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**ON BEING A PHYSICIAN IN THE ELECTRONIC AGE: PEERING
INTO THE MISTS AT POINT-&-CLICK MEDICINE**

ARNOLD J. ROSOFF*

I. INTRODUCTION

Here, in the wee morning hours of the third millennium, we face the dawn of a new world of health care delivery. It is a world electric in its dynamism and capacity for change. It is also a world that is heavily *electronic*, that is, grounded upon the widespread use of computers, electronic information and communication technology. Saint Louis University's 13th Annual Health Law Symposium, held in April of 2001, addressed a range of issues that this new environment will raise, including the ethics of e-medicine, the legal framework for borderless medicine and the balancing of public and private interests in health information.

Drawing upon my presentation at that Symposium, this Article focuses on two related developments—the use of Clinical Decision Support Systems and the growing practice of “e-prescribing”—that will affect in a fundamental way how physicians perform their traditional functions of diagnosing and treating patients. The electronic era will bring profound changes in the art and science of being a physician as well as changes in the relationships physicians have with their patients and other parties in the health care system. In fact, massive changes have already taken place, and continue to take place in health care, quite apart from the e-aspects addressed here. Managed care and related pressures forcing cost consciousness, integrated delivery systems, the corporatization of health care providers and the evolution of new team and organizational approaches to health care delivery have already moved us well away from the traditional one-to-one relationship between doctor and patient. These underlying factors interact with the emergence of the electronic age in manifold and subtle ways, making it impossible to look at one without the other. To give just one example, computerization of patient treatment records may offer substantial savings of time and effort, a change most physicians

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would view positively. But when this same change also enables closer and more constant scrutiny of physicians' practice patterns by managed care entities, physicians may react quite differently—not because they object to the electronic innovation, but rather because they fear what may happen to them as a result of it. Thus, the pace and tenor of physicians' adoption of new technology may be determined by their vision of what kind of world that adoption will bring. This "guilt by association" factor may make it difficult to assess physicians' receptivity to the electronic changes and, thus to project the future of the electronic innovations.

As noted above, this Article addresses two important innovations that will redefine the terrain of physician practice as we move into the e-world of the future: Clinical Decision Support Systems and e-prescribing.¹ As to each of these elements, this Article will attempt to project future developments as they will affect clinicians practicing in the real world. The timeframe for the evolution of these elements is not specified, but is assumed to be within the next decade. Some of the changes will come much faster, some will be realized only in a limited way, some will never come and some are here already, at least in part. The scenarios reflect my vision of how things will evolve—based in part on what I know already to be here, in part on what I have heard and read others saying about the future shape of things, and based in part, frankly, on my imagination and speculation about how things might come to be. I will, of course, use my best efforts to keep these three elements separate—or, at the least, to identify for the reader which is which. The principal problem with this last proposition, however, is the speed with which things are changing. Some of what I think is fanciful projection as I am writing this may well mirror things that are already extant, or become so by the time this Article is published.

In looking at the elements identified above, the Article will flag key technical, structural, practical and legal issues envisioned in connection with each and will point to sources that illuminate these areas. It is not the objective, however, to answer—at least not in any definitive way—the

1. Two other elements of the e-revolution—e-mail communications between doctor and patients and the use of websites by healthcare providers as a part of their business and clinical practice—were touched on in my presentation at the Health Law Symposium. Fascinating topics both, they are not covered here due to space limitations.

A number of sources provide background on healthcare websites. *See, e.g.*, Howard J. Anderson, *Got a Website Yet?*, INTERNET HEALTH CARE MAG., Apr. 2001, at 4; Gary Baldwin, *Physicians Bring Color and Flair to their Web Sites*, INTERNET HEALTH CARE MAG., Apr. 2001, at 28; Dawn Brewer, *More Rules, More Risks for High-Tech Health Care Sites*, THE NAT'L L.J., Jan. 29, 2001, at B19; Jonathan Bush et al., *Navigating the Options: Using the Internet to Improve Doctor-Patient Relationships*, HEALTH MGMT. TECH., Nov. 2000, at 22; MargaretAnn Cross, *What's Next? Experts Look Ahead to 2001*, INTERNET HEALTH CARE MAG., Dec. 2000, at 36; *E-Lab Opportunities: What are the Real Costs and Benefits of Web-Enabled Outreach?*, MED. LABORATORY MGMT. REP., Jan. 2001, at 1.

questions raised. The Saint Louis University School of Law's Health Law Symposium that spawned this issue was oriented toward crystal-balling the health care field and initiating a dialogue about future developments, consequences and implications. We stand much closer to the *beginning* of that inquiry than the *end*.

II. CLINICAL DECISION SUPPORT SYSTEMS

A. *How CDSSs Work – an Overview*

Computer-based Clinical Decision Support Systems (CDSSs) have the potential to revolutionize the way medicine is practiced, affecting both the reality of what the physician is doing and the patient's perception of it and, thus, profoundly changing an intimate relationship of very long standing. Simply put, a CDSS is an "expert system" that merges a powerful data base of health care information, including information specific to a given patient, with a complex set of diagnostic and treatment algorithms—commonly known as Clinical Practice Guidelines, or CPGs.² Using a series of point-and-click steps, the CDSS walks the physician through the diagnostic process, suggesting questions, bringing together data inputs from various sources and ultimately helping to yield a diagnosis of the patient's condition. In many cases, it is not possible to render a definitive diagnosis, and a range of possibilities is given, often with a probability statistic associated with each. (Example: "It is 83% likely that the patient has condition X but there's a 47% probability that it is actually condition Y. Given such a differential diagnosis, it is appropriate to treat for X but continue to gather information and watch for signs that would reveal whether the correct diagnosis is Y.")

Once a tentative, working diagnosis is reached, the system walks the physician through another set of algorithmic steps to determine the appropriate treatment, or range of possibly appropriate treatments, for each of the conditions identified above. Treatment A might be the appropriate treatment generally for patients with Condition X; but in the case of this particular patient, who is suffering from another condition for which he is being treated concurrently, Treatment A is not indicated. Thus, Treatment B is ordered on the assumption that Condition X is the problem, but with the case flagged to watch for signs of Condition Y and change the therapeutic approach if those signs manifest and the tentative diagnosis of X must be modified.

2. A representative definition says that CDSSs are systems that can "synthesize and integrate patient-specific information, perform complex evaluations, and present the results to clinicians in a timely fashion." Dereck L. Hunt et al., *Effects of Computer-Based Clinical Decision Support Systems on Physician Performance and Patient Outcomes*, 280 JAMA 1339, 1339 (1998).

B. What Lies Beneath the CDSS? Clinical Practice Guidelines

CDSSs are propelled by CPGs, which, in turn, are increasingly based upon Evidence-Based Medicine (EBM). Much has been written about the evolution of EBM and how it differs from the traditional approach to the advancement of medical knowledge, the latter a process far more subjective and anecdotal.³ EBM relies heavily on outcomes research, a methodology involving the analysis, usually by computer, of large amounts of encounter and treatment data to determine what works and what does not in terms of yielding the desired clinical outcomes: preservation of life, reduction of symptoms, restoration of normal function, et cetera.⁴ Into this equation, the cost of various treatment inputs can be added, yielding an index not just of a treatment's effectiveness, but also of its *cost-effectiveness*. Armed with this analysis and the empirical data to defend it, the powers that be—whether they are government agencies, health plans, insurers or individual healthcare consumers—can decide what care should or should not be provided, what services should be paid for and so forth.

The cost-effectiveness analysis briefly described above is then turned into CPGs. Here again, there has been a great volume of analysis and commentary on developments in this area.⁵ Until relatively recently, CPGs were generally cast in the form of paper documents, often three-hole-punched for insertion into loose-leaf binders, with periodic updates sent to be inserted into the binders. Once in the hands of affiliated physicians, these CPGs are supposed to guide, but not control, their treatment decisions. While CPGs can be used, and historically were used, to improve and ensure the quality of care, in recent years, they have come to be used more often as a device for cost-containment.⁶ Their parameters have been tuned to cost-effectiveness analysis (CEA) and they have become the tools of choice of Managed Care Organizations (MCOs) for assuring cost-consciousness of affiliated providers.⁷

3. See, e.g., Cynthia D. Mulrow & Kathleen N. Lohr, *Proof and Policy from Medical Research Evidence*, 26 J. HEALTH POL., POL'Y & L. 249, 250-53 (2001).

4. See, e.g., Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL., POL'Y & L. 327, 328 (2001).

5. See generally, e.g., Peter D. Jacobson & Matthew L. Kanna, *Cost-Effectiveness Analysis in the Courts: Recent Trends and Future Prospects. Evidence: Its Meanings in Health Care and in Law*, 26 J. HEALTH POL., POL'Y & L. 291 (2001); Prosser, L. A. et al., *Barriers to Using Cost-Effectiveness Analysis in Managed Care Decision Making*, 6 AM. J. MANAGED CARE 173-79 (2000); Sara Singer et al., *Decreasing Variation in Medical Necessity Decision Making: Final Report to the California HealthCare Foundation*, Center for Health Policy, Stanford University, (Aug. 1999), available at <http://admin.chcf.org/documents/chef/medicalnec.pdf> (last visited Jan. 22, 2002).

6. Troyen A. Brennan, *Practice Guidelines and Malpractice Litigation: Collision or Cohesion?*, 16 J. HEALTH POL., POL'Y & L. 67, 67 (1991).

7. Peter D. Jacobson & Matthew L. Kanna, *Cost-Effectiveness Analysis in the Courts: Recent Trends and Future Prospects*, 26 J. HEALTH POL., POL'Y & L. 291, 294 (2001).

C. Will Physicians Accept CDSSs?

Will physicians accept Clinical Decision Support Systems as the new infrastructure of their clinical practice? This critical and difficult question basically has two parts. The first is whether physicians will accept CPGs. The second is whether they will accept them in the form of CDSSs.

1. Physician Acceptance of CPGs

United States physicians, in general, have not been keen to embrace CPGs or guide their practice decisions by them.⁸ There are a number of reasons for this. First, many clinicians—hands-on practitioners as opposed to academic physicians or medical researchers—do not appear to accept, at least not fully, the EBM science underlying the CPGs. They act as if they believe that patients are too different from each other to be lumped together for research purposes; therefore, these studies do not truly reveal what works and what does not. Physicians have long put CPGs down with the pejorative label “cookbook medicine.”⁹ They believe, even if they may be reluctant to say so, that their personal observations are just as valid as—or, perhaps more valid than—the results of these “large n” studies.” Neither of these positions would be comfortable for them to defend, since as people of science, they routinely deal with statistical proof of things generated by various forms of research studies, including randomized clinical trials. However, when this aspect of their scientific world potentially conflicts with their traditional areas of practice prerogative, they often find ways of challenging the science.

For example, they may accept the concept of Evidence-Based Medicine in a general way but also believe that their patients, for one reason or another, differ sufficiently from the study group that the results of the study group are not applicable to, and thus should not control, their “unique” practice situation.¹⁰ They may also distrust CPGs because of their auspice and the perceived motivations of those who generate them. There is a widespread

8. Sandra J. Tannenbaum, *Knowing and Acting in Medical Practice: The Epistemological Politics of Outcomes Research*, 19 J. HEALTH POL., POL'Y & L. 27, 37-39 (1994).

