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TOO MANY ALERTS, TOO MUCH LIABILITY: SORTING THROUGH THE MALPRACTICE IMPLICATIONS OF DRUG-DRUG INTERACTION CLINICAL DECISION SUPPORT

M. SUSAN RIDGELY AND MICHAEL D. GREENBERG*

INTRODUCTION

Under provisions of the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"),¹ the federal government is undertaking a national campaign to bring health information technology to every hospital and health care practice in the country. As a part of that campaign, the federal government intends to accelerate the use of computer-based clinical decision support ("CDS") interventions to facilitate the practice of evidence-based medicine.² CDS systems, such as those that warn of drug-drug interactions or drug allergies, use patient-specific information to enhance clinical decision-making at the point of care.³ Medication use is one of the most common and fundamental targets for CDS applications, and medication-related CDS has been shown to improve

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1. The Health Information Technology for Economic and Clinical Health (HITECH) Act comprises Title XIII of Division A and Title IV of Division B of the American Recovery Act (ARRA) of 2009, Pub. L. No. 111-5, 123 Stat. 115, 226 (to be codified in scattered sections of 42 U.S.C.).

2. CONG. BUDGET OFFICE, EVIDENCE ON THE COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY 15 (2008), available at <http://www.cbo.gov/ftpdocs/91xx/doc9168/05-20-healthit.pdf>.

3. Eta S. Berner, *Ethical and Legal Issues in the Use of Health Information Technology to Improve Patient Safety*, 20 HEC Forum 243, 251 (2008).

safety, quality and efficiency.⁴ In order to promote quick adoption, the HITECH Act authorizes incentive payments for the “meaningful use” of certified electronic health record technology that includes CDS functionality.⁵ However, the robustness of this program will depend on the development of solutions to address existing barriers to the widespread adoption of CDS.

Despite the evidence of its potential effectiveness, adoption of CDS by health care organizations and professionals is limited. Wider adoption has been held back by a variety of significant socio-technical barriers, such as difficulty developing clinical practice guidelines that can be readily and unambiguously translated into a computable form, challenges in integrating decision support into the clinical workflow, the poor specificity of CDS alerts, and poor support for CDS in commercially available electronic health record (“EHR”) systems. In particular, a number of user organizations have complained that commercially developed knowledge bases that underpin CDS systems “generate excessive number[s] of alerts, many of which are clinically unhelpful.”⁶

In principle, physician adoption of CDS can be expected to improve medication safety. Because it helps prevent medical errors, effective CDS should inherently reduce liability. Unfortunately, not all implementations of CDS are good. CDS software that overwhelms physicians with large numbers of clinically insignificant drug-drug interaction alerts, thus causing them to “tune out” is inherently liability enhancing. “Alert fatigue” may lead physicians to ignore or turn off drug-drug interaction alerts, even though CDS software creates an audit trail to show that physicians have done so.⁷ These sorts of liability concerns could prevent this technology from achieving

4. ETA S. BERNER, AGENCY FOR HEALTHCARE RESEARCH & QUALITY (AHRQ), AHRQ PUBLICATION NO. 09-0069-EF, CLINICAL DECISION SUPPORT SYSTEMS: STATE OF THE ART 6 (2009).

5. HITECH Act § 4101, 123 Stat. at 467, 470 (amending 42 U.S.C. § 1395w-4). The HITECH Act specifies three main components of “meaningful use”: (1) the use of certified EHR in a meaningful manner; (2) the use of certified EHR technology for electronic exchange of health information; and (3) the use of certified EHR technology to submit clinical quality and other measures. *Id.*; CMS EHR Meaningful Use Overview, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp (last visited Feb. 12, 2012).

6. Gilad J. Kuperman et al., *Using Commercial Knowledge Bases for Clinical Decision Support: Opportunities, Hurdles and Recommendations*, 13 J. AM. MED. INFORMATICS ASS’N 369, 369 (2006) [hereinafter Kuperman et al., *Commercial Knowledge Bases*].

7. The audit trail in electronic systems is generally better at capturing data than in traditional paper systems. Arnold J. Rosoff, *On Being a Physician in the Electronic Age: Peering into the Mists at Point-&-Click Medicine*, 46 ST. LOUIS U. L.J. 111, 120 (2002); see also Michael Greenberg & M. Susan Ridgely, *Clinical Decision Support and Malpractice Risk*, 306 JAMA 90, 90 (2011).

full adoption and therefore its potential benefit—which is to make patients in United States health care institutions safer by reducing the risks of medication error.

The health IT (“HIT”) vendor market has not produced a solution to over-inclusive drug-drug interaction (“DDI”) warnings, or to the well-documented problem of physician alert fatigue. As a result, CDS currently runs the risk of contributing to increased provider liability, but without improving the safety of patients: a perverse result for all concerned. What is needed is an optimized DDI list, but vendors are unlikely to produce one, given their concern that excluding any potential drug interactions from the list (or allowing their clients to do so) exposes the vendor to additional liability risk.

The National Coordinator for Health Information Technology (“ONC”) is addressing this problem, and a wide range of barriers to the adoption and use of CDS, through the *Advancing Clinical Decision Support* project, with a particular focus on making CDS ready to function under the HITECH 2013 meaningful use requirements.⁸ *Advancing Clinical Decision Support* project leaders (RAND Corporation and Partners Health Care of Massachusetts) are tasked by the ONC with producing a consensus-driven, clinically significant DDI list that can be vetted for widespread adoption.⁹ Despite the fact that there is practically no case law on the subject, the risk of liability generates anxiety in the provider and vendor communities and concern in policy circles. Unless liability concerns are addressed, vendors may continue to resist implementing a less-than-all-inclusive DDI list within their CDS software, while physicians and institutions may be reluctant to adopt CDS software that neglects to reduce their own risk. Thus, part of the answer to CDS adoption problems involves untying the knot of liability issues surrounding the DDI list.

Our discussion addressing this critical public policy issue is organized as follows. In Part I, we briefly describe CDS and DDI lists—the potential benefits and risks posed by their use and outline the liability concerns driving the public debate.¹⁰ In Part II, we review the fundamentals of medical malpractice liability and product liability (as it concerns medical software) and discuss what legal theory and existing case law suggest about how courts might treat CDS, and in particular a clinically significant DDI list.¹¹ This material provides necessary context for Part III, in which we identify and assess the relative merits of five public policy strategies for establishing

8. *Advancing Clinical Decision Support*, RAND HEALTH, <http://www.rand.org/health/projects/clinical-decision-support.html> (last visited Jan. 22, 2012).

9. *Id.*

10. See *infra* pp. 260-264.

11. See *infra* pp. 264-278.

liability protection for providers who use a clinically significant DDI list and the vendors who develop applications that incorporate it.¹² In Part IV, we summarize and make recommendations.¹³

I. CLINICAL DECISION SUPPORT AND DDI

The Institute of Medicine's landmark report on patient safety, *To Err is Human*, estimated that medical errors may be responsible for as many as 98,000 deaths in the United States each year and may cost the healthcare system up to \$29 billion.¹⁴ A substantial number of these errors are medication errors.¹⁵ When prescribed inappropriately, medications can cause serious harm—including drug-drug interactions that can be lethal.¹⁶

Electronic prescribing systems include DDI alerts as a form of clinical decision support to warn prescribers of potentially harmful drug combinations to help them avoid or mitigate patient harm. A systematic review of the literature conducted by Dorr and colleagues in 2007 determined that several HIT components, including HER and CDS, were associated with improved care and positive patient outcomes.¹⁷ A recent review of the empirical literature identified ten studies that described how CDS affected adverse drug event ("ADE") rates.¹⁸ Of these ten studies, half reported that implementation of CDS significantly reduced the rate of ADEs, four reported a non-significant reduction, and one reported no change.¹⁹

12. See *infra* pp. 278-293.

13. See *infra* pp. 293-295.

14. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 1-2 (Linda T. Kohn et al. eds., 2000).

15. See generally David W. Bates et al., *Relationship Between Medication Errors and Adverse Drug Events*, 10 J. GEN. INTERNAL MED. 199 (1995) (discussing the prevalence of medical errors).

16. Gilad J. Kuperman et al., *Medication-related Clinical Decision Support in Computerized Order Entry Systems: A Review*, 14 J. AM. MED. INFORMATICS ASS'N 29, 29 (2007) [hereinafter Kuperman et al., *Computerized Order Entry Systems*].

17. See generally David Dorr et al., *Informatics Systems to Promote Improved Care for Chronic Illness: A Literature Review*, 14 J. AM. MED. INFORMATICS ASS'N 156 (2007) (revealing a positive impact of specific health information technology components on chronic illness care). It is important to note, however, that most of the CDS shown to be useful was "homegrown" by large institutions such as academic medical centers that invested significant resources in developing their own medication knowledge base rather than purchasing from commercial vendors. As noted by Kuperman and colleagues, the knowledge base vendor market at that time (2007) was "immature." See Kuperman et al., *Computerized Order Entry Systems*, *supra* note 16, at 38.

18. See Jesse I. Wolfstadt et al., *The Effect of Computerized Physician Order Entry with Clinical Decision Support on the Rates of Adverse Drug Events: A Systematic Review*, 23 J. GEN. INTERNAL MED. 451, 451 (2008).

19. *Id.*

RAND Corporation researchers addressed this question as well in a landmark modeling study estimating the potential impact of HIT systems on the United States healthcare system.²⁰ Hillestad and his colleagues projected that a 90% adoption level of HIT in the United States could prevent up to 200,000 ADEs, and accrue as much as \$81 billion in annual savings, over fifteen years.²¹ The same study indicated that the capacity of HIT systems to promote best practices, target preventative interventions, and improve chronic disease management could potentially double the amount saved.²² This is not to suggest that CDS can prevent all medication errors, but such systems hold the promise of reducing a substantial number of ADEs by introducing automation at the time of ordering and by supplying “speedy, available, and usable algorithms that provide parsimonious, clear, concise and actionable warnings and advice.”²³ CDS can aid health care professionals by “automating cognitive aspects of healthcare” in effect, “turn[ing] the blizzard of available input data—from highly structured claims data, lab reports, patient facts and pharmacy records—into information [they] can use to improve practices.”²⁴

CDS is not without limitations, however. In a 2007 review of the literature, Kuperman and colleagues noted that a high percentage of prescribing orders result in alerts being generated by CDS systems (11% in one study) and that clinicians continued with their order in 88% of cases.²⁵ In another study clinicians categorized only one in nine alerts as helpful when questioned at the time of the alert.²⁶ Other studies have also documented extremely high override rates (89%).²⁷ Reviewers caution that clinically significant drug-drug interaction alerts are “buried in a sea of unimportant messages.”²⁸ Information overload undermines the purpose of having automated alerts in the first place, which is to prevent adverse events and make patients safer.

One proposed solution is for hospitals and other provider organizations to customize knowledge bases supplied by vendors in order to improve the technology’s performance and acceptability. However, vendor-supplied

20. Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings and Costs*, 24 HEALTH AFF. 1103, 1104 (2005).

21. *Id.* at 1103, 1105, 1107, 1109.

22. *Id.* at 1114.

23. Kuperman et al., *Computerized Order Entry Systems*, *supra* note 16, at 29.

24. Jonathan K. Gable, *An Overview of the Legal Liabilities Facing Manufacturers of Medical Information Systems*, 5 QUINNIPIAC HEALTH L.J. 127, 135 (2001).

25. Kuperman et al., *Computerized Order Entry Systems*, *supra* note 16, at 33.

26. Jeffrey R. Spina et al., *Clinical Relevance of Automated Drug Alerts From the Perspective of Medical Providers*, 20 AM. J. MED. QUALITY 7, 11 (2005).

