the subcutaneous market share was only 10%, which most likely represents provider disincentives for using subcutaneous dosing.

Similarly certain kinds of phosphate binders are prescribed, often despite the availability of others that are just as effective and less expensive. Frequent compromises in prescribing practice may be demanded by integrated systems not for patient-specific reasons, but because of cost considerations. Although many patients are probably unaware of these issues, physicians should share such evidence-based data in the hope of enlisting the support of their patients and unit management for proposed policy changes designed to improve patient outcome.

Transplantation is the treatment of choice for ESRD. When the mortality of patients on transplant waiting lists is compared to that of patients who are actually transplanted from those lists, transplantation is life extending (5,6). In addition to longevity, transplantation provides a better quality of life than does dialysis (7). Yet access to transplantation for motivated patients may pose a conflict of interest for the physician, who is rewarded based on the number of dialysis patients cared for, and certainly for the dialysis company that generates profits based on the number of dialysis treatments. Ensuring access to transplant care and follow-up is the responsibility of any ethical physician who cares for ESRD patients.

Another important issue is adequate follow-up for these complex patients. Such follow-up care is often not available to patients in managed care plans or for systems that have incentives to use less experienced physicians or even physician extenders. Again, it is the ethical mandate of physicians to offer the most expert care, even if this adversely affects the physician and health system or corporate incomes.

Medical research in renal disease, and in particular ESRD, is now heavily influenced by industry (8,9). Rather than physician-initiated studies asking important scientific questions, the focus in recent years has been on industry initiation of research questions that adhere to regulatory requirements. Academic and research physicians are influenced by this process. In addition to monies gained for their institutions and their laboratories from doing industry-sponsored studies, these studies, by involving "thought leaders," add subtle marketing pressure that influences other physicians' prescribing habits and therapeutic decisions (10). The economic incentives provided to investigators and institutions are marketing strategies well known by pharmaceutical companies and are designed to obtain a competitive advantage even when there are no objective differences between drug products. The example in nephrology that best illustrates the problem is the difficulty that generic preparations have had in penetrating immunosuppressive drug markets. Generic preparations that have been shown to be bioequivalent to the original drugs are available and have been approved by the U.S. Food and Drug Administration (FDA). Nevertheless, more expensive brand-name drugs are prescribed routinely. As a result, many patients cannot afford to be transplanted; their medication bills, even with government Medicare subsidies covering 80%, are still too much, as medication copayments can run as high as $250–$300 per month. While

various companies have assistance programs, the sad reality is that despite these programs, transplantation is denied to many patients without adequate coverage for medications even though their lives would likely be extended and financial savings would be realized by the government (as transplantation is cheaper than dialysis).

Data regarding profit margins of publicly traded companies are available. The pharmaceutical industry, despite protests to the contrary, is doing quite well. The annual reports of Bristol-Myers Squibb and Pfizer show that research and development (R&D) makes up 11% of their budget, profits are 24%, and marketing and administration costs are 34%. One need only look at the salary and bonus compensation of chief executive officers (CEOs) of U.S. pharmaceutical companies (not to mention their stock options) to realize that the high cost of drugs and patient suffering does not resonate with company executives (11).

Since the government is the major purchaser of these expensive medications, there should be a government formulary and decisions made based on efficacy, safety, and cost without relying on information that is inherently biased in favor of the product being tested. It has been reported that 89% of industry-supported trials have a positive outcome, compared to 61% of non-industry-supported trials (12). A review of randomized trials showed that industry-sponsored trials yielded positive results more often than studies funded through other means and that placebos rather than active agents were most often used as comparison groups in the former, resulting in magnification of the favorable results reported (13–16). Many academic institutions "live" on payments for indirect costs from industrial research to pay for day-to-day operations as traditional sources of income dry up. At least for these funds, government oversight should be performed to make sure that this money is used to further the research mission of the institution.

In summary, there are many ethical conflicts for physicians in treating patients with ESRD. There are no easy solutions and this author does not pretend to have all the answers. But there are some principles that we should adhere to as we try to deal with the serious problems outlined here. Physicians should have a strong voice in dialysis unit governance, no matter who owns the unit. Corporate-sponsored studies must be held to the same standards as other research. There needs to be government oversight of dialysis providers and research that is objective and transparent to consumers. And we should always remember that the best a physician can do is to follow the admonition of Maimonides (1138–1204 ad), "Do not allow thirst for profit and vision of renown and admiration to interfere with my profession, for they are the enemies of truth and of love for mankind and they can lead astray in the great task of attending to the welfare of thy creatures" (17).

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