9. What's in a name? Apparently quite a bit. WebEBM, Inc., a Nashville-based company that sells a service enabling physicians to go online to access guidelines aimed at standardizing, and thus improving, clinical care, promotes its online applications as “Evidence-Based Medicine,” believing this term has a much more positive connotation and acceptance among physicians than “clinical practice guideline.” Gary Baldwin, *Bringing Docs Online Takes Tact*, INTERNET HEALTH CARE MAG., Jan./Feb. 2001, at 32, 34 [hereinafter Baldwin, *Bringing Docs Online*]. WebEBM represents a collaboration involving the medical schools at Duke, Emory, Oregon Health Sciences University and Washington University.

10. It is ironic how consistently people are ready to generalize from their own particular situation; that is, to believe that what they have personally experienced reflects the world at large while, at the same time, harboring a deep-seated unwillingness to believe that what is known to be true in general actually applies to their particular situation.

concern, not unfounded, that the guidelines are being used primarily by managed care “bean-counters” to ration care and limit the doctor’s autonomy and judgment in providing for his or her patients what the patients actually need. Finally, physicians may be wary of following CPGs for fear that the patient care actions they take to comply with CPGs may expose them to liability because of the way CPGs relate, or fail to relate, to traditional legal principles measuring the adequacy of physician performance by reference to standard professional practice.¹¹

Important as these philosophical and legal factors are, it may be that the compelling factor that has tended to discourage physicians, as a practical matter, from following CPGs—and perhaps indirectly has motivated them to find justifications for not believing in them—is the sheer difficulty of keeping up to date with the CPGs. Because they have to be revised relatively frequently as medical knowledge advances, CPGs represent a substantial burden to physicians in terms of just staying current with the release of new guidelines and interpretations.¹² This is especially the case where a physician participates in a number of different MCOs, a common situation nowadays. In such situations, she or he has to keep track of several different sets of guidelines—knowing not only what the guidelines say on their face but also how they are implemented in practice—and also has to remember when treating a patient which health plan, and thus which set of guidelines, governs.

2. CDSSs as a New Form of CPGs

For the reasons discussed above, and perhaps others, many physicians have been reluctant to embrace guidelines. However, their response to CDSSs might well be different. In the emerging e-world of health care, CPGs will not often come to doctors in the form of hard-copy documents, meaning, paper supplements to be stuffed into already-bulging loose-leaf binders. Rather, they will be integrated into elaborate, computer-based systems that will be a standard fixture in every practitioner’s office. Not only will the physical form of these CPGs be different, but their entire orientation will be reversed and they will be promoted in a very different way. Instead of constraints or additional obligations that the physician has to satisfy, CPGs, offered in the form of point-and-click CDSSs, will be promoted as tools to make the physician’s job easier. In such a guise, they may be received more enthusiastically and may go much further toward changing physician practice patterns. This is true even though CDSSs may effectively enable much greater

11. See Rosoff, *supra* note 4, at 335-46.

12. One can argue that the burden is not that different from the burden resting on all professionals to stay current with developments in their fields. However, that general burden is placed on physicians by their own pride and conscience and so, perhaps, is not seen as an outside imposition but rather as a matter of personal choice.

external control by MCOs of physician behaviors, something doctors would normally resent and resist. As Dr. Homer Chin, a practitioner in the Kaiser Health Plan network, said in presenting a proprietary CDSS at a major national healthcare information technology conference, “If you make it easy for doctors to do the right thing, they will do the right thing.”¹³

Computerized CDSS tools have the potential, if well designed and properly used, to ease rather than increase the burdens of the physician’s practice—at least once the initial period of learning how to use the system is past. Instead of guidelines being one more aspect of information overload that physicians have to use their valuable time and attention to manage, the CDSS will help them manage other aspects of their workload and, at the same time, help assure that they will not overlook something important, such as a late-breaking piece of medical information that might bear on the patient’s treatment. Certainly as both the volume of information and the pace of change increase, the burden on physicians’ memories will become greater. Computers offer the ability to manage an enormous volume of rapidly changing information and bring key bits forward at the right time and place and in a useful way. This may be just the right time and place for these e-devices to come to the aid of overworked and overstressed medical practitioners.

The medical world of the future will undoubtedly be one with many more constraints and limits. Our recognition that health care resources are finite makes this a virtual certainty. As doctors today contemplate a world with more monitoring, supervision, rules and limitations, the future, not surprisingly, looks bleak. The reality is, however, that the electronic era not only enables close scrutiny, it can also facilitate integration of physicians into a health care network in ways that lessens, rather than adds to, their burdens. We are certainly not at that point yet. Our understanding of the problems has to evolve further before our search for solutions can proceed effectively. The simple message is that the future is not all dark; there are points of light—perhaps not a thousand of them, but enough to offer hope.

D. How Will CDSSs Change Doctor-Patient Relationships?

It is interesting to ponder how CDSSs will affect the way doctors and patients relate to each other. One might think, simplistically, that any device that enables doctors to provide better care would improve doctor-patient relationships, but perhaps there is another side to the picture—the loss of the physician’s mystique as healer and the decline of the “art of medicine.”

The logical, multivariate reasoning process described above under the discussion of how CDSSs work has been used by physicians since time out of

13. Homer Chin, Remarks at the HIMSS annual meeting in Atlanta, Ga. (Feb. 23, 1999) (presenting the Epic Systems Corp. CDSS). For information about the Epic Systems Corp., located in Madison, Wis., contact Susan Effinger at 608-271-9000.

mind. Before the advent of computers, it carried—and still carries today—such honorific labels as “clinical judgment” and “professional expertise.” The ability to collect information, organize it, think through a medical problem and come up with principal and alternative diagnoses and therapies goes to the core of what physicians do, and have done since they first existed. The key to the process has always been the store of knowledge the physician carries, locked in his or her gray matter; and much of the respect and authority that physicians have enjoyed through the ages has come from patients’ awe at the perceived quantity and quality of that knowledge. Now, ironically, as physicians are able to augment the knowledge in their heads with a continuously updated and expanding store of electronically retrievable information,¹⁴ and thus increase the accuracy and effectiveness of their treatments, the patient’s respect for the physician might actually diminish. The key question is how much of that respect comes from that indefinable something known as *mystique*.

Previously the physician’s thought process was largely invisible to the patient. Now, watching a physician point and click his way through a CDSS program, the patient may find himself thinking that he, the patient, has used similar programs to find the lowest airline fares or rental car rates. If he perceives that the doctor is just doing the same thing he himself has done, albeit with a more sophisticated and esoteric guidance system, the mystique of the knowledgeable healer may be significantly eroded. Assuming this is true, how the physician handles his or her use of the CDSS may make a big difference. For example, consider how much different a dynamic is created if the doctor sits side-by-side with the patient and they watch the screen together while the doctor manipulates the mouse than if the doctor sits behind a desk and looks past the screen at the patient, with the screen hidden from the patient’s view. If the patient is aware that the doctor is essentially being guided through a detailed process, practicing “cookbook medicine” using an electronic cookbook, is the therapeutic environment undermined? Will the patient transfer his respect to the computer programmer, or to the company that supplies the CDSS, or will that respect simply dwindle? A magician’s most clever trick loses its wonder when you can see how it is done. How important is the mystique of the learned clinician to the therapeutic process?

Perhaps the physician’s *mystique* is not that central to the patient’s perception of his or her professional competence, after all. Perhaps in the electronic age it will be replaced by a better-informed, ultimately healthier, appreciation of the physician’s expertise in the use of computers, databases and

14. Dr. Andrew Spooner, Director of Pediatrics at the University of Tennessee at Memphis, cites the ability to stay on top of clinical research as a prime reason for using the Internet. He uses, among other services such as Medline and MDConsult, an online library of 40 clinical journals accessible for a \$200/year subscription. See Baldwin, *Bringing Docs Online*, *supra* note 9, at 36.

the Internet. Patients may be drawn to physicians who are adept at using these new e-tools, seeing that as the relevant professional expertise in the new millennium—or, at least, a major part of it. As discussed below, patients may also seek out physicians who offer them other convenience benefits of the *e-age*, such as e-mail communications, online appointment scheduling, e-prescribing, et cetera.¹⁵

If patients are intrigued and attracted by the high-tech appeal of CDSSs, how will they evaluate the quality of the care the systems are capable of providing? An old theme may emerge—the contest between style and substance. Imagine two CDSSs developed and put in place in physicians' offices by two competing MCOs. One MCO invests a substantially greater proportion of its funds available for this use in state-of-the-art computer technology, with attractive (perhaps even animated) graphics, a more user-friendly interface, and more visible “bells and whistles”—a fancy “front-end,” to use e-systems lingo. The other MCO devotes the greater proportion of its CDSS budget to support more exhaustive, more technically sophisticated, analysis of the underlying EBM research—in other words, a more solid, substantive “back-end.” The second system is “clunkier,” superficially less appealing, but let's assume it has notably “better medicine” as its foundation. Which would the patient find more impressive? Which would physicians be more drawn to using? Might this not be the new-age equivalent of the old dilemma: should one choose a doctor who is technically more skilled or a doctor who has a better “bedside manner” (or even a more handsomely decorated office or more up-to-date magazines in his waiting room)? When the question is phrased this starkly, the answer seems clear; one would, presumably, always choose competence over “cosmetics,” meaning, superficial factors, such as appearance or amenities. In practice, however, the choice may not be so clear-cut, in large part because competence is much harder for a prospective patient to assess than other factors that are admittedly less important but more readily discernible. How *would* a patient evaluate the quality of a decision support system? Might there come a time when developers of CDSSs would engage in image-building advertising aimed at health care *consumers* rather than practitioners? Imagine a TV commercial saying, “What kind of decision support system does your doctor use? Ask her the next time you go in for a visit. If she doesn't answer, ‘I use the new HAL 9000 series,’ maybe it's time to look for a new doctor!” Will direct-to-consumer advertising in the e-age ever come to this? Think about it!

E. Practical and Legal Considerations

Fostering an increasing reliance by physicians on electronic decision support devices raises some interesting, but also troubling, questions. First and

15. *Id.* at 37.

foremost, of course, is where the responsibility lies when something goes wrong. Electronic interactions generally leave an excellent “audit trail,” so determining the factual issues underpinning an iatrogenic event may be easier than it is currently in the more traditional world of health care delivery. Even with the facts nailed down, the legal issues may be complex. Who is responsible for errors in the CDSS program—or for errors made by the physician in following its guidance, or in not following its guidance accurately? Would the developers of the CDSS, or its underlying CPG, be liable if its use caused harm to someone?

To the extent that current law might offer an answer to this last question, one would expect that answer to be in the negative. The authors of a flawed research study that is relied on by a physician to the patient’s detriment are not liable to the patient,¹⁶ nor is the journal that published the study.¹⁷ In addition to public policy arguments against stymieing medical progress by chilling the widespread sharing of new ideas, these results rest on the fundamental notion that it is the physician himself on whom responsibility should rest. The physician chooses what sources to turn to and what information to use in his or her decision-making process. It is the physician’s educated discretion that finds, filters and focuses these inputs for the benefit of the patient; thus, it is appropriately the physician’s exercise of that discretion that is the focus of the legal inquiry. The physician’s thought process serves as “insulation,” so to speak, for those who stand behind him or her and provide information inputs. There is a ready analogy to this in the “learned intermediary” doctrine in pharmacy law¹⁸ and an even more pointed reference in the Food and Drug Administration’s concept of *competent human intervention* (CHI), as detailed in the FDA’s medical software policy pronouncements. It is this CHI concept

16. Nicolas P. Terry, *Cyber-Malpractice: Legal Exposure for Cybermedicine*, 25 AM. J.L. & MED. 327, 353 (1999).

17. *Id.* (citing *Jones v. J.B. Lippincott Co.*, 694 F. Supp. 1216, 1216-17 (D. Md. 1988)).