27. Kuperman et al., *Computerized Order Entry Systems*, *supra* note 16, at 33.

28. *Id.*

software is not typically designed with local modification in mind, and knowledge base suppliers discourage providers from making modifications.²⁹ The software itself often allows little flexibility for modification.³⁰ In addition, vendors often use contracts to shift liability risks to providers in connection with any modification of CDS systems through liability limitations, indemnity, and disclaimer of warranty provisions.³¹

Perhaps, then, the ideal policy goal is to encourage both providers and vendors to come together around optimized CDS systems that incorporate highly functional but non-comprehensive DDI lists. Both provider liability and vendor liability will need to be considered in any effort to make this optimal technology solution come about.

A. *Untying the Liability Knot*

The development of a clinically significant DDI list and its implementation in clinical decision support systems poses some difficult liability questions for health care providers. Does the use of CDS involve any incremental malpractice risk for the physicians who opt to use the technology? If so, what is the nature of that risk? How is the law likely to regard a clinically significant DDI list, and how would it comport with existing malpractice standards of care? Are liability risks to physicians potentially influenced by the role of CDS software manufacturers and commercial knowledge base vendors in designing the new technology, and perhaps in turn, by hospitals in purchasing, implementing and training physicians in the use of the technology? Should the federal government take a greater role in regulating CDS software as a medical device? Should Congress create a safe harbor to insulate providers from tort liability for relying upon a clinically significant DDI list?

The liability implications of developing a clinically significant DDI list are important, because the DDI list serves as a key element in helping to build better CDS technology. In turn, improvement in CDS technology should incentivize physicians and hospitals to adopt it more rapidly and more widely. Better CDS software that does not generate provider alert fatigue through over-abundant warnings should be easier to use, more effective in preventing adverse events, and more likely to reduce provider malpractice risk.

How is CDS technology relevant to physician malpractice risk? The answer depends partly on whether a DDI list is not overly inclusive, and yet is accurate for the majority of clinical situations. A good DDI list will not

29. See *id.*

30. See Kuperman et al., *Commercial Knowledge Bases*, *supra* note 6, at 369-70.

31. Elisabeth Belmont & Adele A. Waller, *The Role of Information Technology in Reducing Medical Errors*, 36 J. HEALTH L. 615, 620-21 (2003).

generate alert fatigue, and CDS will help physicians catch some medication errors that otherwise might go undetected. That is an inherently liability reducing result. Even so, one could still ask whether CDS technology might create some new incremental liability problems for providers, perhaps with regard to unalerted, low-likelihood forms of drug interaction.³²

A different situation is posed by CDS software built atop an overly-inclusive DDI list. Such software will give warnings for a much larger class of potentially adverse events, but far less effectively, because physicians will become rapidly desensitized to overly abundant warnings. Presumably, such CDS will increase physician liability risk, since automated warnings will be less helpful in reducing errors, even while the system creates an audit trail for ignored CDS warnings. It is easy to see why providers worry about the potential effect on malpractice. It is also easy to see that providers would have a disincentive to adopt new CDS technology in this case, and that patients also stand to benefit less from ineffective CDS—or even be harmed.

How can policymakers best encourage development and adoption of CDS systems? Is it by changing the law to directly protect providers against liability risk? Or instead by finding ways to ensure that CDS works well, that automated drug warnings are not over-inclusive, and that CDS software therefore will be liability reducing for providers? Our initial intuition is that there is no legal magic bullet for solving the provider liability problems connected with CDS adoption. Although we surely could write new legal protections against malpractice risk connected with CDS, it is not clear that such protections are likely to be necessary if CDS is well implemented, or helpful if it is not.

An important part of the real world problem around CDS is that vendors are also worried about liability risk. The vendors' lawyers are advising them that they could be at risk if missing drug interactions could later become the focus for liability claims.³³ As a result, vendors are creating CDS systems that generate massively over-inclusive automated warnings.³⁴ Vendors also try to protect themselves from risk via contracts with provider organizations

32. Superficially, the liability risk connected with CDS and exotic forms of drug interaction seems low. Keep in mind that adverse drug events (ADEs) that go undetected by a physician using CDS would presumably also go undetected by the same physician not using CDS. Incremental liability risk to the physician only occurs if the presence of the CDS system somehow changes the standard of care, or else captures evidence of negligence that otherwise wouldn't be available to plaintiff. Where a hypothetical DDI list has widespread acceptance and endorsement in the provider community, it is likely that the list itself would become an element of the standard of care and therefore, the failure of CDS to give warnings for interactions not included on a consensus based DDI list would be unlikely, in itself, to create new liability risk for the physician.

33. See Kuperman et al., *Commercial Knowledge Bases*, *supra* note 6, at 370.

34. Greenberg & Ridgely, *supra* note 7, at 90.

(e.g., hospitals) that do not allow the end-users to modify the severity levels of DDI warnings. Such limitations may help protect the vendors from risk for one category of potential tort claims, but the drawback is that it contributes to CDS systems that are not practical to use and not helpful to providers. From the physician's point of view, bad CDS systems may be worse than nothing because they could make it impossible for physicians to pay attention to all of the automated warnings, while simultaneously compiling evidence that those warnings were given and ignored. This scenario represents a "Catch-22" for health care providers and a deterrent to adoption of CDS technology.

II. WHEN SOMETHING GOES WRONG, WHO IS LIABLE?

Evidence from the literature suggests that development and deployment of a clinically significant DDI list within an effective CDS system should improve prescribing accuracy, reduce errors, and be less likely to generate alert fatigue.³⁵ If that is true, such a list should be liability reducing because one of the major drawbacks of current drug-drug interaction checking will be eliminated (or at least greatly reduced). We believe this position is supported by legal theory, if not by existing case law, as we will explain later in this section.³⁶

Below we briefly review the kinds of liability risk borne by the major stakeholders that must come to terms to solve this problem: the physicians and other medical providers; the hospitals and other healthcare organizations; and the CDS software manufacturers and medical knowledge base vendors.

A. Risk Borne By Physicians: Negligence

Typically, when patients suffer harm as the result of negligent³⁷ medical care, they are entitled to pursue compensation for medical malpractice through the tort system. State laws establish the fundamental basis for tort liability in medical malpractice and set out the rules for litigation.³⁸ In principle, the tort system has two objectives: to compensate for injuries to patients, when those injuries have resulted from substandard care or malfeasance on the part of medical providers, and to deter negligence.

35. Kuperman et al., *Computerized Order Entry Systems*, *supra* note 16, at 29.

36. See *infra* p. 269.

37. A negligent act is "one from which an ordinarily prudent person would foresee such an appreciable risk of harm to others as to cause him not to do the act, or to do it in a more careful manner." *BALLENTINE'S LAW DICTIONARY* 840 (3d ed. 1969). Physicians are liable for harm to patients even if unintentionally caused, if their conduct was unreasonable.

38. MICHELLE M. MELLO, *THE ROBERT WOOD JOHNSON FOUND., RESEARCH SYNTHESIS REPORT NO. 8, UNDERSTANDING MEDICAL MALPRACTICE: A PRIMER* 5 (2006).

When a physician is sued for the death or injury of a patient resulting from side effects of a drug the physician prescribed, courts apply rules related to medical malpractice.³⁹

Malpractice liability is premised on a professional standard of care, as defined by the experience and training of a hypothetical “prudent physician” and by the actions that physician would take if confronted by a particular clinical situation and set of circumstances.⁴⁰ In order to prevail in a medical malpractice action, the plaintiff must prove the following: (1) that the physician owed a duty of care to the patient; (2) that the duty was breached by the physician’s negligent act; (3) that the patient was harmed; and (4) that the negligence of the physician was the proximate cause of the harm to the patient.⁴¹

Contrary to popular belief, the vast majority of patients who experience a medical error do not sue⁴² and those plaintiffs who do sue prevail in only a relatively small percentage of cases (about 20%).⁴³ Also contrary to popular belief, empirical evidence suggests that the national volume of malpractice claims has declined in recent years.⁴⁴

Under the law, a physician is not required to provide superior care, but rather care that is typical of physicians in that particular locale (known as the community standard) or typical of the average physician across the nation (the rule in most jurisdictions).⁴⁵ The standard of care is established by

39. See Linda A. Sharp, Annotation, *Malpractice: Physician’s Liability for Injury or Death Resulting from Side Effects of Drugs Intentionally Administered to or Prescribed for Patient*, 47 A.L.R.5TH 433, 451 (1997).

40. PROSSER AND KEETON ON THE LAW OF TORTS 187 (W. Page Keeton et al. eds., 5th ed. 1984).

41. *Id.* at 164-65.

42. MELLO, *supra* note 38, at 7; see generally Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I*, 324 NEW ENG. J. MED. 370 (1991); Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II*, 324 NEW ENG. J. MED. 377 (1991).

43. NICHOLAS M. PACE ET AL., RAND INST. FOR CIVIL JUSTICE, CAPPING NON-ECONOMIC REWARDS IN MEDICAL MALPRACTICE TRIALS: CALIFORNIA JURY VERDICTS UNDER MICRA 51 (2004) (citing the California jury verdicts for medical malpractice cases).

44. HEALTH RES. & SERVS. ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., NATIONAL PRACTITIONER DATA BANK: 2004 ANNUAL REPORT 24 (2004); HEALTH RES. & SERVS. ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., NATIONAL PRACTITIONER DATA BANK: 2006 ANNUAL REPORT 26 (2006); AON INC., HOSPITAL PROFESSIONAL LIABILITY AND PHYSICIAN LIABILITY: 2006 BENCHMARK ANALYSIS 5 (2006).

45. Randolph A. Miller & Sarah M. Miller, *Legal and Regulatory Issues Related to the Use of Clinical Software in Health Care Delivery*, in CLINICAL DECISION SUPPORT: THE ROAD AHEAD 423, 424 (Robert W. Greenes ed., 2007). A minority of jurisdictions follow the *Helling v. Carey* rule which states that physicians may be found negligent even if following national

expert testimony, and evidence (such as relevant clinical practice guidelines developed by professional organizations) may be presented.⁴⁶

If particular clinical practices, including those involving the use of health information technology, became widely accepted as a benchmark of quality care, then those practices might also be integrated into the legal malpractice standard. For example, Hoffman and Podgurski have argued, “physicians who have more complete records, and better decision support and communication tools but who do not have the time or skill to assimilate the unprecedented amount of available data and to optimize their use of technology, may face medical malpractice claims that would never have emerged in the past.”⁴⁷ Eventually, a plausible end result could be to make physicians liable for malpractice for practicing at variance with changing standards of clinical care (i.e., in failing to make effective use of available health information technology tools), or at least to make those clinical standards available as evidence against physicians in malpractice lawsuits.⁴⁸ Moreover, hospitals and other healthcare organizations could also have liability risks, to the extent that such organizations employ physicians or neglect to appropriately fulfill their oversight functions (see discussion in next section).

In the case of CDS, physicians are using the medical software as a diagnostic and treatment aid, not as a substitute for their own medical judgment. Thus commentators have suggested that the courts would likely find a physician liable for harm that resulted from the use of CDS—even if there were a mistake in the medical knowledge database—if the physician failed to question bad advice given by the CDS software and provided improper care to the patient that caused harm.⁴⁹ Courts would assume that

custom if it is found that a “‘reasonably prudent’ physician would have followed another treatment that might have averted” the injury/harm. *Id.*

46. Daniel Jutras, *Clinical Practice Guidelines as Legal Norms*, 148 CANADIAN MED. ASS’N J. 905, 906-07 (1993).

47. Sharona Hoffman & Andy Podgurski, *E-Health Hazards: Provider Liability and Electronic Health Record Systems*, 24 BERKELEY TECH. L.J. 1523, 1528 (2009) [hereinafter Hoffman & Podgurski, *E-Health Hazards*].

48. On the other hand, use of clinical decision support could assist physicians in defending against malpractice claims if compliance with clinical practice guidelines is better documented through the use of CDS. See Sandeep S. Mangalmurti et al., *Medical Malpractice Liability in the Age of Electronic Health Records*, 363 NEW ENG. J. MED. 2060, 2063 (2010).

49. Miller & Miller, *supra* note 45, at 435. We previously described a “bad” CDS as one that is massively over-inclusive in the warnings it provides for DDI. Here, we are describing an even “worse” CDS: one that simply gives flat-out erroneous advice to the physician. Clearly, we could imagine hypothetical computerized physician order entry (CPOE) technologies that might do all sorts of defective things unrelated to DDI. Although physicians and vendors both might face liability risk in these situations, they represent a more extreme and more unlikely set

trained physicians would use their own judgment and rely on their professional knowledge, irrespective of whether any diagnostic and treatment aids (such as a DDI list) were used.⁵⁰ As stated by Miller and Miller, “this is consistent with the aims of CDS software: when functioning properly, it can help enhance diagnostic abilities and prevent misdiagnosis or other errors. However, decisions in treatment are ultimately left to the care provider, and the care provider should be considered responsible for these decisions.”⁵¹

It seems reasonable to assume that manufacturers of CDS software would enjoy liability protection similar to that provided under the “learned intermediary” doctrine regarding prescription drug and (implantable) medical devices.⁵² The latter allows manufacturers to discharge their duty of care to patients by providing warnings to the prescribing physicians.⁵³ The Fifth Circuit Court of Appeals stated the policy as follows: “prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment based on a knowledge of both patient and palliative.”⁵⁴

Does using CDS add additional potential liability for physicians? On the one hand, physicians are already held accountable by courts for exercising appropriate medical judgment, as defined by what a prudent physician would do under the same or similar circumstances. On the other hand, it has been suggested that, “evidence that a doctor ignored automated alerts or recommendations may serve as compelling proof of physician wrongdoing for plaintiffs who suffer poor outcomes because of a doctor’s treatment decision.”⁵⁵ We suspect that both points could be valid.

of problems from those that we are primarily concerned with, which involve liability risk that specifically attaches to DDI alerting.

50. As explained by Rosoff: “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.” Rosoff, *supra* note 7, at 120.

51. Miller & Miller, *supra* note 45, at 435.

52. See also Rosoff, *supra* note 7, at 120 (discussing the concept of “competent human intervention” referenced by the Food and Drug Administration with regard to medical software policy).

53. RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6(d) (1997).

54. *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974).

55. Hoffman & Podgurski, *E-Health Hazards*, *supra* note 47, at 1546.

Whatever the ambiguity surrounding the liability consequences of CDS use, what our analysis suggests is that reliance on CDS, or in particular on a drug-drug interaction list, will not provide a defense to an allegation of negligence. However, the availability of CDS may decrease the risk of error, which should in turn decrease the overall risk of liability. Nevertheless, even a remote possibility of additional liability associated with the use of new kinds of health information technologies might hinder adoption by the provider community. Given these sorts of legal concerns, some have suggested that federal policymakers should consider insulating providers from liability by establishing statutory protections (a so-called "safe harbor"). We discuss the pros and cons of establishing such a safe harbor later in this paper.⁵⁶

In principle, improving patient safety through use of health information technologies should reduce the volume of malpractice claims against physicians and institutions. But that principle is premised on the view that CDS will be effective and therefore liability reducing. CDS with over-inclusive warnings could be an entirely different story—especially where the noise-to-signal ratio is so high as to make it impossible for physicians to heed CDS automated warnings, but the system itself compiles compelling evidence that those warnings were given.

*B. Risk Born by Hospitals and Other Health Care Organizations:
Negligence*

The implementation of HIT applications such as CDS represents a major undertaking for hospitals and clinics, absorbing millions of dollars and hundreds of thousands of person-hours because of the complexity of the environments into which new software applications are embedded.⁵⁷ Any new software product has to be integrated into an existing IT infrastructure, which means some measure of local configuration. Problems resulting from systems integration are highly likely, even in situations where the CDS software functions exactly as promised.

Hospitals are not directly liable for the negligence of non-employee physicians, but the hospital may face lawsuits for corporate negligence.⁵⁸ Courts have found that hospitals owe four duties to their patients independent of the duties owed by a treating physician: (1) use of reasonable care in maintaining safe and adequate facilities and equipment; (2) to select and retain only competent physicians; (3) to oversee all persons who provide health care services within its walls; and (4) to formulate, adopt

56. See *infra* p. 285.

57. MEDPAC, REPORT TO THE CONGRESS: NEW APPROACHES IN MEDICARE, INFORMATION TECHNOLOGY IN HEALTH CARE 167, 170 (2004).

58. Hoffman & Podgurski, *E-Health Hazards*, *supra* note 47, at 1535.

and enforce adequate rules and policies to ensure quality care for the patients.⁵⁹ For a plaintiff to prevail on a theory of corporate negligence, the plaintiff would have to show, in part, that the hospital had actual or constructive knowledge of the flaws or procedures that caused the injury.⁶⁰ Hospitals and other health care organizations would do well to select an EHR system designed to minimize the risk of user error, and then proactively develop the ability to detect clinical software problems, analyze their impact, address the problems in a timely way, and ensure that the overall EHR system (including CDS) performs as it was designed to do.⁶¹ Another way to actively manage risk is to ensure that clinicians receive thorough and adequate training in how to use the system, as well as in hospital policy regarding use of CDS.⁶² These actions together will allow hospitals to anticipate and prevent avoidable hazards and put them in a better position to manage unavoidable ones. Commentators have also recommend that when deciding whether to install and how to monitor clinical software, hospitals and other healthcare organizations consider the clinical risks posed by software malfunction or misuse and the extent to which there is appropriate opportunity for qualified end users to recognize and easily override erroneous recommendations, among other considerations.⁶³

In addition, if the physicians, nurses, residents, interns, other health care workers are employees, the hospital could also be held liable for their negligence.⁶⁴ Based on case law regarding vicarious liability, Hoffman and Podgurski suggest that hospitals could share liability with physicians for injuries caused by faulty equipment or health care providers' inept use of HIT software:

In many instances, physicians are considered independent contractors rather than employees, and this status shields hospitals from liability for their acts. Nevertheless, courts have found that a hospital's imposition of workplace rules and regulations upon staff physicians is enough to undercut the doctors' independent contractor status and expose the hospital to liability. Therefore hospitals that establish EHR use protocols and policies may be responsible for clinicians' negligent operation of these systems.⁶⁵

59. *Thompson v. Nason Hosp.*, 591 A.2d 703, 707 (Pa. 1991); see also Hoffman & Podgurski, *supra* note 47, *E-Health Hazards*, at 1535.

60. Hoffman & Podgurski, *E-Health Hazards*, *supra* note 47, at 1535-36.

61. Miller and Miller recommend a kind of "IRB" model of local review boards to serve as guardians to see that institutional health IT processes are carried out properly. Miller & Miller, *supra* note 45, at 441. These local oversight boards for clinical software systems would work with administrators, vendors and end users. *Id.*

62. Mangalmurti et al., *supra* note 48, at 2065.

63. *Id.*; see also Miller & Miller, *supra* note 45, at 439.

64. Hoffman & Podgurski, *E-Health Hazards*, *supra* note 47, at 1536.

65. *Id.*

C. *Risks Borne by Software Vendors and Knowledge Base Providers:
Product Liability*

A major part of the real world problem regarding CDS-related liability risk is that the CDS and knowledge base vendors are also worried about it. The vendors' lawyers are advising them that they could be at risk if missing drug-drug interactions later become the focus for product liability claims. In response, vendors are creating CDS systems that are massively over-inclusive in the automated drug-drug warnings they give to providers.⁶⁶ Vendors also try to protect themselves from risk via contracts with providers that do not allow the providers to modify the severity levels of the warnings.⁶⁷ The drawback of this approach is that it creates CDS systems that are impractical to use and unhelpful to providers.⁶⁸

Under the doctrine of product liability (generally), "a plaintiff harmed by a seller or manufacturers' product could recover for injuries if they were caused by manufacturing, design or warning defects in the product, regardless of the care the seller or manufacturer used in manufacturing, designing and marketing the product."⁶⁹ However, in their analysis of product liability in the context of clinical software, Miller and Miller argue that such liability is most appropriate in situations in which the software is an integral part of a medical device—a device that can be thought of as a "product"—and provides little opportunity for human intervention (for example, closed software systems such as those employed in implantable pacemakers).⁷⁰ To this point, no court has applied product liability standards to computer software, and Miller and Miller argue that the use of CDS by physicians represents a distinguishable situation:

In contrast, when physicians use computer software as a diagnostic aid, strict liability is less apposite, as the physicians are using the software to enhance what is ultimately their own judgment and professional responsibility regarding diagnosis. Moreover, vendors of clinical software and its [end] users—hospitals and physicians—may face different liability

66. Greenberg & Ridgely, *supra* note 7, at 90.

67. Aaron S. Kesselheim et al., *Clinical Decision Support Systems Could Be Modified to Reduce 'Alert Fatigue' While Still Minimizing the Risk of Litigation*, 30 HEALTH AFF. 2310, 2311 (2011).

68. *Id.* While it could be the case that over-inclusive warning lists on CDS systems help to protect vendors from product liability claims, the opposite could also be true – a plaintiff might argue that massively over-inclusive warnings on a CDS system make those warnings useless for safety purposes, and hence represent a design defect in the product. In practice, it is not at all clear where the greater risk for vendors actually lies.

69. Miller & Miller, *supra* note 45, at 425.

70. *Id.* at 426-27.

standards based on their relative ability to prevent accidental injuries and the [social] desirability of distributing such costs.⁷¹

As noted above, the learned intermediary doctrine endorsed by the courts requires that pharmaceutical and medical device manufacturers provide “reasonable instructions or warnings regarding foreseeable risks of harm” to the trained professionals who prescribe their products, and then holds the physician liable for making individualized medical judgments for patients (as well as for providing effective warnings to their patients).⁷² Nevertheless, vendors are correct in believing that negligence lawsuits could involve multiple defendants, not only physicians but also the hospital or clinic and possibly the software providers. An argument for joint and several liability⁷³ might go like this: the harm would not have occurred without both the vendor’s and the physician’s negligence. For example, it could be argued that the erroneous advice provided by the CDS (which was the responsibility of the vendor) was harmful only because the physician failed to correct it. Or the argument could be that the physician may have recommended the erroneous course of treatment that harmed the patient only because the CDS software gave the physician clinically inappropriate advice.⁷⁴ However, plaintiffs could have an uphill battle in proving negligence against a software vendor or knowledge base supplier. Plaintiffs would have to provide evidence that the vendor failed to take sufficient precautions or diverged from their industry’s standard of practice,

Absent evidence of very poor programming practices or a vendor’s failure to test the software, plaintiffs may find it difficult to hold vendors responsible for their injuries. Moreover, if an institution’s technicians have made even seemingly trivial modifications to the equipment or the software, vendors may be able to avoid or mitigate liability on the grounds that the institution contributed to the negligence or that it constituted an intervening cause of the accident that should break the chain of liability.⁷⁵

Other commentators have argued that if a healthcare organization selected a software system that was widely recognized as inadequate, purchased the system and discovered that it was defective, or failed to maintain the system in good working order, the organization could be found liable for resulting injuries.⁷⁶

71. *Id.*

72. RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6(d) (1997).

73. Joint and several liability requires that the concurrent acts of two or more parties caused the harm to the individual. *BALLENTINE’S LAW DICTIONARY* 840 (3d ed. 1969).

74. *Miller & Miller, supra* note 45, at 435.

75. *Id.* at 428.

76. Hoffman & Podgurski, *E-Health Hazards, supra* note 47, at 1553.

A hospital could sue a vendor on a contractual theory (as opposed to tort) for breach of implied or express warranty for the software, but as mentioned previously, most medical software vendors disclaim warranties in their contracts⁷⁷ and insist on “hold harmless” (indemnification) clauses that protect the vendor from liability even when HIT users are strictly following vendor instructions.⁷⁸

D. To What Extent Are Drug-Drug Interactions the Subject of Litigation, and Are These Cases Making Law?

Having examined legal theory, we sought to understand how courts actually treat these issues in the context of medical malpractice or product liability lawsuits. To understand trends over time, we searched both jury verdict databases (which provide information from court decisions as well as settlements and arbitration agreements), and case law (appellate decisions).