18. For an overview of the “learned intermediary” doctrine, see *Hernandez v. Ciba-Geigy Corp., USA*, 200 F.R.D. 285, 294 (S.D. Tex. 2001).

For cases involving a drug manufacturer’s duty to warn, . . . courts apply the “learned intermediary” doctrine. Under that doctrine, a physician stands as an intermediary between a product manufacturer and the patient. The manufacturer satisfies its duty by warning the physician of the dangers of the drug. The product manufacturer relies on the physician to pass on its warnings. The physician, relying on his medical training, experience, and knowledge of the individual patient, then chooses the type and quantity of drug to be prescribed. “Once the physician is warned, the choice of which drugs to use and the duty to explain the risks become that of the physician.”

Id. (citations omitted).

that will likely serve as the base point for the current analysis, but CHI is a slippery notion that has generated much of controversy.¹⁹

1. FDA Regulation of Medical Software and the CHI Concept

For the past quarter-century, the FDA has had the legislative authority, under the Medical Device Amendments of 1976,²⁰ to regulate medical devices, defined as

an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals.²¹

The authority clearly extends to software that is integral to, or closely connected with, hardware that one would normally think of as a medical device—such as equipment involved in the physical delivery of patient care. Examples would include the software that operates a CAT scanner or software used to monitor a patient's vital signs and regulate a respirator based upon that monitoring. Less obvious is the FDA's authority to regulate "stand alone" medical software, such as that used to operate epidemiological information databases, patient electronic medical records and CDSSs. Although in a 1989 draft policy Guidance memorandum,²² the FDA declared unclassified medical software products to be medical devices and, thus, potentially subject to FDA regulation—defining the scope of its authority expansively—it had earlier articulated a policy decision to "apply the least possible regulatory action required by law to fulfill our public health responsibility."²³ Thus, the 1989 Guidance exempted computer products intended only for use:

- in traditional "library" functions, such as storage, retrieval and dissemination of medical information

19. See, e.g., Dee Simons, *Medical Device Software Regulation: An Industry Perspective*, 52 FOOD DRUG L.J. 189, 190 (1997); E. Stewart Crumpler & Hargey Rudolph, Ph.D., *FDA Software Policy and Regulation of Medical Device Software*, 52 FOOD DRUG L.J. 511, 513-14 (1997).

20. 21 U.S.C. § 360(c) (1994).

21. *Id.* § 321(h).

22. U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FDA Policy for the Regulation of Computer Products, (Draft) (Nov. 13, 1989), available at <http://www.fda.gov/cdrh/ode/351.pdf> (last visited Jan. 16, 2002) [hereinafter FDA 1989 Draft Policy].

23. Former FDA Commissioner Frank E. Young made this statement in 1986. U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FDA Software Policy Workshop (Sept. 3-4, 1996), *FDA Regulation of Medical Device Software: Background Information*, available at <http://www.fda.gov/cdrh/ost/points.html> (last visited Jan. 16, 2002).

- in general accounting or communication functions; or
- solely for educational purposes, rather than for diagnosis or treatment of patients²⁴

Moreover, the Guidance stated that the FDA did not contemplate regulating computer products “that are intended to involve *competent human intervention* before any impact on human health occurs, (for instance, where clinical judgment and experience can be used to check and interpret a system’s output.)”²⁵ The idea was, of course, that the software would be exempt from regulation if, in the ordinary course of using it, a knowledgeable professional would be in a position to interpret and, if necessary, override its recommendation.

Making the exemption turn on competent human intervention seems a reasonable approach in concept, but it has proved troublesome in practical application. Manufacturers reportedly have misconstrued the exemption in order to apply it more broadly than the FDA intended. Moreover, and more to the point of our present discussion, the increased use and sophistication of medical software, and the presumably greater reliance of physicians on systems utilizing such software makes it ever more difficult to apply the CHI concept. Thus, the FDA has more recently, in 1996, moved beyond the CHI concept to a more comprehensive risk assessment concept that classifies medical software on the basis of the following five factors:

- the seriousness of the disease or condition being diagnosed or treated,
- the amount of time available before the practitioner uses the information provided by the software,
- whether the data output departs from customary use or data presentation,
- whether the information is individualized for each patient, and the relative risk to the patients if the software fails, and
- the extent to which the practitioner would be exercising independent judgment in assessing the conclusion reached by the software.²⁶

24. See FDA 1989 Draft Policy, *supra* note 22, at 1.

25. *Id.* at 3 (emphasis added).

26. U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FDA Software Policy Workshop (Sept. 3-4, 1996), *Classification and Risk-Based Criteria*, available at <http://www.fda.gov/cdrh/ost/classif.html> [hereinafter FDA, *Classification and Risk-Based Criteria*]. See also Dee Simons, *Symposium—Drug Development: Who Knows Where the Time*

Based on these factors, software applications are classified as high-, moderate-, or low-risk and this classification affects the strictness of the FDA's scrutiny and the fullness of the regulatory requirements.²⁷ This new five-pronged test is not necessarily easier or more certain in its application than the old CHI approach, especially since the CHI factor is folded into it and remains an important component. However, under the new approach, the slippery CHI determination is now just one of a number of factors, not in itself determinative of exemption from FDA regulation. Also, the decision on regulation is no longer an all-or-nothing decision, since different levels of regulation are possible. Whether, given the subtlety of the other factors in the new test, it is more workable than the old is not an easy judgment call. For one thing, in the five years since the "new" test was introduced, there have been substantial changes in the sophistication of medical software, in the extent of its dissemination and adoption, and in the degree to which practitioners routinely rely upon it in making diagnostic and treatment decisions. Thus, there are important new developments and environmental factors bearing on any assessment of the FDA's regulatory strategy.

That strategy remains essentially the same as before—to "use the least amount of regulatory control necessary to control risks" and, further, to "regulate medical software devices innovatively to minimize impact on product development."²⁸ The industry, not surprisingly, has pushed the FDA to adopt a low-intervention policy, fearing that the costs, cumbersomeness and constraints of aggressive regulation could seriously impede the development and adoption of new software innovations and applications.²⁹ The challenge for the regulators is, of course, a common one: walking the fine line between responsibly protecting the public against inadequately tested and unproven innovations on the one side and, on the other, not overly encumbering and chilling a promising new field of health care technology.

Although the topic is intrinsically interesting and worth pursuing, a fuller exposition of FDA regulation of medical software is beyond the intended scope of this Article. In closing on this general area, however, two other points are

Goes? Medical Device Software Regulation: An Industry Perspective, 52 FOOD & DRUG L.J. 189, 191 (1997).

27. FDA, *Classification and Risk-Based Criteria*, *supra* note 26.

28. E. Stewart Crumpler & Harvey Rudolph, *FDA Software Policy and Regulation of Medical Device Software*, 52 FOOD & DRUG L.J. 511, 514 (1997).

29. See CTR. FOR HEALTHCARE INFO. MGT., RECOMMENDATION TO THE FOOD AND DRUG ADMINISTRATION FOR "STAND-ALONE" SOFTWARE MEDICAL DEVICE DECISION ALGORITHM 17-18 (Mar. 18, 1997), available at <http://www.chim.org/pdfs/1997StandAloneAlgorithm> (last visited Nov. 8, 2001); Randolph A. Miller & Reed M. Gardner, *Recommendations for Responsible Monitoring of Clinical Software Systems*, 4 J. AM. MED. INFORMATICS ASS'N 442, 443 (1997).

worth noting. One is the question of what constitutes “commercial distribution” of software, a significant issue because only commercially distributed software is subject to FDA regulatory control as a medical device.³⁰ Software that is shared “in-house” among users and developers “solely for research purposes” is exempt.³¹ Since CDSSs are still, one could well argue, in a developmental stage, the form of the relationship between a CDSS vendor and a customer, such as an MCO, might determine whether it is subject to FDA regulation.³² The other point to note is the FDA’s proposal to use *software quality audits* in lieu of the Agency’s traditional 510(k) process as a safeguard of quality.³³ Again, it is not this Article’s intent to delve into the intricacies of FDA regulation but, rather, to raise the policy question of how much and what kind of regulation best serves society’s interest in responsible development of medical software applications.

2. Liability of Software Developers

Quite apart from FDA regulation, there is the possibility of common law liability on the part of the developers and sellers of CDSSs (hereinafter “vendors”). As between a vendor and a provider group that uses its system, that liability would turn significantly, but not solely, on the nature and details of the vendor’s undertaking. It is to be expected that vendors will attempt to cover their liability exposure either by contractual disclaimers or by insurance. The latter approach, coupled with a contractual undertaking to indemnify and hold harmless the health care professionals using the CDSS, would seem to be the better market strategy, counteracting possible concerns of providers that by using a new, largely unproven, software tool they would be exposing themselves to significant liability potential. However, the feasibility of this approach would necessarily turn on the price of the liability insurance, which

30. U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FDA Software Policy Workshop (Sept. 3-4, 1996), *Commercial Distribution*, available at <http://www.fda.gov/cdrh/ost/distrib.html> (last visited Jan. 16, 2002).

31. Bruce Merlin Fried & Jason Mark Zuckerman, *FDA Regulation of Medical Software*, 33 J. HEALTH L. 129, 139 n.30 (2000).

32. Of course, using the terms “vendor” and “customer” begs the question. Should these parties want to escape FDA control, they would certainly not structure their relationship so as to make these labels seem appropriate.

33. The FDA’s 1996 policy workshop paper defines the Software Quality Audit as: a critical review of the software quality assurance system, performed by a qualified and independent third-party quality auditor, to provide documentary evidence that a particular medical software device was developed in accordance with appropriate industry standards or according to a recognized quality process, specification, and procedure established by the developer.

U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FDA Software Policy Workshop (Sept. 3-4, 1996), *An Alternative to Current Premarket Notification (Software Quality Audit)*, available at <http://www.fda.gov/cdrh/ost/sqa.html> (last visited Jan. 16, 2002).

would have to be built into the price of the product, the CDSS. Given the cutting-edge nature of the product and the lack of legal precedents in this area, it would be difficult for the insurer's actuaries to project the liability potential; thus the cost of the insurance might be steep.

Contractual liability occurs when a vendor promises one thing in the contract and then does not fully deliver on that promise. A recent advertisement by a company called Healthwise, Inc.³⁴ describes the health information service it provides to healthcare consumers this way:

Evidence-based medicine is changing medical practice. Outcomes research is systematically revealing the risks and benefits of different treatments for the same condition. Doctors are finding more reasons to follow practice guidelines based on this research. When patients have access to the same evidence-based information as their doctors, better health decisions are made. Where medical science is not clear, or issues are controversial, Healthwise provides a balanced and unbiased view that allows the individual to make a well-informed judgment.³⁵

Healthwise claims that all of its decision-support information is referenced to the best evidence-based sources available and that the reader knows who wrote it, who reviewed it, on what research it was based and when it was last reviewed and updated. Healthwise also claims that it seeks experts in every medical specialty to review and critique every piece of its medical information.³⁶ Inherent in this advertising text are several promises that a user of the information service might later claim were not met. For one thing, "the best evidence-based sources available" is a judgmental statement that could support an argument if certain sources were either overlooked or deliberately not included in the information base.³⁷ For another, the claim that "[t]he reader knows . . . when it [the research] was last reviewed and updated" can be read to mean that information available as of the last update was adequately folded into the analysis.³⁸ In either case, there could be potential for liability if important medical developments were not included in the information base—for example, a recently discovered contraindication to a treatment that the user of the service could claim would have caused him or her to decline that treatment if he had known about it. Note that the example above is not

34. Healthwise, *available at* <http://www.healthwise.org/index2.html> (last visited Jan. 16, 2002).

35. Healthwise, *About Us: Prescription-Strength Information Tools from Healthwise*, at http://www.healthwise.org/ps_prescription.html (last visited Jan. 16, 2002). The Healthwise service is marketed as being intended for patients, not for providers. However, the liability bases would be largely the same in either case. The difference lies in the "learned intermediary" concept, which is discussed just below in the text.

36. *Id.*

37. *Id.*

38. *Id.*

extravagant in its claims, making the point that even a conservatively worded advertising statement can hold potential for contractual liability.

If the information service described above were intended for use by the physician, it is unlikely that the vendor would have significantly more liability potential than the publisher of a journal—except, possibly, where the vending contract was held to have made more extravagant promises and those promises were not countered by adequate disclaimers. When one provides information to a health care professional, it can reasonably be assumed that the professional will subject that information to all the usual “filters” and will not rely upon that information to the exclusion of other appropriate sources. This is the core premise of the “learned intermediary” doctrine. Moreover, the information is provided in a format whereby the professional is expected to read, analyze, check and otherwise “digest” it before making a treatment decision. This is the *competent human intervention* (CHI) upon which the FDA exemption described above was predicated. Even where the information was intended for the patient himself, this concept might apply, on the theory that the plaintiff would not take any action based on the information except in consultation with the attending physician—again engaging the professional’s judgment and “filter.”

3. Justifiable Reliance by the Provider

The analysis leads back, then, to the linked questions of how much and in what way physicians will rely upon CDSSs and to what extent the law will regard such reliance as legitimate. As long as it is reasonable to assume that the CDSS only provides information that is subject to CHI, the rationale that underlies the “learned intermediary” doctrine will apply, and the responsibility will continue to rest primarily on the physician. But at some point, arguably, CDSSs will become so commonplace, so standard a part of the physician’s tool-set and practice routine, that physicians will be justified in relying wholly upon them. To illustrate, imagine the following situation:

Dr. X uses a digital thermometer to take an infant’s temperature. The instrument suffers a non-obvious failure and registers “normal” although, in fact, the child has a fever high enough that, if known, would call for the doctor to begin immediate antibiotic treatment. Upon seeing the “normal” readout on the instrument, Dr. X momentarily doubts it, because the child feels feverish to his touch, but then decides to rely upon the instrument. The child comes to harm because of the resulting delay in treatment.

The question, of course, is to what extent the physician is entitled to rely on the electronic “diagnosis support” device. In the example just described, the digital thermometer would be classified as a medical device, subject to FDA regulation and that classification would bear significantly on, but probably not be fully determinative of, the physician’s potential liability for negligence in relying on the device. In other words, just because a device is

FDA-regulated upon the premise that its output might be used by a physician without a separate confirming analysis—meaning, without competent human intervention—it is not necessarily the case that the physician is free of liability for “overly relying” on the device. The question would be, presumably, to what extent a reasonable and prudent physician would have relied on the device’s output under the circumstances. Obviously, the greater the potential risk to the patient if the device were defective, the more responsibility the physician would have to doubt the device’s output and seek independent confirmation of its readings. Note how this analysis borrows from and follows the “risk-based” approach, described above, that the FDA has adopted for classification of medical software.

Even with powerful diagnostic tools becoming more commonplace, physicians will likely continue for some time to rely principally upon their own powers of observation, judgment and intuition in treating their patients. Even as Dr. McCoy on the original *Star Trek* series used his “medical tricorder” to diagnosis a patient’s condition, he continued to place great reliance on his own human intuition.³⁹ But in *Star Trek – The Next Generation*, the medical officer was much more comfortable relying upon computer-based diagnostic devices; and in the generation after that (*Star Trek – Voyager*), the doctor was a computer-generated hologram. One can scarcely expect a physician to distrust the medical software when he himself is a sub-program of that software! We obviously have a long way to go before our physicians are literally creatures of the medical software we are now discussing, but it is not so fanciful to project a day when heavy reliance upon medical software becomes the rule.

Now, for a more challenging contrast to the digital thermometer hypothetical above, imagine the following scenario:

Dr. B uses a CDSS in deciding what drug to prescribe for a patient’s condition. Knowing that the patient’s electronic medical record (EMR) is supposed to contain information about all medications the patient is currently taking and that the CDSS is programmed to flag potential drug-drug interactions, she relies upon the CDSS’s recommendation without taking the time to ask the patient if he is taking any other medications. As luck would have it, the patient is on a drug, prescribed a week before by Dr. A, that should not be taken concurrently with the one Dr. B is now prescribing. The patient assumes Dr. B knows about the medication previously prescribed by Dr. A and makes no mention of it; and the patient suffers a serious adverse reaction from the drug interactions. Upon investigation, it is found that either Dr. A failed to enter the prescription properly, the CDSS software “mis-posted” that information and it

39. As Dr. McCoy stated in *Star Trek*, “Dammit, Jim, I’m a physician.” *Star Trek* is a set of television series and movies produced by Paramount Pictures Corporation. *Star Trek* (The Original Series) aired from 1966 to 1969. *Star Trek: The Next Generation* aired from 1987 to 1994. *Star Trek: Voyager* aired from 1995 to 2001. For more information, see the Star Trek website, at <http://startrek.com/library/episodes.asp> (last visited Jan. 16, 2002).

never made its way into this patient's record, or the information was correctly posted but the CDSS program failed for some reason to flag the drug interaction potential.

Who would be liable – Dr. A, Dr. B, the CDSS vendor or some combination of these parties? You decide! In so doing, however, keep in mind that you will necessarily be making an underlying assumption as to how much Dr. B is entitled to rely upon her computer-based decision support system. Moreover, even if you find that the precipitating error in this case was that of Dr. A, who failed to enter his prescription properly, you might find the CDSS company responsible for negligent design of its system—meaning, absence of a “fail-safe” feature—that allowed the prescription to be filled without its being properly entered in the patient's EMR.⁴⁰

To end this section by saying “in conclusion,” or anything of like effect, would be misleading folly. There are no conclusions in sight as to any of the issues raised above, only questions and more questions. Courts that are not fully sensitive to all that is going on in the development and dissemination/adoption of CDSSs may try to deal with questions of liability by adhering to traditional notions of physician responsibility, such as those underlying the learned intermediary doctrine. However, this is an overly simple approach that disregards important realities of how practices of physicians will evolve in the electronic age. Up to a point, the law can disregard realities, either consciously or unwittingly, and at times they have done that in the name of public policy.⁴¹

4. The Impact on Medical Education

It is interesting to ponder how the increasing availability and use of CDSSs will affect medical education in the United States. For one thing, a physician who has ready e-access to comprehensive data need not spend much of his or her education internalizing that data. In fact, if the data is changing rapidly, committing it to memory would be inadvisable and a waste of time. For

40. Safeguards against this sort of thing happening will be touched on in the upcoming discussion of e-prescribing. See *infra* Part III.

41. See, e.g., *Schultz v. Mutch*, 211 Cal. Rptr. 445, 450 (Cal. Ct. App. 1985) (upholding the “captain of the ship” doctrine). Another California court of appeals struck down this doctrine as being no longer supported by actual practice in health care delivery. See *Truhitte v. French Hosp.*, 180 Cal. Rptr. 152 (Cal. Ct. App. 1982). The *Truhitte* court said: “A theory that the surgeon directly controls all activities of whatever nature in the operating room certainly is not realistic in present day medical care.” *Id.* at 160. The *Schultz* court did not take issue directly with this view of the “real world” but countered with its belief that it is in the patient's interest to focus legal responsibility on the physician whom the patient chose “presumably based on faith in his competence and expertise. The patient reasonably expects the doctor to oversee her care and to look out after her interests while in and immediately pending surgery.” *Schultz*, 211 Cal. Rptr. at 450.

another, it may take significant training and practice to prepare a physician to use the various e-tools of his or her trade naturally and confidently. Thus, if one assumes continuation of the standard four-year medical school program, there will inevitably be shifts in the curriculum from traditional topics to new computer-oriented skills training. It is hard to predict how substantial those shifts will be, for two readily apparent reasons, and perhaps others.

First, computers are becoming so prevalent in every stage of education, from grade school onward, that students reaching medical school may already have an almost intuitive command of them. Second, there are so many new developments in medicine—for example, genomics, “smart” medicines and nano-technology, that these will compete powerfully with e-subjects for space in the evolving curriculum. But, while predictions are difficult to make, it seems fairly certain that medical education will move away from the goal of committing current information—that is, the information current during the student’s four years in school—to memory and in the direction of teaching students how to access the constantly expanding database that is modern-day “medicine in motion.” As part of this transition, students will become more and more dependent on the electronic databases and less on their own personal memory banks—or, to put it differently, their personal memory banks will be used not so much to store medical information as to store the knowledge of how to manipulate their computer tools. If this is so, how will it bear upon the question that kept recurring above: to what extent will the law endorse or condone a physician’s reliance upon the computerized information? In the new e-world of medicine, the term *competent human intervention* may come to mean something quite different than it does today.

III. E-PRESCRIBING OF PHARMACEUTICALS

Another aspect in which the future is already upon us is “e-prescribing.” A number of pioneer systems are in place today,⁴² and the healthcare system in the United States is clearly moving toward establishing electronic links between physicians and pharmacists to facilitate ordering and dispensing prescription drugs more efficiently and safely. The advantages of e-prescribing are important and obvious and there are few voices, if any, raised in opposition to this trend. However, there are substantial obstacles to be overcome before e-prescribing is a fully realized feature of the health care system.

42. For a list of the major companies offering hand-held electronic prescribing systems, see Institute for Safe Medication Practices, White Paper, *A Call to Action: Eliminate Handwritten Prescriptions within 3 Years!* (2000), available at <http://www.ismp.org/MSAarticles/Whitepaper1.html> (last visited Jan. 8, 2002) [hereinafter ISMP White Paper].

A. Point-of-Care Systems

E-prescribing is an application of what are generically called “point of care” (POC) medical information systems. Such systems allow the treating physician to bring all information elements bearing upon the patient’s care together at a single point when diagnostic and treatment decisions have to be made or implemented. Imagine the myriad situations when, for example, a doctor is seeing a patient and needs a radiological study, or test results from the medical or pathology laboratory, or a specialist’s consultation report in order to decide upon the patient’s treatment regimen. The relevant information may have been generated hours or even days before, but if the doctor cannot access it currently, the patient’s treatment is stalled. The electronic era offers exciting possibilities for “shrinking time and space” and bringing all necessary data together when and where needed. Moreover, a “smart system” does not just rely on the treating physician to ask the right questions and call for the right information. It can prompt, suggest, and remind; and, thus, it can protect against human error and oversight. Hand-held Personal Digital Assistants (hereinafter “PDAs”), known to many as Palm Pilots,⁴³ have the potential to make the patient’s traditional medical and nursing charts—collections of scraps of paper held together in a manila folder or on a clipboard—obsolete.