Jury Verdicts

In order to understand the extent to which drug-drug interactions are currently the subject of malpractice litigation, we ran searches in two national jury verdict databases (JV-NAT⁷⁹ and VS-JV⁸⁰) available through Westlaw, an on-line legal research service. In JV-NAT, the search terms “medicine or medication or drug w/1 interaction” generated twenty-two “hits,” of which perhaps six to eight actually involved malpractice claims against physicians based on drug-drug interactions. A similar search of VS-JV netted four hits—none of which involved medical malpractice cases involving drug-drug interactions. By contrast, when we searched the same database using the string “medical malpractice” we received more than 10,000 hits.

77. Miller & Miller, *supra* note 45, at 428; see also Gable, *supra* note 24, at 141.

78. Ross Koppel & David Kreda, *Health Information Technology Vendors’ “Hold Harmless” Clause: Implications for Patients and Clinicians*, 301 JAMA 1276, 1276 (2009).

79. Jury Verdicts National (JV-NAT) database “contains verdict, judgment, settlement, arbitration and expert witness information compiled by” national and state jury verdict publishers. Scope JV-ALL, WESTLAW, http://web2.westlaw.com/scope/default.aspx?db=JV-ALL&RP=/scope/default.wl&RS=WLV12.01&VR=2.0&SV=Split&FN=_top&MT=208&MST= (last visited Feb. 25, 2012). Some of the records go back as far as 1982. Westlaw describes the database as follows: “summaries consist of information such as case type, geographical area where a case was tried, party names, attorneys’ names, expert witnesses’ names, factual information about the case, and verdict amounts. A document is a summary of a jury verdict, judgment, settlement or arbitration.” *Id.* At the time of this research, JV-NAT was still available through Westlaw, however it has since been combined with VS-JV into one database: JV-ALL. *Id.*

80. At the time of this research, VS-JV was still available through Westlaw, however it has since been combined with JV-NAT into one database: JV-ALL. *Id.*

We then searched all available federal and state jury verdict databases in Westlaw using a richer set of search terms (enumerated below).

Search - ("DECISION SUPPORT" "DECISION AID" "DECISION ANALYS*S" "CLINICAL DECISION SUPPORT" "clinical decision support system" CDS CDSS "CLINICAL REMINDER" "AUTOMATIC REMINDER" "REMINDER SYSTEM") & (((MEDICAL CLINICAL DOCTOR PHYSICIAN) /S (MISTAKE ERROR)) (ADVERSE /S DRUG & (EVENT REACTION)) (DRUG /S TOXI) (MEDICAL /P MALPRACTICE) ((LIABILITY "DUTY OF CARE") /P (PHYSICIAN SURGEON DOCTOR))) JV-PI,VS-JV,JV-11TH,JV-10TH,JV-9TH,JV-8TH,JV-7TH,JV-6TH,JV-5TH,JV-4TH (2 Docs) JV-3RD,JV-2ND,JV-1ST (0 Docs) FL-JV-PLUS,AL-JV-PLUS,AK-JV-PLUS,DC-JV-PLUS,DE-JV-PLUS,CT-JV-PLUS,CO-JV-PLUS,CA-JV-PLUS,AR-JV-PLUS,AZ-JV-PLUS (0 Docs) ME-JV-PLUS,LA-JV-PLUS,KY-JV-PLUS,KS-JV-PLUS,IA-JV-PLUS,IN-JV-PLUS,IL-JV-PLUS,ID-JV-PLUS,HI-JV-PLUS,GA-JV-PLUS (0 Docs) NH-JV-PLUS,NV-JV-PLUS,NE-JV-PLUS,MT-JV-PLUS,MO-JV-PLUS,MS-JV-PLUS,MN-JV-PLUS,MI-JV-PLUS,MA-JV-PLUS,MD-JV-PLUS (0 Docs) RI-JV-PLUS,PA-JV-PLUS,OR-JV-PLUS,OK-JV-PLUS,OH-JV-PLUS,ND-JV-PLUS,NC-JV-PLUS,NY-JV-PLUS,NM-JV-PLUS,NJ-JV-PLUS (0 Docs) WI-JV-PLUS,WV-JV-PLUS,WA-JV-PLUS,VA-JV-PLUS,VT-JV-PLUS,UT-JV-PLUS,TX-JV-PLUS,TN-JV-PLUS,SD-JV-PLUS,SC-JV-PLUS (0 Docs) WY-JV-PLUS (0 Docs)

Search - ((CLINICAL /3 GUIDELINE) "EVIDENCE BASED MEDICINE") & (((MEDICAL CLINICAL DOCTOR PHYSICIAN) /S (MISTAKE ERROR)) (ADVERSE /S DRUG & (EVENT REACTION)) (drug /s interaction) (DRUG /S TOXI) (MEDICAL /P MALPRACTICE) ((LIABILITY "DUTY OF CARE") /P (PHYSICIAN SURGEON DOCTOR))) JV-PI,VS-JV,JV-11TH,JV-10TH,JV-9TH,JV-8TH,JV-7TH,JV-6TH,JV-5TH,JV-4TH (2 Docs) JV-3RD,JV-2ND,JV-1ST (0 Docs) FL-JV-PLUS,AL-JV-PLUS,AK-JV-PLUS,DC-JV-PLUS,DE-JV-PLUS,CT-JV-PLUS,CO-JV-PLUS,CA-JV-PLUS,AR-JV-PLUS,AZ-JV-PLUS (1 Doc) ME-JV-PLUS,LA-JV-PLUS,KY-JV-PLUS,KS-JV-PLUS,IA-JV-PLUS,IN-JV-PLUS,IL-JV-PLUS,ID-JV-PLUS,HI-JV-PLUS,GA-JV-PLUS (1 Doc) NH-JV-PLUS,NV-JV-PLUS,NE-JV-PLUS,MT-JV-PLUS,MO-JV-PLUS,MS-JV-PLUS,MN-JV-PLUS,MI-JV-PLUS,MA-JV-PLUS,MD-JV-PLUS (1 Doc) RI-JV-PLUS,PA-JV-PLUS,OR-JV-PLUS,OK-JV-PLUS,OH-JV-PLUS,ND-JV-PLUS,NC-JV-PLUS,NY-JV-PLUS,NM-JV-PLUS,NJ-JV-PLUS (1 Doc) WI-JV-PLUS,WV-JV-PLUS,WA-JV-PLUS,VA-JV-PLUS,VT-JV-PLUS,UT-JV-PLUS,TX-JV-PLUS,TN-JV-PLUS,SD-JV-PLUS,SC-JV-PLUS (1 Doc) WY-JV-PLUS (0 Docs)

Search - ("DRUG ALERT" ((DRUG DRUG-DRUG FOOD-DRUG HERB-DRUG DRUG-ALLERGY) /S INTERACTION) DDI "DRUG-DOSE ALERT" "DRUG-DOSE SUPPORT") & (((MEDICAL CLINICAL DOCTOR PHYSICIAN) /S (MISTAKE ERROR)) (ADVERSE /S DRUG & (EVENT REACTION)) (DRUG /S TOXI) (MEDICAL /P MALPRACTICE) ((LIABILITY "DUTY OF CARE") /P (PHYSICIAN SURGEON DOCTOR))) JV-PI,VS-JV,JV-11TH,JV-10TH,JV-9TH,JV-8TH,JV-7TH,JV-6TH,JV-5TH,JV-4TH (25 Docs) JV-3RD,JV-2ND,JV-1ST (6 Docs) FL-JV-PLUS,AL-JV-PLUS,AK-JV-PLUS,DC-JV-PLUS,DE-JV-PLUS,CT-JV-PLUS,CO-JV-PLUS,CA-JV-PLUS,AR-JV-PLUS,AZ-JV-PLUS (16

Docs) ME-JV-PLUS,LA-JV-PLUS,KY-JV-PLUS,KS-JV-PLUS,IA-JV-PLUS,IN-JV-PLUS,IL-JV-PLUS,ID-JV-PLUS,HI-JV-PLUS,GA-JV-PLUS (23 Docs) NH-JV-PLUS,NV-JV-PLUS,NE-JV-PLUS,MT-JV-PLUS,MO-JV-PLUS,MS-JV-PLUS,MN-JV-PLUS,MI-JV-PLUS,MA-JV-PLUS,MD-JV-PLUS (15 Docs) RI-JV-PLUS,PA-JV-PLUS,OR-JV-PLUS,OK-JV-PLUS,OH-JV-PLUS,ND-JV-PLUS,NC-JV-PLUS,NY-JV-PLUS,NM-JV-PLUS,NJ-JV-PLUS (18 Docs) WI-JV-PLUS,WV-JV-PLUS,WA-JV-PLUS,VA-JV-PLUS,VT-JV-PLUS,UT-JV-PLUS,TX-JV-PLUS,TN-JV-PLUS,SD-JV-PLUS,SC-JV-PLUS (19 Docs) WY-JV-PLUS (1 Doc)

Search - ((computer! /s physician /s order) OR CPOE OR (electronic /5 record) OR "e-health record") & (((MEDICAL CLINICAL DOCTOR PHYSICIAN) /S (MISTAKE ERROR)) (ADVERSE /S DRUG & (EVENT REACTION)) (DRUG /S TOXI) (MEDICAL /P MALPRACTICE) ((LIABILITY "DUTY OF CARE") /P (PHYSICIAN SURGEON DOCTOR))) JV-PI,VS-JV,JV-11TH,JV-10TH,JV-9TH,JV-8TH,JV-7TH,JV-6TH,JV-5TH,JV-4TH (10 Docs) JV-3RD,JV-2ND,JV-1ST (0 Docs) FL-JV-PLUS,AL-JV-PLUS,AK-JV-PLUS,DC-JV-PLUS,DE-JV-PLUS,CT-JV-PLUS,CO-JV-PLUS,CA-JV-PLUS,AR-JV-PLUS,AZ-JV-PLUS (4 Docs) ME-JV-PLUS,LA-JV-PLUS,KY-JV-PLUS,KS-JV-PLUS,IA-JV-PLUS,IN-JV-PLUS,IL-JV-PLUS,ID-JV-PLUS,HI-JV-PLUS,GA-JV-PLUS (6 Docs) NH-JV-PLUS,NV-JV-PLUS,NE-JV-PLUS,MT-JV-PLUS,MO-JV-PLUS,MS-JV-PLUS,MN-JV-PLUS,MI-JV-PLUS,MA-JV-PLUS,MD-JV-PLUS (5 Docs) RI-JV-PLUS,PA-JV-PLUS,OR-JV-PLUS,OK-JV-PLUS,OH-JV-PLUS,ND-JV-PLUS,NC-JV-PLUS,NY-JV-PLUS,NM-JV-PLUS,NJ-JV-PLUS (5 Docs) WI-JV-PLUS,WV-JV-PLUS,WA-JV-PLUS,VA-JV-PLUS,VT-JV-PLUS,UT-JV-PLUS,TX-JV-PLUS,TN-JV-PLUS,SD-JV-PLUS,SC-JV-PLUS (5 Docs) WY-JV-PLUS (0 Docs)

We reviewed all of the hits and found no cases that involved drug-drug interactions. Only two cases uncovered in the search were somewhat relevant. In one, liability was based on the fact that a computerized testing system read a high result as an error, rather than a real result, and so did not report it to the physician.⁸¹ The plaintiff's condition went undiscovered and the plaintiff died.⁸² In the other case, there was an issue created by the inability to amend an electronic record, although the case was decided in favor of the doctor.⁸³

Cases in which drug-drug interactions figure in the assessment of liability comprise a very small part of all medical malpractice litigation. We have no idea how comprehensive any one of these jury verdict databases is in absolute terms. However, the fact that the proportion of DDI cases is so small across the databases (i.e., substantially less than one drug-drug interaction case for every 100 medical malpractice trial court cases and settlements) tells us that there will be even fewer at the appellate level, which

81. *Johnson v. Kromhout*, No. 86-19508, 1988 WL 509474 (Minn. Dist. Ct.).

82. *Id.*

83. *Adams v. Bahalla*, NC034293, 2005 WL 3729065 (Cal. Super. Ct. Dec. 9, 2005).

is where decisions establish legal precedent that affects the determination of future cases.

Appellate Decisions

To determine whether cases related to drug-drug interactions have made law (i.e., whether courts spoke to these specific issues within the context of malpractice or product liability law in appellate decisions), we searched the Westlaw ALLCASES database⁸⁴ using the following search terms:

Search - ("DECISION SUPPORT" "DECISION AID" "DECISION ANALYSIS" "CLINICAL DECISION SUPPORT" "clinical decision support system" CDS CDSS "CLINICAL REMINDER" "AUTOMATIC REMINDER" "REMINDER SYSTEM") & (((MEDICAL CLINICAL DOCTOR PHYSICIAN) /S (MISTAKE ERROR)) (ADVERSE /S DRUG & (EVENT REACTION)) (DRUG /S TOXI) (MEDICAL /P MALPRACTICE) ((LIABILITY "DUTY OF CARE") /P (PHYSICIAN SURGEON DOCTOR))) & SY,DI("313AK223" "198HV") (30 Docs)

Search - ((CLINICAL /3 GUIDELINE) "EVIDENCE BASED MEDICINE") & (((MEDICAL CLINICAL DOCTOR PHYSICIAN) /S (MISTAKE ERROR)) (ADVERSE /S DRUG & (EVENT REACTION)) (drug /s interaction) (DRUG /S TOXI) (MEDICAL /P MALPRACTICE) ((LIABILITY "DUTY OF CARE") /P (PHYSICIAN SURGEON DOCTOR))) (110 Docs)

Search - ("DRUG ALERT" ((DRUG DRUG-DRUG FOOD-DRUG HERB-DRUG DRUG-ALLERGY) /S INTERACTION) DDI "DRUG-DOSE ALERT" "DRUG-DOSE SUPPORT") & (((MEDICAL CLINICAL DOCTOR PHYSICIAN) /S (MISTAKE ERROR)) (ADVERSE /S DRUG & (EVENT REACTION)) (DRUG /S TOXI) (MEDICAL /P MALPRACTICE) ((LIABILITY "DUTY OF CARE") /P (PHYSICIAN SURGEON DOCTOR))) & SY,DI("198HV") (51 Docs)

Search - ("DRUG ALERT" ((DRUG DRUG-DRUG FOOD-DRUG HERB-DRUG DRUG-ALLERGY) /S INTERACTION) DDI "DRUG-DOSE ALERT" "DRUG-DOSE SUPPORT") & (((MEDICAL CLINICAL DOCTOR PHYSICIAN) /S (MISTAKE ERROR)) (ADVERSE /S DRUG & (EVENT REACTION)) (DRUG /S TOXI) (MEDICAL /P MALPRACTICE) ((LIABILITY "DUTY OF CARE") /P (PHYSICIAN SURGEON DOCTOR))) & SY,DI("313Ak223") (77 Docs)

84. The Westlaw ALLCASES "database contains documents from the U.S. Supreme Court, courts of appeals, former circuit courts, district courts, bankruptcy courts, former Court of Claims, Court of Federal Claims, Tax Court, related federal and territorial courts, military courts, the state courts of all 50 states and the local courts of the District of Columbia," with coverage beginning in 1658. Scope ALLCASES, WESTLAW, http://web2.westlaw.com/scope/default.aspx?db=ALLCASES&RP=/scope/default.wl&RS=WLV12.01&VR=2.0&SV=Split&FN=_top&MT=208&MST= (last visited Feb. 25, 2012). Westlaw notes that "[a] document is a decision or order decided by one of these courts." *Id.*

Search - ((computer! /s physician /s order) OR CPOE OR (electronic /s record) OR "e-health record") & (((MEDICAL CLINICAL DOCTOR PHYSICIAN) /S (MISTAKE ERROR)) (ADVERSE /S DRUG & (EVENT REACTION)) (DRUG /S TOX!) (MEDICAL /P MALPRACTICE) ((LIABILITY "DUTY OF CARE") /P (PHYSICIAN SURGEON DOCTOR))) & SY,DI("313AK223" OR "198HV") (23 Docs)

These search terms identified only a single case where the court mentions in the statement of facts that the nurses and nurse practitioners involved in the patient's care knew of the existence of Centers for Disease Control and Prevention ("CDC") clinical guidelines related to the diagnosis and treatment of the condition at issue (lactic acidosis), that the guidelines warned of a potentially fatal side effect of the antiretroviral treatment, and that the guidelines were available in binders in all nursing stations in the federally-funded clinic at which they practiced.⁸⁵ The court found the clinic and its employees liable for failure to diagnose and treat lactic acidosis in a timely manner and awarded damages.⁸⁶ In testimony, the nurses stated that they did not know if they had referred to the clinical guidelines, but the court does not discuss how that affected the court's decision on liability, if at all.⁸⁷

We also searched for citations within relevant scholarly articles in Lexis-Nexis Academic Universe and Social Science Research Network ("SSRN") databases, using the search terms "decision support," "clinical guidelines" and "drug (or drug-drug) interaction" along with "medical malpractice" and/or "liability." We discarded many articles because they dealt with legal obligations for pharmacies and pharmacists (topics outside of the scope of this article) and concentrated on articles focused on e-health and the law – including those that considered liability aspects of electronic medical records, computerized physician order entry and clinical decision support. We reviewed approximately twenty-five articles and culled from them the very few cases that were cited in support of various legal theories.

We found only six pertinent cases cited in this literature, two of which broadly concerned physician liability for adverse drug events that might have been prevented had available warning information been accessed.⁸⁸ In these cases, a physician was found to have failed to meet the standard of care by not considering warnings in the Physician Desk Reference (suggesting that it is even more likely that a physician would be found liable in similar circumstances if the warning had appeared on a computer screen

85. *Kasongo v. United States*, 523 F. Supp. 2d 759, 778, 780 (N.D. Ill. 2007).

86. *Id.* at 793, 812.

87. *Id.* at 780.

88. *Jones v. Bick*, 2004-0758, pp. 1, 13 (La. App. 4 Cir. 12/15/04); 891 So. 2d 737, 739, 744; *Fournet v. Roule-Graham*, 00-1653, pp. 1, 5-6 (La.App. 5 Cir. 3/14/01); 783 So. 2d 439, 440, 443.

in the course of prescribing).⁸⁹ The other two cases were not on point but were used by commentators to suggest that courts might also find hospitals negligent for furnishing defective software, for inadequate testing and maintenance of equipment, or for inadequate training for clinicians who were using CDS under hospital policy decisions.⁹⁰

Although these cases are not setting legal precedent on drug-drug interactions, it does not mean that cases involving adverse drug events are not affecting the practice of medicine. For example, there was a case in the mid-1980s, well known in medical circles as the “Libby Zion” case, in which there was an allegation of medical malpractice related to a drug-drug interaction that resulted in a death.⁹¹ The doctors were found negligent (while the hospital was exonerated) and the plaintiffs were awarded damages for wrongful death and pain and suffering.⁹² The decision of the trial court was not appealed (and therefore “Libby Zion” did not make law in the judicial sense) but the controversy stimulated by this case did lead to legislation in New York that in turn significantly influenced the training rules for interns and residents in hospitals across the nation, resulting in a limit on hours worked per week, a higher resident-to-patient ratio, and closer supervision of trainees, especially in busy and often chaotic emergency rooms.⁹³ Even without legislation, cases such as *Zion v. New York Hospital* can have a dramatic influence on practice as a cautionary tale.

It is worth remembering that despite the interest in the legal literature and predictions about how HIT might affect liability over time, medical malpractice decisions that turn specifically on DDI are rare, and DDI itself has not been an issue that finders of fact (judges and juries) have focused

89. *Jones*, 2004-0758 at p. 16; 891 So. 2d at 746; *Fournet*, 00-1653 at pp. 5-6; 783 So. 2d at 443.

90. *Lamb v. Candler Gen. Hosp., Inc.*, 413 S.E.2d 720, 721-22 (Ga. 1992) (holding the hospital liable in ordinary negligence for furnishing defective equipment); *Berg v. United States*, 806 F.2d 978, 983 (10th Cir. 1986) (upholding the verdict for plaintiff whose injuries were caused in part by lack of adequate testing and maintenance of equipment and lack of adequate training of technicians).

91. David A. Asch & Ruth M. Parker, *The Libby Zion Case: One Step Forward or Two Steps Backward?*, 318 NEW ENG. J. MED. 771, 771, 773 (1988). Unfortunately, there are no published trial court opinions on this case. There were appeals during pre-trial proceedings that did produce written opinions, but those opinions had nothing to do with DDI, and were only peripherally relevant to the subsequent trial court case. The disputes that went up to the appeals court had to do with the admissibility of evidence concerning a hospital's own quality improvement activities. *Zion v. N.Y. Hosp.*, 183 A.D.2d 386, 389 (1992).

92. Jennifer F. Whetsell, *Changing the Law, Changing the Culture: Rethinking the “Sleepy Resident” Problem*, 12 ANNALS HEALTH L. 23, 35 (2003); Craig Horowitz, *The Doctor Is Out*, NEW YORK, Nov. 2003, at 35, 38.

93. Asch & Parker, *supra* note 91, at 773.

on when deciding whether medical negligence has occurred in particular cases.

III. FIVE STRATEGIES TO ADDRESS LIABILITY CONCERNS

Prior case law related to medical malpractice outlines the liability that health care providers face when harm results from a lack of care exercised in diagnosing and treating patients. Research evidence suggests that CDS may reduce medical error by automating much of the function of prescribing and therefore has the potential to reduce error and liability risk.⁹⁴ However, real world practice, backed by empirical evidence, also suggests that CDS programs that overwhelm physicians with clinically insignificant alerts cause physicians to “tune out” and miss or override potentially important alerts.⁹⁵ Tuning out in this manner is inherently liability enhancing, and the CDS program provides a clear evidence trail.

The solution proposed by the ONC and the members of the *Advancing Clinical Decision Support* project team is development and endorsement of a clinically significant DDI list that vendors can embed in their CDS systems.⁹⁶ Access to this product would be provided free of charge. The hurdle is to get vendors and healthcare organizations to adopt the clinically significant DDI list in lieu of the overly inclusive DDI lists developed by commercial knowledge base vendors or those homegrown at various institutions.

In consultation with the *Advancing Clinical Decision Support* team, we focused on five possible strategies to address CDS-related liability concerns. Again, the ultimate policy aim is to encourage better CDS technology and stronger adoption of the technology by health care providers. One avenue for doing that is directly through legal reform. Another is to promote CDS systems that draw on a consensus based DDI list. The latter involves addressing vendor liability concerns as a precursor to improving the technology, and decreasing provider liability risk as a result. Some strategies focus primarily on provider liability, while others focus more on vendor liability. They represent a range of possible interventions to untie the liability knot that has so far inhibited adoption of CDS systems.

94. Kesselheim et al., *supra* note 67, at 2310, 2310 (2011).

95. *Id.* at 2311.

96. RAND HEALTH, *supra* note 8.

Strategy #1: Initiate a national “expert” process to endorse a clinically significant DDI list that is likely to carry weight in tort actions in state courts (i.e., likely to be admitted into evidence regarding the standard of care).