When these systems are used for the ordering of tests and medications, the process is known as e-prescribing, and it has been widely proclaimed as the “next thing” in healthcare delivery. E-prescribing is a logical next step in the evolution of e-health for a number of reasons. First, the electronic infrastructure it requires is closer to the reach of most physicians than that required for the more sophisticated CDSSs discussed above. Some form of Electronic Medical Record (EMR) is at the base of most e-prescribing systems, but e-prescribing does not require a full-featured EMR system like a CDSS does. It has to have patient identification data and information on what drugs have been dispensed for the patient; but full information on the patient’s condition, medical history, test results, et cetera, is not needed to accomplish the e-prescribing piece. Second, e-prescribing does not vary the doctor’s traditional role as much as the CDSS. The e-prescribing software is much more likely to be seen as a time and labor-saving tool the doctor manipulates than as an “electronic partner” in the decision-making process regarding the patient’s care. Third, there is already a loud call for a move toward e-prescribing, in the name of patient safety.

43. Palm Pilot is a registered brand name of the 3-Com Corporation. By virtue of this brand’s popularity and ubiquity, “palm pilot” has become a generic label, like “Kleenex,” although there are a number of other brands of PDAs. For information on the major brands, see 800.com Electronics, at <http://www.800.com> (last visited Nov. 12, 2001).

B. Patient Safety Benefits

E-prescribing addresses one of the most serious problems affecting patient safety: errors in ordering, dispensing and administering prescription drugs. This type of error has received considerable attention in the past couple of years, largely as a result of the Institute of Medicine's (IOM's) recent report, *To Err Is Human: Building a Safer Health System*.⁴⁴ According to this widely cited and discussed research study, a whopping nineteen percent of all iatrogenic injuries are caused by medication errors.⁴⁵ Errors come not just from the legendary difficulties in reading doctors' handwritten (or scrawled) prescriptions, but also from a failure to identify and/or anticipate potential drug interactions. This second piece—often an example of the left hand (of the treatment team) not knowing what the right hand is doing—highlights the desirability of moving toward a unified Electronic Medical Record.⁴⁶

The health care field has long recognized both the critical importance and the difficulty of maintaining a comprehensive patient medical record that is kept scrupulously up-to-date, and, for over a decade, influential groups have called for that record to be computerized.⁴⁷ When a patient is under active care, there may be many different data elements generated in a single day and many different diagnostic and treatment decisions made. Ideally, each decision should be made with full knowledge of all other care decisions made or pending, of all aspects of the regimen the patient is embarked upon, and the most complete and current information about how that regimen is progressing. Unfortunately, even with a system organized to place principal coordinating responsibility on a single individual, the attending physician, that ideal is commonly not achieved. Diagnostic test results come in from various sources at their own speed. Specialists treating various aspects of the patient's condition do not necessarily communicate their actions and findings immediately to the attending physician. The attending physician, even when she is doing her best to touch all bases and gather all information before making a decision or taking an action, too often has to go forward with one or more pieces of information missing or questionable. A unified electronic record simultaneously accessible to all authorized persons dealing with the patient, either directly or indirectly (that is, either as a hands-on provider or, say, a laboratory analyzing a specimen delivered to it at a remote location), has

44. COMM. ON QUALITY OF HEALTH CARE IN AMERICA, INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000).

45. *Id.* at 221.

46. *See, e.g., White Paper Proposes Elimination of Handwritten Prescriptions by 2003*, MED. INFO. TECH. L. REP., Nov. 2000, at 1, 5.

47. *See, e.g., COMM. ON IMPROVING THE PATIENT RECORD*, INST. OF MED., *THE COMPUTER-BASED PATIENT RECORD: AN ESSENTIAL TECHNOLOGY FOR HEALTH CARE* (Richard S. Dick & Elaine B. Steen eds., 1991).

long been a dream. That dream is on the verge of becoming a reality, especially within an integrated delivery system (IDS), such as a health maintenance organization (HMO), where everyone who deals with the patient is part of the same system, has access to the same computer network and plays by the same procedural rules.

Even without a fully integrated delivery system network, however, it is currently possible in many areas to develop a functional e-prescribing system.⁴⁸ That is because PBMs, or Pharmacy Benefits Managers,⁴⁹ and even chain retail pharmacies currently maintain fairly sophisticated pharmacy computer systems that track drug-related information for their client-customers. Prescriptions, including those entered through traditional handwritten “scripts,” are logged into a computer system as they are received and filled. This information can be shared with every pharmacy in the system, as well as with those in other prescription-tracking systems that maintain reciprocal, cooperating relationships. It can also be shared with the patient’s physician and any third-party payer responsible for the patient’s care. Many of these systems are programmed to screen for possible drug-drug and drug-diet interactions, dosage errors, allergy screening, prescription duplication, special safeguards for geriatric and pediatric patients, IV compatibility checks, drug-disease contraindications, et cetera.⁵⁰

C. Convenience and Cost Savings

A simple and readily achievable benefit of e-prescribing is that the patient is spared the inconvenience of taking a handwritten prescription to the pharmacy, handing it in and waiting, sometimes for an hour or more, for the prescription to be filled. Assuming an office visit with the physician has generated a prescription, it can be electronically entered, and the prescription can be processed and waiting to be picked up when the patient arrives at the pharmacy. The initial cost of setting up these e-prescribing systems may be substantial, but it will be justified by the marketing benefits to be expected from them. Moreover, once patients have become accustomed to having their prescriptions handled this way, they will prefer to deal with pharmacies that

48. E-prescribing is a logical, incremental step toward a fully computerized practice environment. See, e.g., Bruce Kleaveland, *Incremental Approach to Electronic Medical Records*, HEALTH MGMT. TECH., June 2001, at 18.

49. For an introduction to PBMs generally, see Arnold J. Rosoff, *The Changing Face of Pharmacy Benefits Management: Information Technology Pursues a Grand Mission*, 42 ST. LOUIS U. L.J. 1 (1998) [hereinafter Rosoff, *Changing Face of Pharmacy Benefits Management*].

50. Salvatore M. Barcia, *Reducing Medication Errors*, HEALTH MGMT. TECH., Jan. 2001, at 26. Note that some of the functions mentioned above—such as drug-food interactions, allergy screening and drug-disease contraindications—are feasible only in systems that track more than just pharmaceutical-related information. The comprehensiveness and sophistication of extant systems varies considerably.

participate in such a system. The MCO that sets up and operates the system will exert considerable influence over the patient's purchasing behavior and can parlay this influence into bargaining power with pharmacies that want to be participating providers. To the extent that the bargaining power lowers prices and the savings are shared with the patient-consumer, the above relationship is further reinforced and solidified.⁵¹ The physician-patient-pharmacy-payer network offers great potential. It is by no means certain that MCOs will take advantage of this potential; but it exists and it seems likely—subject to a reservation to be discussed shortly—that in today's highly competitive healthcare environment, some MCOs will do so. When that happens, competition will dictate that (at least some) others will follow suit.

D. Compliance with Managed Care Formularies

Over the past several years, MCOs have increasingly used formularies to help control runaway prescription drug costs. Formularies are lists of drugs approved by a governing body—typically called a Pharmacy & Therapeutics or “P&T” committee—for use in care rendered in a given institution or through a particular health plan. MCOs use formularies to identify which drugs they would prefer their affiliated physicians to use in treating plan members.⁵² Although it is possible for a formulary to be “closed”—meaning, the physician can use only drugs included on the formulary list—it is far more common for a plan to maintain an “open” formulary. This is because it is politically very sensitive to try to control the doctor's ultimate choices with regard to the patient's treatment and, beyond politics, such domination of the physician's judgment poses significant legal risk. Numerous cases have held that a managed care entity can become liable when it “takes the reins” and tries to control the physician too completely. Influencing the physician's judgment may be acceptable; overweighing it clearly is not.⁵³

But the choice is not a simple dichotomy between a closed and an open formulary; different degrees of freedom—or degrees of constraint, if one is disposed to see things in a “glass half empty” kind of way—are possible. A health plan's drug benefit can be set up so that if the physician prescribes for his patient a drug “preferred” by the plan's formulary, there is no charge to the

51. Commenting on a draft of this article, the author's principal pharmaceutical industry source, consultant Elan B. Rubinstein, Pharm. D., M.P.H., of Oak Park, California, was skeptical that such savings would be passed through, at least in any direct way, to consumers. An indirect savings might be possible, however, in that MCOs might save money on their drug benefit coverage and some of that savings could find its way to members in the form of lower premiums. E-mail correspondence with Dr. Elan B. Rubinstein, Nov. 10, 2001.

52. See Rosoff, *Changing Face of Pharmacy Benefits Management*, *supra* note 49 (discussing the use of formularies by PBMs).

53. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 559-60 (4th ed. 2001) and references cited therein.

patient for the medication—except, perhaps, a basic pharmacy visit co-payment (dispensing fee). On the other hand, if the physician prescribes a “non-preferred” drug—most likely one that costs the plan more money and for which there is no pharmaco-economic proof that it yields a better outcome—the patient has to pay significantly more. The potential that e-prescribing offers to deal efficiently with information makes possible a new range of options for maximizing cost savings in ordering pharmaceuticals. Consider the following hypothetical:

Dr. Y has diagnosed his patient, Mr. D as having a chronic illness that requires treatment with drugs. Of the four or five drugs that could be used, drugs #1 and #2 seem most appropriate for a person of D’s age, gender and comorbidities. Drug #1 is preferred by D’s MCO because it costs the plan 20% less. However, for some 15% of the patients suffering Mr. D’s condition, drug #1 has side effects that, although not seriously health-threatening or permanent, are unpleasant (assume such effects as dry mouth, headache, disturbed sleep or stomach upset). Drug #2, costing 20% more, rarely causes any side effects. Over the years, Dr. Y has adopted a personal policy of always prescribing drug #2 because he does not want to risk his patient’s discomfort and also does not want to take the time to explain the possible side effects and what to do if they occur. But now, in an atmosphere of heightened cost-consciousness, one of the health plans with which Dr. Y participates is putting pressure on him to use the cheaper drug whenever possible. For the doctor to remember which plans prefer which drugs and which patients are covered by which plans is a significant burden,⁵⁴ particularly given Dr. Y’s busy practice schedule.

Let’s assume first a situation without e-prescribing:

Dr. Y handwrites a prescription for Drug #2 and gives it to Mr. D, who takes it to his local pharmacy to be filled. D has to wait half an hour for the prescription to be filled and when he steps up to the counter to pay, he is shocked by how high the price of the drug is. D knew he would have to pay a nominal dispensing fee but thought his health plan would pay the actual cost of the drug. He complains to the pharmacist that there must be some mistake because he pays extra for a health plan that supposedly has a good drug benefit. The pharmacist explains to him that he has to pay more because he is getting a drug that is not the “preferred” drug in the plan’s formulary. He also explains why this matters for reimbursement purposes and, further, that D’s physician, who undoubtedly has access to the plan’s formulary guidelines, could have recommended the cheaper drug. He speculates that maybe Dr. Y was trying to avoid a side-effect D had experienced on some previous occasion when using the cheaper drug, but D interrupts to say that could not be the case

54. Note that, given the way PBMs, health plans and other third-party payers negotiate with pharmaceutical companies, a drug that is cheaper for one plan is not necessarily cheaper for another, making it harder for the doctor to keep in mind which is the preferred drug for a given plan.

because he has never before been treated for this condition and, so, he has had no experience with any drug of the type in question. D is annoyed that his physician made a decision that required him to incur a significant out-of-pocket cost without even mentioning this to him. D's annoyance could also extend to the MCO for its perceived cheapness in not covering the drug his doctor thought was best for him and even to the pharmacist, who filled the prescription while D was in the store but did not mention the price difference until it was time for D to take his drugs and pay the bill. The point is that "business as usual" today has real potential for causing consumer dissatisfaction and adding to "managed care backlash."