In their 2009 study of the implementation of computerized physician order entry (“CPOE”) in seven Western countries, Aarts and Koppel selected the Dutch, and to a lesser extent Australian, systems for comment because in those systems, “pharmacy departments have been major drivers of CPOE because of their roles as being legally co-responsible for patient care.”⁹⁷ They point to the importance of the Dutch national drug interaction alert database, which underlies all of that country’s CPOE decision-support systems.⁹⁸ This is in stark contrast to the situation in the United States and has implications for pushing forward the adoption of CPOE and CDS. As they view it:

The United States is the only country in this study where industry groups effectively lobby for health IT. Although this may spur health IT spending, it also encourages many differing and proprietary systems, few of which communicate with each other. Such fragmentation retards CPOE implementation. In the United States, there are more than 200 EMR vendors. Few other countries face similar challenges. Also, U.S. state or regional authorities often encourage health IT and CPOE use - especially since control of health care is not nationally centralized. This localized approach may lead to uneven development and contrasting platforms, which can be counterproductive for broader implementation of CPOE and health IT.⁹⁹

Based on their observations, Aarts and Koppel suggest:

National strategies would also help reduce the “noise” and wasted effort of competing vendors and lack of interoperability, both within institutions and across them—perhaps also increasing funding for more institutions via economies of scope and scale . . . Our data also suggest that having a national standard for prescribing medications and identifying harmful interactions might help CPOE adoption.¹⁰⁰

Their recommendation is to develop and implement national standards for decision-support reminders and alerts, they believe should come from professional associations.¹⁰¹ Using professional associations rather than the

97. Jos Aarts & Ross Koppel, *Implementation of Computerized Physician Order Entry in Seven Countries*, 28 HEALTH AFF. 404, 412 (2009).

98. *Id.*

99. *Id.*

100. *Id.*, *supra* note 97, at 412.

101. *Id.* at 412-13. In a commentary, Miller and colleagues also argue the need for a national standard for drug interaction information. See Randolph A. Miller et al., *Clinical*

government to develop and endorse a DDI list would achieve two goals: it would create a single standard for drug-drug interaction alerts, and at the same time, it would engage relevant expertise in the development of an “open source” standard that vendors can embed in proprietary products, if desired.

Among those professional groups that should be involved in such a consensus-oriented process are the American Medical Association (“AMA”), the American College of Physicians (“ACP”), the American Academy of Pediatrics (“AAP”), the American Academy of Family Physicians (“AAFP”), the American Society of Clinical Pharmacology and Therapeutics (“ASCPT”), the American Society of Health-System Pharmacists (“ASHP”) and the American Medical Informatics Association (“AMIA”). There are also specialty medical societies that may wish to be involved.

If the DDI list is good, and useful vendor and homegrown systems are built around it, then almost by definition, the technology should be liability-reducing and therefore attractive for physicians. Widespread adoption of the CDS technology with an open source DDI list that has been vetted and endorsed by a wide range of professional associations would likely shift the standard of care and would perhaps pull the DDI list into the definition of the legal standard of care. Given that the law in most states now recognizes a national (as opposed to local) standard of care,¹⁰² having a group of appropriate national professional societies involved in ratifying a national DDI list should have the effect of “moving the goal posts” even faster. Malpractice liability will continue to be judged based on negligence, and by comparison with professional standards of care, so moving the goal posts in terms of the standard of care seems like a reasonable strategy to employ.

Key to this effort is reaching consensus on a clinically significant DDI list. The experience of the *Advancing Clinical Decision Support* project has been that reaching consensus is not easily achieved. It is an open question whether a group of private organizations would be willing to take on such an effort without a partnership with the government (or at a minimum some source of ongoing funding) since it would require not only endorsing a clinically significant DDI list but also establishing a system for updating the list over time.

Decision Support and Electronic Prescribing Systems: A Time for Responsible Thought and Action, 12 J. AM. MED. INFORMATICS ASS'N 403, 406-07 (2005).

102. Michelle Huckaby Lewis et al., *The Locality Rule and the Physician's Dilemma*, 297 JAMA 2633, 2634 (2007).

Strategy #2: The Food and Drug Administration (“FDA”) could reverse its current policy and regulate medical software as a Class III medical device, thus possibly pre-empting tort actions at the state level.

A second avenue that might be considered is immunity from tort for medical device manufacturers, in connection with FDA-approved products. In 2008, the Supreme Court addressed this issue in *Riegel v. Medtronic*, concluding that state tort claims are expressly pre-empted by FDA authority and product review in connection with Class III medical devices (i.e., those which have gone through the full FDA review and pre-market approval process).¹⁰³

This ruling has several implications for our work. If subjected to a Class III FDA approval process, CDS software would become insulated from product liability tort claims. This outcome would likely eliminate the perverse incentives for building “bad” CDS systems (i.e., those with overly inclusive DDI lists) and for ignoring a federal DDI list in designing those systems. A robust DDI list is potentially a linchpin for implementing effective CDS systems, for facilitating FDA safety oversight, and for reducing vendor and physician liability risk, all at the same time.

Does the FDA have the legal authority to regulate CDS software programs as medical devices? The answer depends on whom you ask. Briefly, Congress framed a broad scheme for regulating food, drugs and medical devices under the Federal Food, Drug and Cosmetic Act of 1938 (“FDCA”).¹⁰⁴ In part, the original intent of the statute was to protect the public from fraud, in connection with a variety of product categories.¹⁰⁵ Congress brought medical devices under more stringent regulatory control with the 1976 Medical Device Amendments (“MDA”) to the FDCA. Under the amendments, a medical device is 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 . . .

103. 552 U.S. 312, 312 (2008).

104. Federal Food, Drug, and Cosmetic (FDCA) Act, 21 U.S.C. § 301 (2006 & Supp. 2010). The original section numbers of the FDCA do not appear in the United States Code, therefore parallel citations are given to the FDCA sections and the code sections. The FDA provides FDCA section numbers corresponding to the code provisions on its website. *Federal Food, Drug, and Cosmetic Act (FD&C Act)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm> (last visited Feb. 24, 2012).

105. Vincent Brannigan, *The Regulation of Medical Expert Computer Software as a “Device” Under the Food, Drug and Cosmetic Act*, 27 JURIMETRICS J. 370, 371 (1987).

(2) 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.¹⁰⁶

The amended FDCA also categorizes devices to indicate rising levels of regulatory burden.¹⁰⁷ Class I devices (for example, crutches) do not require pre-market approval and are subject only to manufacturing controls.¹⁰⁸ Class II devices (the bulk of medical devices) are cleared using the “Section 510(k)” process for “substantially equivalent devices.”¹⁰⁹ Section 510(k) requires more stringent performance testing but does not require pre-market approval.¹¹⁰ Class III devices are subject to the most stringent requirements—analogueous to a New Drug Application (“NDA”)—including full pre-market approval for higher risk products based on appropriate testing that proves the device performs its stated functions safely and effectively.¹¹¹ Class III devices include cardiac pacemakers and heart valves.¹¹² Needless to say, if the FDA determined that medical software was a Class III device, regulatory compliance costs for software vendors would be substantial.

In a recent analysis, Hoffman and Podgurski argue that FDA authority to regulate electronic health records systems is “much more dubious.”¹¹³ They point out that electronic medical records (and by corollary CDS systems), unlike the computer software that is an integral part of a medical apparatus that is implanted in a human (such as a pacemaker) or that delivers patient care (such as a respirator), “have no impact without human input and human intervention.”¹¹⁴ Therefore, from their point of view, electronic health records would be excluded from FDA regulation.¹¹⁵

Whatever the ambiguity about FDA authority to regulate electronic health record systems, the FDA has chosen not to do so, and courts have

106. FDCA § 201(h), 21 U.S.C. § 321(h) (2006).

107. FDCA § 513, 21 U.S.C. § 360c.

108. FDCA § 510(l), 21 U.S.C. § 360(l).

109. See FDCA § 510(o), 21 U.S.C. § 360(o). Section 510(k) of the Federal Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify the FDA of their intent to market a medical device at least 90 days in advance. FDCA § 510(n), 21 U.S.C. § 360(n). This is known as Pre-market Notification (PMN). This notification allows the FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. FDCA § 510(k), 21 U.S.C. § 360(k).

110. FDCA § 513, 21 U.S.C. § 360c.

111. Brannigan, *supra* note 107, at 372.

112. *Id.*

113. Sharona Hoffman & Andy Podgurski, *Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems*, 22 HARV. J.L. & TECH. 103, 134 (2008) [hereinafter Hoffman & Podgurski, *Finding a Cure*].

114. *Id.* at 135.

115. *Id.*

traditionally given deference to FDA decisions about its own jurisdiction.¹¹⁶ In the agency's 1989 guidance on such regulation (although it was never formally adopted), the agency stated that:

the FDA [has] declined to extend its regulatory authority to software that is 'intended for use only in traditional library functions, such as storage, retrieval, and dissemination of medical information'—functions traditionally carried out through textbooks or journals . . . Of particular significance is the draft policy's exemption of computer products, such as decision support systems, that involve 'competent human intervention before any impact on human health occurs.'¹¹⁷

Stated another way, computerized software that generates advice but operates in a manner that allows clinician-users to easily override the advice should be exempt from FDA regulation.¹¹⁸ As summarized by the FDA in the Federal Register in 1996:

in the 1989 draft . . . medical software devices (unclassified medical software devices that are not components, parts, or accessories to classified devices) would not be subject to active regulatory oversight if they 'are intended to involve competent human intervention before any impact on human health occurs (e.g., where clinical judgment and experience can be used to check and interpret a system's output).'¹¹⁹

However, at a public workshop in July 1996, the FDA suggested that they might revisit the issue of regulating software programs as medical devices.¹²⁰ The FDA observed that:

the increasing complexity and sophistication of current software devices makes it increasingly difficult to decide when healthcare practitioners can, in fact, comprehend the functions performed by the software sufficiently to know when significant errors have occurred.¹²¹

116. *Id.* at 371.

117. Hoffman & Podgurski, *Finding a Cure*, *supra* note 113, at 134-35; see U.S. FOOD & DRUG ADMIN., FDA POLICY FOR THE REGULATION OF COMPUTER PRODUCTS (DRAFT) (1989).

118. Miller & Miller, *supra* note 45, at 439.

119. Medical Devices; Medical Software Devices; Notice of Public Workshop, 61 Fed. Reg. 36,886, 36,886 (July 15, 1996).

120. *Id.* at 36,887. "The Food and Drug Administration (FDA) and the National Library of Medicine (NLM) are announcing a public workshop to discuss definitions of medical software devices, criteria for defining risk categories, software quality audits and pre-market notification, commercial distribution of software, and the options available for regulating medical software devices. FDA has noted some confusion among manufacturers regarding which requirements apply to medical software devices and accessories. This workshop will help to clarify the requirements, and provide FDA with information to better assess the risks to public health associated with different types of medical software devices." *Id.* at 36,886.

121. *Id.* at 36,887.

During the workshop, the FDA discussed the difficulty of determining with precision what “competent human intervention” means in the face of increasingly complex computer programs whose underlying algorithms may not have accounted for conditions (such as co-morbidities) that are important to a particular patient.¹²² Physician end-users may not be in a position to “adequately protect against potentially harmful software defects, since most clinicians will not be able to determine whether these sophisticated tools have formulated the correct approach in a particular instance.”¹²³

In response to the FDA’s concerns, a consortium of industry groups published recommendations “for public and private actions that were intended to accomplish responsible monitoring and regulation of clinical software programs,” and urged end-users, vendors, and regulatory agencies to adopt them.¹²⁴ The consortium supported FDA regulation only for categories of software deemed to be of high clinical risk with “the lack of opportunity for qualified users, such as licensed practitioners, to recognize and easily override clinically inappropriate recommendations.”¹²⁵

The FDA has not initiated regulatory action in this area, but the FDA’s Center for Devices and Radiological Health did create a Working Group in 2009 to examine whether regulation of electronic health records is required to prevent patient harm and risk to privacy.¹²⁶ According to one analysis, the role of systems such as CDS may prove to be key in the FDA’s determination:

The more the FDA finds that such systems function largely as electronic equivalents of traditional paper recordkeeping systems, the less likely it is that FDA will seek to regulate them actively. By contrast, to the extent that FDA finds such systems have *clinically directive functions that health care providers may come to rely upon in treating patients* the more likely it is that FDA will scrutinize EHRs closely and consider actively regulating them. One option the FDA will likely consider is whether to establish a tiered system of regulation based on the degree of sophistication of a particular EHR system,

122. Hoffman & Podgurski, *Finding a Cure*, *supra* note 113, at 135.

123. *Id.*

124. These recommendations are described in detail in Miller & Miller, *supra* note 45, at 439-442.

125. *Id.* at 439.