Now, let's consider how the same situation might have played out if Dr. Y were using an e-prescribing (e-Rx) system:

Upon diagnosing Mr. D's condition, Dr. Y would have picked up his PDA and easily pulled up a menu listing the drugs that could be used to treat it. Information would have been instantly available on the possible contraindications, including side-effects, of each drug. Upon entering the patient's name or identification number, Dr. Y would have seen if D was currently taking any other drugs that might pose a drug-interaction problem. He would also have seen what health plan D was enrolled in, and that plan's formulary information would have been displayed on the screen. With this reminder of which drugs were preferred in that plan and which were not, Dr. Y could easily have told D of the cost difference and asked whether that was significant to him or not. The conversation about possible side effects of the cheaper, preferred drug would have taken place at that point, heading off the patient's surprise and displeasure later on. The decision, reached jointly, would have been communicated instantaneously when Dr. Y clicked on the button for the chosen drug and pushed "enter" and the prescription, already filled, would be waiting for Mr. D when he arrived at the pharmacy. The safety benefits of not having to deal with a handwritten script have already been noted.

The potential benefits of the e-prescribing system do not stop here. Presumably, most managed care companies, while intent on saving money, would be willing to pay the extra cost of the more expensive drug (#2) in those specific cases (assumed to be fifteen percent in the above hypothetical) where it is needed, that is, where a patient actually experiences the unpleasant side effects associated with the cheaper drug (#1).⁵⁵ Given the convenience and information-tracking ability of the e-prescribing system, Dr. Y could be authorized to make the following sort of offer to his patient:

"Mr. D, your plan will only cover the cost of the more expensive drug when it has been shown that the drug is actually needed for a particular patient. If you want, I can start you on a short course of the cheaper drug, #1. I'll explain the

55. Elan Rubinstein cautions that insurers will not necessarily be willing to pay hard dollars to avoid patient's unpleasant side effects or inconvenience. *See supra* note 51.

negative side-effects you might possibly experience with it and give you a print-out that details the symptoms to watch for. If any occur, you let me know and I'll switch the prescription immediately. The pharmacy will deliver a substitute prescription of drug #2 to your home, with no charge for the drug or the delivery, and you can simply discard the unused portion of drug #1. Thereafter, if refills are needed, your health plan will pay for the more expensive drug without any additional charge to you. How does that sound?"⁵⁶

That would probably sound quite good to most patients. This positive outcome is possible because the information specificity of e-prescribing makes it practicable to tailor each prescription to the particular patient and avoid wasteful "excess of caution" approaches, such as Dr. Y employed in the original hypothetical.

E. Documentation for Reimbursement Purposes

This next point is directed not just to e-prescribing but, more broadly, to the use of Point-of-Care systems generally, and particularly to the use of hand-held devices ("PDAs") by the physician at the time of contact with the patient. Careful accounting of the time spent attending to patients is an important part of the reimbursement (billing and payment) process. As third-party payers, both private and governmental, have become more sensitive to and wary of problems of overbilling, "upcoding"⁵⁷ and charging for services as if they were rendered by a senior physician when, in fact, they were rendered by one less qualified (and thus commanding a lesser reimbursement rate), the precision and accuracy of accounting for healthcare practitioners' time has become more of an issue. Ratcheting up the care with which mundane accounting tasks have to be handled is inconsistent with the more time-pressured and frenetic pace of practice today. Therefore, what is needed is a way of recording care provided more efficiently—meaning, generating records that are more accurate, precise, reliable and unassailable while consuming less of the provider's time in doing so.

PDAs offer the potential of accomplishing this win-win objective. With a well-designed POC system, when the physician turns his or her attention to the patient, this is signaled by picking up the PDA and accessing the patient's file. The doctor's arrival at the bedside can be documented by scanning a bar code at the foot of the bed. All of the information called up while that file is open—

56. Dr. Rubinstein points out that in today's work – and perhaps into the future as well – the physician might approach this situation by giving the patient a free sample of the cheaper drug (#1). The impact of giving "free samples," a relatively common practice in today's pharmaceutical marketplace, is hard to assess, since these transactions bypass the normal channels for tracking use of prescription drugs. *See supra* note 51.

57. *See generally* United States v. Krizek, 859 F. Supp. 5, 8-9 (D.C. Cir. 1994), rev'd 111 F.3d 934 (D.C. Cir. 1997) (demonstrating the use and perils of "upcoding").

lab and X-ray reports, nursing records of the patient's progress and reaction to medications, recording of vital signs, et cetera—helps to document that the physician was working with and thinking about that patient during that time period. Any treatment or diagnostic orders entered by the physician using the PDA also helps to accurately document the physician-patient interaction. When the physician logs out, or calls up the records of another patient, or when a pre-set amount of time elapses without any activity on the PDA, that signals and records the end of that treatment encounter. No longer should there be difficult factual questions concerning whether, for example, the physician's visit with the patient is properly classified as long, short or intermediate. The PDA will know and will record this information automatically in a system that routinely tracks this kind of information. It also can be programmed to bill the third-party payer for the physician's service in the way authorized by the relevant reimbursement protocols, eliminating much of the cumbersome paper burden that currently bogs down clinical practice and makes it tedious.

F. How Will E-prescribing Change Doctor-Patient Relationships?

It was speculated above that Clinical Decision Support Systems, despite their potential for improving the quality of patient care, might have the ironic side-effect of lowering physicians' stature in their patients' eyes. The relational aspects discussed under the CDSS section are somewhat the same here, but would seem to be less problematic. While the physician's PDA might prompt him or her in the same way as a CDSS does, it would probably not be as likely to seem controlling; that is, it would be seen more as a tool in the doctor's hands than an electronic "partner" sharing decision-making power with her or him.

As discussed above, the physician's interaction with the formulary will be streamlined in ways that can yield both convenience and cost-saving benefits to the patient. When the electronic tool visibly and palpably yields benefits for the patient as well as the physician, patients can be expected to support its use. The pharmaceutical and handheld device industries will likely be supportive too, because of the market implications of this development; however, as discussed below, the nature and extent of their support may be constrained by legal considerations.

G. Practical and Legal Considerations

The move to e-prescribing will take time and will pose some tough challenges. Perhaps more than other practice innovations, e-prescribing may prove an extreme case because it has so many different elements. First, it represents a change in a system that has been firmly entrenched for a very long time. For generations, physicians have been handwriting paper prescriptions and giving them to patients to have them filled in a “drug store” marketplace of the patient’s choice. A change to e-prescribing requires not just a shift in the physician’s own practices, such as, swapping a pad for a PDA; it also entails tying the physician in with a large and complex system that involves health plans, pharmacy chains and often PBMs, as well as the vendors and others who work directly with the e-Rx systems. The change involves new hardware, the handheld device, the cost of which is not insignificant; but, beyond that, the individual doctor’s PDA has to connect with an intricate data bank and information system. The cost of refining that system to enable it to link with the handheld devices will be substantial and will be reflected in the end-user price of the e-Rx service. The cost of that service will be large enough that physicians will be hesitant to pay for it themselves,⁵⁸ especially since, as will be discussed below, it will likely be unclear at the outset which e-Rx system(s) ultimately will prevail.⁵⁹

Given our pluralistic economy, e-prescribing systems will undoubtedly be proprietary, with numerous competitors each jockeying for its niche in the marketplace. However, the overall effectiveness of all e-Rx systems will be greatly compromised if there is not a relatively free exchange of large amounts of data from one proprietary system to another. For example, if a patient gets one prescription from a physician affiliated with his MCO and has it filled at a CVS pharmacy, then sees another physician not affiliated with that MCO and gets a second prescription, which he has filled at a Rite-Aid store, the electronic system will fail—perhaps with disastrous consequences—unless the CVS and Rite-Aid systems “talk” to each other and share this information. If the two retail chains use different data-handling systems, those systems will have to be compatible and be able to “query” each other electronically while respecting the rights each participating system has in its own proprietary information.⁶⁰ Moreover, everything has to be handled in a way that assures

58. *But see* ISMP White Paper, *supra* note 42, at 12, which asserts that “it is probably safe to say that clinicians can obtain electronic prescribing capability at what may be a surprisingly low cost of entry.”

59. Recall the contest in the early days of VCRs between Sony’s Beta format and the VHS format, which latter eventually became the industry standard, turning Beta systems into useless white elephants!

60. Of course, to the extent that the patient’s drug purchases are handled through his or her MCO or a PBM, coordination will be much more likely, since mechanisms for information-sharing through those channels are already fairly well established.

patient confidentiality will be unfailingly maintained. This is no small order. Fortunately, we are not starting from scratch in this monumental undertaking; progress in the electronic storage and sharing of prescription drug information has been ongoing for well over a decade, and there is a substantial infrastructure of electronic and contractual networks to build upon.⁶¹ Still, there are a number of intertwined, knotty issues that will have to be surmounted before an effective, comprehensive e-prescribing system can be implemented. The following discussion highlights the major ones.

1. Technical issues with wireless handheld systems

The utility of e-prescribing will be greatly compromised if it has to be tied to desktop computers. Mobility is key to adoption and use by physicians, who do much of their ordering of tests and prescriptions at the patient's bedside while making rounds, or otherwise on the move. That is why the development of e-prescribing systems has focused on the use of handheld devices, or PDAs.⁶² Moreover, PDAs will be compromised if they have to be connected by wire to the data source. This dictates the use of wireless systems, connected by radio or infrared light to an institution-based (meaning, hospital, nursing home, et cetera) network. One problem that has surfaced in the early stages of development of these systems is the possibility of interference from other electronic devices in the hospital environment. This is a technical problem and presumably a detail that can be worked out.⁶³ It is mentioned here because such details are the inevitable bumps in the road toward a technologic future world. With rare exceptions, such problems get solved in time. The question is how much time . . . and at what cost? The pace of adoption of computer technology over the past few decades has been staggering. It is tempting to assume that pace will continue, but a flagging economy could slow it substantially.

61. Rosoff, *Changing Face of Pharmacy Benefits Management*, *supra* note 49, at 1.

62. See ISMP White Paper, *supra* note 42.

63. See, e.g., Don Witters, *Medical Devices and EMI: the FDA Perspective*, at <http://www.fda.gov/cdrh/emc/persp.html> (last visited Jan. 16, 2002); Jeffrey M. Gilfor, *Report on Electromagnetic Interference in Hospitals: Debunking an Urban Myth*, at <http://www.rnpalm.com/EMI.htm> (last visited Jan. 16, 2002); Jay Wrolstad, *Study: Cell Phones Interfere with Medical Devices*, at <http://wireless.newsfactor.com/perl/printer/6567.html/> (last visited Jan. 16, 2002); Bill Saltztein, *Where Have all the Cables Gone?*, at <http://www.codebluecommunications.com/Documents/Bluetooth%20Monaco%20article.pdf> (last visited Jan. 16, 2002); U.S. Food and Drug Administration, *Performance Plan (2002)*, at http://www.fda.gov/ope/fy02plan/part2_cdrh.html (last visited Jan. 16, 2002); *Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service*, at http://www.fcc.gov/Bureaus/Engineering_Technology/Notices/1999/fcc99182.txt (last visited Jan. 16, 2002).