126. FDA Creates Working Group on Regulation of Electronic Health Record Systems, ROPES & GRAY, 1 (Apr. 2, 2009), http://www.ropesgray.com/files/Publication/23e027f0-d874-44db-9b1c-026fe32099c8/Presentation/PublicationAttachment/7619c9c8-7d24-4b50-b6d3-4cee91f3cb7e/RopesGray_Alert_FDARegulationOfElectronicHealthRecordsSystems.pdf [hereinafter ROPES & GRAY].

similar to the classification scheme the agency created in the late 1990s for software systems that store, transmit, or manipulate radiological images.¹²⁷

More recently, Jeffrey Shuren, Director of the Center for Devices and Radiological Health, testified before the Health Information Technology Policy Committee's Adoption/Certification Workgroup on February 25, 2010.¹²⁸ During that testimony, he asserted the FDA's authority over HIT software, described "serious safety concerns that have come to light" and discussed a "range of approaches" that the FDA might take to "play an important role in preventing and addressing HIT-related safety issues, thereby helping to foster confidence in these devices."¹²⁹ Among these approaches was the application of FDA's "traditional regulatory framework," including Class III pre-market approval for "high and medium risk HIT devices before they go into market use."¹³⁰

The most obvious objection to FDA regulation is that many vendors do not want their CDS systems to be reviewed by FDA at all, because obtaining FDA approval would be burdensome both in time and money. In fact, some industry members have argued that EHR systems do not meet the definition of a medical device and are therefore outside of FDA's statutory jurisdiction.¹³¹ Some legal commentators have also argued against FDA regulation, based on a concern that the traditional FDA framework is inadequate as applied to this sort of technology.¹³²

We suggest two responses to the vendors' perspective. First, if FDA review and approval were available to CDS vendors, it would potentially be

127. *Id.* (emphasis added).

128. *Health Information Technology (HIT) Policy Committee Adoption/Certification Workgroup* (testimony by Jeffrey Shuren, Dir. of FDA Ctr. for Devices and Radiological Health) (Feb. 25, 2010), available at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_910717_0_0_18/3Shuren_Testimony022510.pdf.

129. *Id.* at 2.

130. *Id.* at 3.

131. ROPES & GRAY, *supra* note 126, at 2. Not all EHR vendors are opposed to FDA regulation. According to a story in the Huffington Post, Cerner Corporation has voluntarily reported safety problems to the FDA and believes that all vendors should be required to do the same. Fred Shulte & Emma Schwartz, *FDA Considers Regulating Safety of Electronic Health Systems*, HUFFINGTON POST (Apr. 25, 2010, 6:12 AM), http://www.huffingtonpost.com/2010/02/23/fda-considers-regulating_n_474137.html (last updated May 25, 2011, 4:35 PM).

132. See, e.g., Hoffman & Podgurski, *Finding a Cure*, *supra* note 113, at 139. They argue, instead, that Congress should give jurisdiction to the Centers for Medicare and Medicaid Services (because CMS already has enforcement authority for the HIPAAA Security Rule) or create a new regulatory agency. *Id.* Note, however, that their paper was published prior to the adoption by Congress of the HITECH Act, which placed some regulatory authority for HIT in the hands of two agencies of the Department of Health and Human Services – CMS and the ONC. See, e.g., HITECH Act § 13301, 123 Stat. at 246 (to be codified at 42 U.S.C. § 300jj-31).

a complete bar to product liability tort risk in state courts, at least if these systems were deemed to require Class III pre-market approval. That would be a significant benefit to the vendors. As a strategy for mitigating liability risk, it seems better than the arguably foolish alternative of building CDS systems that are massively over-inclusive in the warnings that they give. In theory vendors can be sued if they take the latter course—and arguably they are creating new forms of tort risk for themselves when they do so. An FDA or inter-agency review approach might be presented to the vendors in a far more palatable way, simply by framing the positive liability implications more clearly.

Second, it may not matter whether or not vendors like the idea of FDA review. If the FDA decides that EHR and CDS systems are within their jurisdiction, and if it continues to receive reports of death and injuries through its voluntary notification system, the agency may decide to regulate the systems regardless of vendor arguments against doing so. Should the question of FDA jurisdiction be contested, Congress could explicitly provide jurisdiction. FDA or other federal agency review (see below) could serve as a stick, as well as a carrot, in driving the adoption of a clinically significant DDI list, assuming that federal policymakers want to compel vendors to move in that direction.

Strategy #3: ONC could work with the Centers for Medicare and Medicaid Services (“CMS”) to revisit the issue of endorsing a clinically significant DDI list in the HITECH meaningful use regulations.

The HITECH Act, signed into law on February 17, 2009 as a part of the American Recovery and Reinvestment Act (“ARRA”), amended the Public Health Service Act to codify the Office of the National Coordinator for Health Information Technology, required the national coordinator to establish a governance mechanism for a nationwide health information network, and required the national coordinator to establish a voluntary program to certify HIT.¹³³ Through HITECH, Congress also amended the Social Security Act to provide incentive payments to hospitals and physicians to promote adoption and use of certified HIT.¹³⁴ It has been argued that through HITECH Congress sought a financial incentive that would prove to be a catalyst with the potential to transform the healthcare system.¹³⁵

133. HITECH Act § 13101, 123 Stat. at 228, 230-32 (to be codified at 42 U.S.C. § 300jj-11).

134. HITECH Act § 4101(a), 123 Stat. at 467 (amending 42 U.S.C. § 1395w-4); HITECH Act § 4102(a), 123 Stat. at 477 (amending 42 U.S.C. § 1395ww).

135. Marilyn Lamar & Daniel Orenstein, *Medicare and Medicaid Incentives for Healthcare Providers to Adopt Electronic Health Records*, in HITECH ACT RESOURCE GUIDE, AHLA MEMBER

Title IV of ARRA provides significant financial incentives through the Medicare and Medicaid programs to encourage hospitals and doctors to adopt and use certified EHR.¹³⁶ It also reduces payments for those who are not meaningful EHR users, beginning in 2015.¹³⁷ As specified in the HITECH Act, meaningful users must meet each of three requirements:

1. Demonstrate to the satisfaction of the Secretary [of HHS] that they are using *certified* EHR technology in a meaningful manner;
2. Demonstrate that the certified technology is connected in a manner that provides for electronic exchange of information to improve the quality of health care, including care coordination; and
3. Use the certified EHR to submit information on clinical quality and other measures specified by the Secretary.¹³⁸

Congress gave the Secretary of HHS wide latitude with regard to regulating meaningful use.¹³⁹ The definition of meaningful use was not meant to be static. Congress specifically authorized HHS to require more stringent measures of meaningful use over time.¹⁴⁰ In fact, the statute includes a provision that actions may not be brought in court to challenge the Secretary's determination of what constitutes a meaningful EHR user or the methodology and standards of determining the incentive payment amounts.¹⁴¹

On July 28, 2010, CMS published the final rules that govern the meaningful use incentive program within Medicare and Medicaid for Stage 1 (implementation beginning in 2011).¹⁴² The rules were effective on September 27, 2010.¹⁴³ Among the Stage 1 objectives and measures were two that are relevant to this discussion. The Stage 1 final rules required CPOE for medication orders (30%) and also required drug-drug interaction and drug-allergy interaction checks as core measures.¹⁴⁴

BRIEFING: AN ANALYSIS OF THE HITECH ACT 56, available at <http://www.healthlawyers.org/Members/PracticeGroups/HIT/memberbriefings/Documents/HITECHActResourceGuide.pdf>.

136. HITECH Act § 4101(a), 123 Stat. at 467 (amending 42 U.S.C. § 1395w-4).

137. HITECH Act § 4101(b), 123 Stat. at 472 (amending 42 U.S.C. § 1395w-4).

138. Lamar & Orenstein, *supra* note 135, at 57.

139. HITECH Act § 4101(a) (codified at 42 U.S.C. § 1395w-4(o)(2)(4)(iii)).

140. HITECH Act § 4101(a), 123 Stat. at 468-470 (to be codified at 42 U.S.C. § 1395w-4(o)(2)).

141. HITECH Act § 4101(a), 123 Stat. at 471 (to be codified at 42 U.S.C. § 1395w-4(o)(3)(C)).

142. Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314, 44,326 (July 28, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, and 495).

143. *Id.* at 44,314.

144. *Id.* at 44,332-35.

The text of the final rules specifically addressed comments that the agency had received questioning the inclusion of drug-drug interaction alerts and drug-allergy alerts as core measures:

Comments: Several commenters expressed concern of “alert fatigue” occurring with drug-drug interaction checks. Alert fatigue or otherwise known as “pop-up” fatigue is a commonly perceived occurrence with electronic medical records and clinical decision support tools in which alerts are presented to the user when a potential safety issue is identified by the system (for example, drug to drug interaction). The alerts, while beneficial in some cases, can result in a type of “fatigue” whereby the provider, after receiving too many alerts, begins to ignore and/or override the alerts. Receiving too many alerts can result in slowing the provider down rendering the alert useless. Commenters recommended some changes to the objective and associated measure to mitigate the risk of “alert fatigue” such as limiting the checks for interactions to only the most critical medications or allowing for adjustment of risk levels rather than an on/off functionality.

Response: We recognize “alert fatigue” is a potential occurrence with drug-drug and drug-allergy checks. However, meaningful use seeks to utilize the capabilities of certified EHR technology and any means to address alert fatigue requires a critical evaluation of each alert. We believe this is beyond the scope of the definition of meaningful use. We believe these checks are valuable and improve patient care and therefore do not remove them to address alert fatigue.¹⁴⁵

The relevant question for this discussion is whether ONC could work with CMS to resurrect the issue of whether promoting a clinically significant DDI list is outside the scope of the meaningful use regulations. Work is underway on development of the proposal for Stage 2 meaningful use regulations.¹⁴⁶ For example, the Health Information Technology Policy Committee, the federal committee that advises HHS on HIT matters has recently released a Request for Comment on Meaningful Use Stage 2.¹⁴⁷ The Committee has proposed for the Stage 2 rules that providers “employ drug-drug interaction checking and drug allergy checking “on appropriate evidence-based interactions.”¹⁴⁸

Whether or not CMS endorses the use of a clinically significant DDI list in the next set of meaningful use regulations, some might interpret the Stage 1 requirements to have effectively given the federal government’s imprimatur

145. *Id.* at 44,335.

146. See, e.g., HIT POL’Y COMM., MEANINGFUL USE WORKGROUP REQUEST FOR COMMENTS REGARDING MEANINGFUL USE STAGE 2, at 1, 2, 4 (2011), available at http://healthit.hhs.gov/media/faca/MU_RFC%20_2011-01-12_final.pdf (describing what the committee has done thus far and what areas they seek public input).

147. *Id.* at 1.

148. *Id.* at 5.

on the use of CDS—such that a physician defendant in a malpractice action could argue that the use of CDS with a DDI list was required by federal law. In that way, it could be argued that the federal government, through the meaningful use regulations, is creating a new standard of care at least with regard to the Medicare and Medicaid programs.

Strategy #4: ONC could certify the clinically significant DDI list as the standard for drug-drug interaction lists within certified EHR.