2. Security of transmitted information

Another “technical detail” that goes to the very core of the feasibility of medical PDAs is the security of confidential patient data. Data security and confidentiality generally are issues that by their very magnitude exceed the scope of this paper. Fortunately, they are issues that have been covered in many other places and need not be visited in any substantial way here.⁶⁴ Suffice to say, it is assumed that some combination of advancing technology, marketplace creativity and government regulation will provide a satisfactory answer to the problem. If it does not, then most of what is projected in this Article may simply not come to pass. Data security is the *sine qua non* of the electronic age in healthcare.⁶⁵ Many companies that have staked their futures on supporting POC systems claim to have “secure solutions,” some of them using a proprietary intranet instead of the more accessible and, presumably, less secure Internet.⁶⁶ And, of course, the federal government has weighed in heavily with the Health Insurance Portability and Accountability Act (HIPAA) legislation,⁶⁷ which has seemingly generated an entire compliance industry.⁶⁸

3. Fraud and Abuse Implications

As noted above, the significant cost of the needed handheld devices is a possible impediment to the implementation of e-prescribing. Attempting to counter this cost obstacle to adoption, pharmaceutical distributors and retailers, especially large drug chains or PBMs, might provide PDAs to physicians with the vendor’s system software pre-loaded to ease the transition to e-prescribing.⁶⁹ The vendor might also provide instruction on how to use the supplied devices and technical support, such as a toll-free telephone “help desk,”—for those who wish to participate in its system.⁷⁰ Recruiting

64. See, e.g., COMM. ON QUALITY OF HEALTH CARE IN AMERICA, INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 171-74 (2001) [hereinafter CROSSING THE QUALITY CHASM].

65. See, e.g., *Cyberhealth – Hand-Held Rx Security*, HEALTH MGMT. TECH., Nov. 2000, at 8.

66. Richard R. Rogoski, *LIS Shake-out*, HEALTH MGMT. TECH., June 2001, at 14-16; *Doylestown Hospital to Participate in DrFirst.com’s Pilot Program for RcopiaSync, the Newest Enhancement to its Electronic Prescription Management System*, BUSINESS WIRE, Jan. 5, 2001.

67. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996), cited in 29 U.S.C. §§ 1001-1461 (1994), 42 U.S.C. §§ 201-299 (1994), 26 U.S.C. §§ 1-9806 (1994 & Supp. 1996) [hereinafter HIPAA].

68. *Sale of Prescription Information Subject of Lawsuit*, THE MED. INFO. TECH. L. REP., July 2001, at 5-6; *Privacy Turmoil Continues*, THE MED. INFO. TECH. L. REP., Mar. 2001, at 1-3.

69. ISMP White Paper, *supra* note 42, at 12.

70. The following twist on this approach raises an even higher legal risk. Since there will be competing networks, physicians might seek participation in two or more of them, perhaps getting multiple PDAs, but ultimately using one of them very little or not at all for e-prescribing. Obviously, companies supplying PDAs and other support would want to be sure they are getting

customers to use an e-prescribing network by offering goods and services might seem like simply good business—assuming, of course, that the cost of these things is justified by the long-term revenues to be expected from the network. However, there is a serious risk in this approach.⁷¹ The federal laws concerning “fraud and abuse” make it a felony to offer or give anything of value in return for referrals for goods or services paid for under federal healthcare programs, most notably Medicare and Medicaid.⁷² To the extent that physicians use PDAs and/or e-prescribing systems supplied or subsidized by sellers of pharmaceuticals to enter prescriptions for drugs paid for under federal programs, this is arguably a violation.⁷³ The severity of the sanctions possible under the fraud and abuse laws makes it critical that their application to this context be carefully considered.

4. The Need for a “Common Platform”

Another technical challenge that stands at the threshold of e-prescribing is the establishment of a “common platform”—or, at least, a system for ensuring compatibility of platforms—for the electronic devices used to link physicians with pharmacies, patient records and third-party payers. At the core of the purpose and power of POC systems is their ability to access data from many

their money’s worth for their investment. Thus, e-prescribing firms might naturally think of offering deals whereby “forgiveness” of the cost of the PDA would be based upon the volume of e-prescribing the physician did in a given timeframe. Any arrangement that ties the provision of goods or services to the volume of referrals is a “red flag” situation under the fraud and abuse laws.

71. See generally Linda Abdel-Malek, *Fraud and Abuse in ‘E-Health’ Arena*, 225 N.Y. L.J. S7 (2001).

72. 42 U.S.C. § 1320a-7b (1994 & Supp. V 2000). If the physician has a financial interest, even an indirect one, in the e-prescribing network, the Ethics in Patient Referrals Act, the so-called Stark laws, might also come into play. 42 U.S.C. § 1395nn (1994 & Supp. V 2000). Note that the same legal issues would be triggered by relationships at an organizational level – for example, a collaboration between an MCO and a PBM whereby the PBM supplied, or subsidized, PDAs, or other goods or services, to the MCO’s participating providers. Note further, that unless and until Medicare’s prescription drug benefits are expanded, only inpatient drugs are a potential problem in this regard (except for a few special cases, most notably the provision of immunosuppressive drugs for organ transplant recipients).

73. It has been held to be a violation of the statute if any part of the reason for offering something of value is to induce referrals under these programs. *United States v. Greber*, 760 F.2d 68, 72 (3rd Cir. 1985). *Greber* is generally regarded as the strictest interpretation of the fraud and abuse laws, with regard to the “inducement to refer” requirement. *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989). Other cases have held that the fraud and abuse law is not violated unless inducement of referrals was the “primary purpose” of the arrangement. *Id.* The Department of Health and Human Services, Office of the Inspector General (OIG) follows the stricter *Greber* standard. 42 C.F.R. § 1001.951(a)(2)(i) (2000). On the question of which is the appropriate standard, see Eugene E. Elder, *The Hypocrisy of the One Purpose Test in the Anti-Kickback Enforcement Law*, 11 BNA MEDICARE REP. 802 (2000).

different sources, subject it to common processing and analysis, and send it back out to the various authorized parties in the data network—all seamlessly and transparently. The use of multiple, incompatible systems is fundamentally inconsistent with this objective. Yet, in the early stages of the movement toward e-prescribing, the industry is struggling to achieve an adequate level of standardization or compatibility. Anything less would balkanize the field, and block attainment of its most desirable benefits.

Responding to this problem, three of the largest players in the pharmacy benefits management (PBM) field have formed a coalition organization called RxHub to work toward the establishment of compatibility standards and a common platform for e-prescribing.⁷⁴ The three companies—AdvancePCS, Express Scripts, and Merck-Medco—have together contributed twenty million dollars to fund the development of what they call an “electronic exchange” or “connectivity hub,” a portal through which physicians, PBMs, health plans and pharmacies can connect for information-sharing and e-prescription purposes.⁷⁵ In addition, RxHub will work with other organizations to establish universal electronic prescribing standards and a personal identification system to link members with a participating PBM and health plan. RxHub claims that its connectivity hub “will improve the functionality of electronic prescribing by eliminating certain communication barriers.”⁷⁶ Prior to the establishment of RxHub, dozens of different, potentially incompatible e-prescribing platforms were developed by PBMs in conjunction with various e-prescribing device (PDA) manufacturers, laying the foundation for an e-prescribing “Tower of Babel.” RxHub says

[its] ultimate goal is to create universal electronic prescribing standards analogous to the development of common claims transmission standards by the National Council for Prescription Drug Programs (NCPDP) which have enabled all retail pharmacy prescription claims to be transmitted in an identical format, regardless of the health plan or PBM receiving the information.⁷⁷

The three founding companies have issued an open invitation to other companies to join with them over time to help speed the development and spread the benefits of a common platform throughout the industry. Agreement on standards to assure compatibility is crucial to achieving universal information-sharing capability, which, in turn, is necessary to meet calls to move to electronic prescribing with all deliberate speed. Indeed, one

74. For more information about RxHub see <http://www.rxhub.net/about> (last visited Nov. 8, 2001).

75. *Id.*

76. Health Strategies Group, *RxHub May Expedite Electronic Prescribing: Some Hurdles Remain*, at http://www.healthstrats.com/products/news/010409_RxHub/eb_010409_RxHub.html (last visited Nov. 3, 2001).

77. *Id.*

organization, the Institute for Safe Medication Practices, has called for eliminating all handwritten prescriptions by 2003.⁷⁸

In addition to addressing the technologic and practical issues raised above, development of a common platform will speak to potential legal issues as well. Fraud and abuse concerns are lessened by the adoption of a common platform. If a given PBM provides a PDA or technical support for e-prescribing, it is less likely to be characterized as an attempt to induce referrals if the platform being supported can also be used to refer patients to other pharmaceutical suppliers. Antitrust concerns should be reduced as well, because the e-prescribing system would no longer serve to tie its users to a particular pharmaceutical supplier. With a common platform in place, the e-system becomes a facilitator of competition in the pharmaceuticals marketplace rather than a device to forestall competition.

5. Physicians' Adoption of the New Technology

Assuming that the technical and legal impediments to e-prescribing can be worked out, there remains the non-trivial problem of getting physicians to use the systems. At present, physicians' familiarity and comfort level with computers, e-mail and other electronic applications varies widely. It has been estimated that only about five percent of physicians e-prescribe.⁷⁹ Physicians are bright people and generally quick to learn, but they are also widely seen as creatures of habit who can be stubbornly resistant to innovations in their practice environment. This is particularly the case where the innovations are complex enough that their use requires substantial training. Because physicians are so busy and commonly must process a large number of "transactions" each day, adoption even of time- and labor-saving devices and procedures poses a problem in the short run if it takes a fair amount of "gear-up" time or effort. This problem is especially acute when change in the routine way of doing things poses an increased risk of error during the adaptation period. This last point could easily apply to e-prescribing—depending, of course, on how complicated these systems actually are to learn and to use.⁸⁰ Contrast, for example, two competing e-prescribing systems, one of which automatically flags potential drug interactions by checking for any other drugs the patient may be taking currently while the other requires the doctor to "query" the system for such information. Particularly for physicians who may have occasion to work with two or more different systems—as, for example,

78. CROSSING THE QUALITY CHASM, *supra* note 64, at 166; ISMP, White Paper, *supra* note 42.

79. MargaretAnn Cross, *Competitors Set to Launch Pharmacy Info Exchange*, INTERNET HEALTH CARE MAG., Apr. 2001, at 6.

80. The ISMP White Paper, *supra* note 42 (asserting that "[m]any prescribers can master the basics in half an hour, largely through point-and-click software.").

where a physician practices at a hospital and a nursing home—there is a danger of errors that could harm patients.