The HITECH Act established a voluntary certification process for HIT products and directed the National Coordinator to support the development and routine updating of qualified EHR technology, and to make it available, unless the Secretary determines that provider needs and demands are being met by the marketplace.¹⁴⁹ This latter provision was designed to allow the federal government to develop EHR technology to address needs that were not being “substantially and adequately met through the marketplace.”¹⁵⁰

Section 3004 of the HITECH Act specified the process for adopting a set of standards, implementation specifications, and certification criteria.¹⁵¹ The program is voluntary—the HITECH Act does not mandate a set of national standards but it does effectively impose the standards developed on any person or entity that participates in federal healthcare programs (which is the vast majority of health care providers).¹⁵²

On July 28, 2010, the same day that CMS published the final rules on “meaningful use,” ONC published a companion final rule that describes the standards, specification, and certification criteria for electronic health records that qualify for the Medicare and Medicaid EHR Incentive Programs.¹⁵³ These rules were effective on August 27, 2010.¹⁵⁴ Asserting that confidence in HIT systems is critical to advancing adoption, ONC emphasized that the purpose of the Permanent Certification Program is to:

provide assurance to purchasers and other users that an EHR system, or other relevant technology, offers the necessary technological capability,

149. HITECH Act § 13101, 123 Stat. at 241 (to be codified at 42 U.S.C. § 300jj-17).

150. *Id.*

151. HITECH Act § 13101, 123 Stat. at 240 (to be codified at 42 U.S.C. § 300jj-14).

152. HITECH Act § 13101, 123 Stat. at 241 (to be codified at 42 U.S.C. § 300jj-16).

153. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 44,590 (July 28, 2010) (to be codified at 45 C.F.R. pt. 170).

154. *Id.*

functionality, and security to help them meet the meaningful use criteria established for a given phase.¹⁵⁵

The certification rules specify the performance capabilities of EHR and include a set of certification standards related to drug-drug, drug-allergy and drug-formulary checking.¹⁵⁶ According to the final rules, a certified EHR must include the following capabilities:

- (1) Notifications: automatically and electronically generate and indicate in real time notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE).
- (2) Adjustments: provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.¹⁵⁷

The certification standard does not specify what the DDI list should be, but the final rules did address the inclusion of a means for adjusting the severity level for which alerts are presented.¹⁵⁸ In explaining the change between the requirements in the proposed and final rules, the final rules state:

With respect to customization, we sought to provide users of Certified EHR Technology with a way to adjust the severity level for which alerts are presented. In response to public comment, and to clarify what we believe Certified EHR Technology must include as a condition of certification, we have removed the "alert statistics" part of the certification criterion altogether and revised the "customization" part of the certification criterion to more clearly specify this capability. Our revisions focus on Certified EHR Technology's capability to allow certain users (e.g., those with administrator rights) with the ability to adjust notifications provided for drug-drug and drug-allergy checks (e.g., set the level of severity).¹⁵⁹

The question pertinent to this article is whether the ONC has the authority to specify a consensus-driven, clinically significant DDI list as the standard DDI list for certified EHR. The HITECH Act appears to grant ONC broad authority to set standards and certification criteria, although endorsing a single DDI list appears to go beyond certifying functionalities and into certifying the content of a knowledge base that underlies an EHR function.

155. *Certification Programs*, U.S. DEP'T OF HEALTH & HUMAN SERVICES, http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_certification_program/2884 (last visited Feb. 25, 2012).

156. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. at 44,600.

157. *Id.*

158. *Id.* at 44601.

159. *Id.*

Strategy #5: Congress could create a statutory “safe harbor” for health care providers who adopt and use the approved DDI list.

A safe harbor is generally defined as a regulation that reduces or eliminates liability under the law for excusable violations, provided the person or organization acted in good faith.¹⁶⁰ The safe harbors with which most healthcare professionals are familiar are those promulgated by the Department of Health and Human Services (“HHS”) to protect healthcare organizations from anti-trust violations under the Criminal Penalties for Acts Involving Federal Health Care Programs (known as the Anti-Kickback Statute), enacted by Congress in 1972.¹⁶¹ The statute was meant to prevent fraud and abuse in federal healthcare programs by assessing criminal penalties against individuals and entities that willingly provided bribes or kickbacks in order to generate business that would be reimbursed by federal healthcare programs such as Medicare and Medicaid.¹⁶²

Congress recognized, however, that the broad language of the statute might result in prosecution of health care providers for “innocuous and even beneficial arrangements” that were also prohibited under a literal reading of the statute.¹⁶³ To address that possibility, fifteen years later, Congress enacted the Medicare and Medicaid Patient Protection Act which authorized HHS’ Office of the Inspector General to promulgate regulations that would provide exclusions for certain types of payment arrangements among health care providers.¹⁶⁴ These exclusions, embedded in the regulations, are commonly called safe harbors.¹⁶⁵ By promulgating the regulations, HHS created thirteen specific safe harbors. In 1996, Congress created yet more safe harbors related to permissible remuneration by amending the anti-kickback statute through passage of the Health Insurance Portability and Accountability Act (“HIPAA”).¹⁶⁶

160. While it is not clear in what context the concept of a “safe harbor” was first introduced, we found definitions of safe harbor in both the financial and real estate sectors, as well as in healthcare.

161. See Social Security Amendments of 1972, Pub. L. No. 92-603, § 242, 86 Stat. 1329, 1419-20 (codified as amended at 42 U.S.C. §§ 1395ii, 1396). Among its provisions, the statute requires that the party at issue, “knowingly and willingly” engage in the prohibited conduct. *Id.*

162. Douglas A. Blair, *The New Proposed Safe Harbors for Certain Managed Care Plans and Risk-Sharing Arrangements: A History, Analysis, and Comparison with Existing Safe Harbors and Federal Regulations*, 9 HEALTH MATRIX 37, 39 (1999).

163. *Id.*

164. 42 U.S.C. § 1320a-7d (2006).

165. Blair, *supra* note 162, at 39.

166. Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, § 216, 110 Stat. 1936, 2007 (codified at 42 U.S.C. § 1320a-7b).

Congress could authorize HHS to create a safe harbor to protect hospitals and health care providers who adopt and use a consensus-developed, clinically significant DDI list. In this case, Congress would not be protecting providers from prosecution under a statute that Congress itself had passed, but rather would be passing a statute that would result in protecting providers from liability under state tort law.

A majority in Congress would have to be persuaded that the liability risk associated with the use of a clinically significant DDI list is a sufficiently important risk to health care providers that Congress should act to override state law. One could anticipate that the state legislatures (and possibly the governors) would not support Congress usurping state authority over tort law within their borders. For example, the National Conference of State Legislatures has criticized federal attempts at tort reform as an unnecessary intrusion on state lawmaking.¹⁶⁷ But, it's unlikely that a federal regulator could eliminate tort liability under state law without a specific federal statute to that end.

The notion of a CDS liability safe harbor does not imply broad tort reform. We are not suggesting that malpractice liability be eliminated, nor are we suggesting that physicians should have a free pass whenever they are managing medications, or even when using CPOE systems. Rather, the intent would be to stipulate that where a physician has managed medications using CDS with a clinically significant DDI list, then the end user's choice not to receive a more inclusive set of DDI warnings cannot itself be used as a basis for medical malpractice liability, or as evidence of negligence on the part of the physician or hospital.¹⁶⁸

Hospitals and other healthcare organizations could also be included under the language of the safe harbor because hospitals will likely be the buyers of CPOE systems, and implementers of the DDI lists: thus insulating them from liability may be important to promoting CDS adoption. Furthermore, if policymakers really want to make the safe harbor sufficiently

167. *Deficit Reduction Talking Points*, NAT'L CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/state-federal-committees/taskforce/deficit-reductiontalking-points.aspx>.

168. It is important to distinguish a safe harbor from a no-fault compensation program. For example, the National Vaccine Injury Compensation Program was designed by Congress to protect vaccine manufacturers from product liability suits with the goal of improving vaccine availability in the United States. A no-fault compensation program—unlike a safe harbor—would substitute for the tort system by paying compensation to any one harmed, without requiring that the plaintiff prove causation. For a thorough discussion of the NVICP, see Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59 (1999). Such a program is a potentially more complex and expensive undertaking than is a safe harbor, and in our judgment not narrowly tailored to the problem we are trying to fix.

airtight to fully encourage use of a consensus-developed, clinically significant DDI list, protection for CDS vendors might be added as well (i.e., the safe harbor could stipulate that CDS software that allows users to modify the scope of DDI alerting is not inherently defective, and that product liability claims against vendors on that basis will not be allowed.) It would be fairly easy to write a safe-harbor provision that is tailored narrowly to protect physicians, hospitals and vendors as described above. Whether Congress would actually pass such a provision is another question.

Developing a safe harbor like the one described above invites the question “what is a good DDI list?” The answer would have to be specified in legislation or regulation, but probably reverts to: A DDI list is good if it is developed through formal expert-consensus process, endorsed by one or more medical professional societies, and certified or otherwise formally adopted by an appropriate government regulator, such as the ONC.

The most important unanswered question is whether a safe harbor in this instance would be good policy. As we have shown in this discussion, there is no compelling evidence—based on current case law and trial court decisions—that providers will be at any greater risk from using CDS with a clinically significant DDI list than exists currently. Where is the justification, then, for Congressional action that would serve to override state tort law?

IV. SUMMARY AND RECOMMENDATIONS

Medication-related clinical decision support can reduce or prevent medication errors. It is thus inherently liability reducing. However, as a result of vendor concerns about liability, current CDS systems generate overly inclusive drug-drug interaction warnings that overwhelm physicians with clinically insignificant alerts, thus reducing patient safety and increasing physician liability.

A key element in promoting adoption of CDS is to develop a clinically significant DDI list. As part of its mission, the ONC is supporting development of such a list that can be vetted for widespread adoption. But unless liability concerns are addressed, vendors may be reluctant to implement the list in their systems, and physicians and institutions will be reluctant to adopt a CDS system that they perceive as exposing them to liability.

A clinically significant DDI list, when implemented in CDS, will not increase liability for physicians, over the liability risk they already bear. Rather, the list would be potentially liability reducing – especially if it were endorsed or certified by a consensus of the professional medical community and by the relevant government agencies.

There is no legal magic bullet that will give full liability protection to physicians and healthcare organizations that adopt and use a clinically significant DDI list. To address this barrier, we offer five public policy

options that could help shield end users of CDS from liability. ONC's best option for promoting CDS will probably involve a combination of these, including development of a good, consensus based DDI list with widespread acceptance in the provider community; endorsement of the DDI list by appropriate professional organizations and government regulators; concomitant reductions in patient risk and provider liability by virtue of new CDS systems that use the DDI list; and protection of vendors against increased liability through government endorsement/certification of appropriate DDI and CDS, together with software contracts that include appropriate indemnification provisions.

Under several of the policy options that we have assessed, the federal government would be required to endorse or certify a consensus based DDI list as a critical initial step to promote wider acceptance of the list, to create momentum for provider adoption of the list, and to shelter providers (and perhaps vendors) from any incidental liability risks that might otherwise attach. One concern that might arise for ONC is whether endorsement or certification of a DDI list would create grounds for government liability, in the event that patients are injured when the list is subsequently used in CDS systems. Although we cannot offer legal advice or provide a formal legal opinion on this question, superficially at least the answer appears to be no. Under the doctrine of sovereign immunity, the United States government is generally immune to tort claims, except in instances where it has waived that immunity. Although the Federal Tort Claims Act waives government immunity in instances where federal employees are negligent within the scope of their employment, it seems unlikely that this waiver would apply to the issue of regulatory endorsement of a DDI list.

Assuming that a government regulator like ONC has the power to endorse or certify a DDI list, and assuming that the agency exercises that power non-negligently, then the potential for civil liability under the Federal Tort Claims Act is low. Clearly ONC will want to consult with its own counsel on this point, and perhaps investigate more deeply the contours of its own authority under existing law. We think that government liability risk is likely to be the least of the challenges that need to be overcome in pressing the development of a good DDI list via regulatory endorsement or certification.

We conclude with the observation that creating effective CDS with a consensus-driven, clinically relevant DDI list could have the additional advantage of moving the goal posts of medication management relative to the malpractice standard of care.¹⁶⁹ Legal standards for negligence are set by state courts and legislatures, but the federal government and the medical

169. Mangalmurti et al., *supra* note 48, at 2064.

profession could strongly influence the standard of care against which medical practice is judged. We suspect that the end result for the medical community would be positive, affirming medication practices that are already widely accepted, while facilitating robust decision support that helps to prevent errors and the malpractice claims that spring from them.