Given the heightened risk of errors during the transition phase, the challenge is to get the e-prescription system set up and running, and get the physician fully oriented to its use in the shortest possible time. In most cases, this will involve more than just supplying the device and an instruction manual. Some training exercises will be required and, for a time at least, technical staff support will have to be made readily available.⁸¹ If this is not done, adoption of the e-prescribing system may be slowed or stalled, or perhaps even blocked entirely, as might be the case if a physician has a bad experience with his or her early use of the system. The more difficult it is to master a new system—and the more new systems a physician has to master—the more likely it is that adoption will be a troubled and protracted process, with a higher likelihood of patient harm occurring along the way. Because of the difficulty of getting used to a number of different e-prescribing systems, and having to move back and forth among them if the doctor's patients belong to different plans, the development and adoption of a "common platform" becomes extremely important. Another variable that affects the rate of adoption of new technology is the type of organization in which the physician practices. Those who are affiliated with large group practices, IPAs, or IDSs are more likely to be accustomed to working within an information system infrastructure. They will also more commonly have technical staff available through their practice affiliation(s) to help them master new e-technology. Physicians in solo practice and small-group practices represent a much greater challenge.⁸²

IV. THE DIFFICULT PASSAGE TO THE NEW E-WORLD

Moving to the new e-world will not be easy. As intriguing as it is to envision a healthcare practice environment where things are different, getting from here to there will take time and will pose difficulties. The major difficulties foreseen are highlighted below.

A. *The High Cost of Getting There*

Any serious—as opposed to "pie in the sky"—discussion of the electronic era in healthcare has to address the massive costs of switching over to new technology and systems. Virtually all of the CDSS and e-prescribing systems being developed and promoted, as well as the underlying Electronic Medical Record (EMR) systems upon which they largely depend, are based on state-of-the-art web-based technology. The systems currently in place in many health

81. See, *The Fault Line of Physician Adoption*, INTERNET HEALTH CARE MAG., Jan.-Feb. 2001 at 38 [hereinafter *Fault Line of Physician Adoption*].

82. *Id.*

care institutions are so-called “legacy systems,” meaning, old-technology systems left over from previous generations of computer applications.⁸³ Designed for use by hospitals, other providers, and health plans for billing, claims-handling and other administrative purposes, they are not “web-enabled” and will not support many of the functions discussed here. To scrap the old systems and move whole organizations into the new ones is a massive undertaking, not just in terms of direct system costs, but also in terms of personnel retraining and decreased productivity during the transition period. The cliché sign “Temporary inconvenience . . . permanent improvement” hints at, but understates, perhaps grossly, the complexity and cost of bringing about the desired change.

Unlike some transitions, where things can be done piecemeal, the move to the kind of e-health innovations considered here is much more of an all-or-nothing affair. Given the importance of wide-scale information-sharing, there must be a very high level of systems compatibility for things to work properly. This is true with regard to a single organization—an academic medical center, say—but even more so when considering aspects of integration that span the entire healthcare system. Moreover, whether with regard to CDSSs, e-prescribing or EMRs, there is not a single, “anointed” system just sitting there waiting to be adopted. Rather, there are competing systems and approaches, some of which, presumably, will succeed and survive while others fail and disappear. When considering whether to invest millions of dollars in a new system and accompanying technology upgrade, healthcare organizations legitimately fear being a too-early adopter and heading off in the wrong direction. Recalling, perhaps, the Beta-VHS face-off in the VCR revolution of the 1980s, many now considering e-health systems are waiting for others to point the way. They will come along only after they are confident they know which way things will go. Recognizing the massive systems investments required to change the industry, the Institute of Medicine has called for “a renewed national commitment to building an information infrastructure . . .”⁸⁴ and has specifically recommended that Congress create a one billion dollar Health Care Quality Innovation Fund to help support this development.⁸⁵

As if the above cost problems were not enough, the current downturn in the economy, particularly in the tech and Internet sectors, has arguably slowed the progress. Several well-known companies have gone out of business, and

83. CROSSING THE QUALITY CHASM, *supra* note 64, at 167, 174 (citing EFRAIM TURBAN ET AL., INFORMATION TECHNOLOGY FOR MANAGEMENT: IMPROVING QUALITY AND PRODUCTIVITY (1996)).

84. CROSSING THE QUALITY CHASM, *supra* note 64, at 166.

85. *IOM Strikes Again: Second Report Calls for Transforming Failing Industry; Money Is Big Question*, MODERN HEALTHCARE, Mar. 5, 2001, at 4.

many others have been acquired or are up for acquisition.⁸⁶ Even such front-running companies as *drkoop.com* are feeling the pinch; its stock fell to a 52-week low of six cents a share on October 3, 2001.⁸⁷ While the decline of this market sector will slow progress in countless ways, it may also offer some benefits. The shakeout will inevitably bring consolidation, the strongest companies will survive, and the market that remains will have a smaller number of more widely adopted formats. Since one impediment to progress in this area is agreement on "common platforms," market factors that weed out the outliers may exert a useful, if painful, Darwinian evolutionary force on the entire field.

B. Physicians' Resistance to the Use of E-tools

Concerns about physicians' reluctance to adopt new tools and new ways of doing things are indeed significant, but may be overblown. Stories of physicians' behavior run both ways. They can be as curious as they can be set in their ways, as pragmatic as they can be rigid; much depends on their environment and the way they are approached to consider changes. Particularly with regard to computer usage, problems of slow adoption may fade rapidly as a new generation of physicians takes the stage. Younger physicians, having had the opportunity to hone their computer skills from grade school on, are comfortable with the equipment and bring an intuitive understanding to its use.⁸⁸

Increasingly, there are claims that physician reluctance is disappearing, particularly when savings in time, effort and money can be convincingly demonstrated.⁸⁹ Adoption numbers should go up exponentially because with increased use it is possible to document a positive return on investment. Emerging statistics confirm what some have assumed from the beginning while others have doubted, that is, that use of computer tools does increase the efficiency and productivity of the practice. Early anecdotal accounts pointed some potential users away, since the difficulties of getting new systems up and running efficiently, working out bugs and maintaining physician "buy-in" during the teething process have all been troubling matters.

86. Jim Hinton, Presbyterian Healthcare Services, *Business Outlook "From the Executive Desk,"* at <http://www.phs.org/aboutpres/outlook.htm> (last visited Jan. 16, 2002); Amy Tsao, *Can WebMD Heal Itself?*, BUSINESSWEEK, available at http://www.businessweek.com/bwdaily/dnflash/may2001/nf20010516_054.htm (last visited Jan. 16, 2002).

87. Fred Bazzoli, *Drkoop.com Changes its Business Plan Again*, INTERNET HEALTH CARE MAG., Jan./Feb. 2001, at 8. See also Yahoo! Finance, Profile – *drkoop.com, inc.*, at <http://biz.yahoo.com/p/k/koop.html> (last visited Jan. 8, 2002).

88. One source estimates that "10% to 15% of physicians are trying hand-held computers, with the number higher (perhaps 60% to 70%) among doctors in training who have come of age in a computer-oriented culture." ISMP White Paper, *supra* note 42.

89. Baldwin, *Bringing Docs Online*, *supra* note 9, at 33.

In a statement reminiscent of Dr. Homer Chin's about the use of CDSSs,⁹⁰ David Lacher, M.D., research medical officer of the National Center for Health Statistics in Hyattsville, Maryland says, "[i]f an application saves time, is easy to use, and reduces overhead, physicians will find ways to use it."⁹¹ It is possible to prove substantial time savings in the use of computers—as, for example, the amount of time saved by not having to pull charts to get information about patients before making a treatment order, writing a prescription, et cetera. But the irony, true in so many applications of computers, is that physicians are reluctant to use computer applications because of the time required to learn how to use them. The busier a person is, the more important the time savings possible through computer use, but also the more reluctance the person may have to using computers initially.⁹²

"Train up a child in the way he should go, and when he is old he will not depart from it," goes the old saying.⁹³ Recognizing the importance of getting physicians acclimated early to the new world of healthcare, some medical schools are making special efforts to incorporate PDAs and their applications into the curriculum. One example is Wake Forest University's Baptist Medical Center, in North Carolina, where medical students are required to use mobile handheld devices throughout their medical training.⁹⁴ Medical information technology companies are enthusiastic supporters of such training programs, at times providing equipment and technical assistance.⁹⁵ The benefits to academic institutions and their e-industry partners can be substantial, both in terms of reputation and credibility and more concrete aspects, such as joint research to develop products that will be more useful and acceptable to physicians.⁹⁶ Ultimately, though, it may be "demand-pull" from computer- and web-savvy patients, not the "supply-push" from technology developers and vendors that drives physicians to adopt the new technologies.⁹⁷

Finally, progress in the area under discussion is likely to be exponential. Once a solid foundation of EMRs is established, the expanded applications will start to flow. Things will come together: CDSSs, e-prescribing, disease management, et cetera, to name just a few. There are educational synergies and complementarities that will move things along as soon as some momentum is established.

90. See Chin, *supra* note 13, and accompanying text.

91. See Baldwin, *Bringing Docs Online*, *supra* note 9, at 34.

92. *Id.*

93. See *Proverbs* 22:6.

94. See *In the Wake of Wireless*, HEALTH MGMT. TECH., Nov. 2000, at 8.

95. *Id.* The systems used at Wake Forest, for example, are supplied by Aether Systems, Inc. of Owings Mills, Maryland. For information, see the Aether website, at <http://www.aethersystems.com> (last visited Jan. 8, 2002).

96. Baldwin, *Bringing Docs Online*, *supra* note 9, at 34.

97. See *Fault Line of Physician Adoption*, *supra* note 81.

C. *The Digital Divide*

No discussion of the changes the electronic revolution will bring to medical practice would be complete without reference to the “digital divide,” the modern-day equivalent of the age-old dichotomy between the “haves” and the “have-nots.” In today’s world, the have-nots are those who lack access to computers and the Internet, either because they do not have the needed equipment or lack the knowledge to use it. Often, discussions of the digital divide in healthcare are focused on the patients’ side, with reference to the fact that many members of the general public do not have access to e-mail, use of the Internet, and the ability to help maintain and access their electronic medical records. However, there are some positive views on this issue. The IOM reports that “[t]he share of households with Internet access grew from 26.2 percent in December 1998 to 41.5 percent in August 2000, an increase of 58 percent in 20 months.”⁹⁸ On the physician side, too, there is a significant digital divide, but that is, presumably, easier to rectify. When a physician comes to believe that her practice is being held back by lack of e-devices, she will respond by obtaining such devices and learning how to use them. Moreover, as noted above, there is evidence that physician use of computers is going up.⁹⁹

V. CONCLUSION

This Article has attempted to project how the future world of physician clinical practice will evolve and to provide some insight into what it will be like to be a doctor in the digital, or electronic age. That new practice environment is coming; and, despite jerks and false starts along the way, it will likely come sooner rather than later. It will be a world of connectivity, where the doctor does not function alone, but rather, in concert with a large and sophisticated network for information-gathering and analysis. The notion of a physician who relies solely on his or her own knowledge and judgment will have to be abandoned, and there may be some professional “sadness” about this. But a new notion, based on technical competence and the ability to do things far more important and impressive for patients, will replace it. All things considered, it will be a better world that all of us, providers and consumers of healthcare services alike, will ultimately welcome.

98. See, e.g., CROSSING THE QUALITY CHASM, *supra* note 64, at 166; U.S. Dept. of Commerce, *Falling Through the Net: Toward Digital Inclusion* (2000), at <http://www.ntia.doc.gov/ntiahome/fttn00/contents00.html> (last visited Jan 9, 2002).

99. See, e.g. Press Release, *AMA Survey Finds Upsurge in Physician Usage and Regard for Internet*, at <http://www.ama-assn.org/ama/pub/article/1616-4692.html> (last visited Nov. 12, 2001).