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LEGAL ISSUES IN MEDICAL COMPUTER SOFTWARE AND
EXPERT SYSTEMS IN UNITED STATES LEGISLATION AND
PRACTICE

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Legislation and Practice*

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Abstract

Today, hospitals are heavily computerized, but this process is still far from its ultimate goals and suffers from many deficiencies. Good quality software, correctly used, can improve health care under many different circumstances, e.g. good administrative software can improve the efficiency of health care delivery and can speed up the flow of patient information; good clinical software can greatly improve health care, helping physicians in their work (for instance by assisting them in their decisions); good software embedded in medical devices can improve the quality of life of patients. In fact, every subject involved in the health care field is likely to be a user of very complex software, sometimes even without noticing it. However, the more complex the software, the more susceptible it may be to errors that may cause malfunctions.

Although many ethical, legal and technology-related issues have been raised over years of public discussion, there are few definitive answers to these difficult questions. Questions continue to arise due to a range of forces: from the perceived necessity of adopting more complex, versatile and probably more expensive systems, to the need to assign responsibility for the consequences of their malfunction. Finding certain answers in this field at the intersection of health, law and technology is always difficult: only a comprehensive analysis of all the interdisciplinary aspects can help to achieve this task.

This paper aims to explore and clarify the legal issues related to computer software and expert systems in the medical field, taking into account United States legislation on the one hand, and more general and theoretical aspects on the other hand.

Keywords

Medical computer software, medical expert system, medical device, liability, tort law

This paper is the result of a research project started in 2005 at the Massachusetts Institute of Technology (Computer Science and Artificial Intelligence Laboratory) under the direction of Prof. Peter Szolovits (Head of the Clinical Decision Making Group) and completed at the European University Institute with the help of Prof. Giovanni Sartor.

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1. Introduction

Technology advances very rapidly, but not as quickly as many predicted just a few decades ago. Judges and doctors have not been replaced by computers, and robots are not walking among us as in science fiction novels or movies. However, the evolution and the diffusion of computers has been rapid and it has changed many aspects of modern society. In particular, much has been achieved in the medical field and both health care professionals and patients have received great benefits from the advance of technology.

Today, hospitals are heavily computerized, but this process is still far from its ultimate goals and suffers from many deficiencies. Certainly, good quality software, correctly used, can improve health care under many different circumstances, e.g. good administrative software can improve the efficiency of health care delivery and can speed up the flow of patient information; good clinical software can greatly improve health care, helping physicians in their work (for instance by assisting them in their decisions); good software embedded in medical devices can improve the quality of life of patients. In fact, every subject involved in the health care field is likely to be a user of very complex software, sometimes even without noticing it. However, the more complex the software, the more susceptible it may be to errors that may cause malfunctions.

Ideally, we would rely on a clearly enunciated and settled body of law and practice to help analyze the potential risks and benefits of the use of complex software in health care, and to help decide when it is appropriate to deploy useful, though imperfect, software, and whom to hold responsible when malfunctions do occur.

Although many ethical, legal and technology-related issues have been raised over years of public discussion, there are few definitive answers to these difficult questions. Questions continue to arise due to a range of forces: from the perceived necessity of adopting more complex, versatile and probably more expensive systems, to the need to assign responsibility for the consequences of their malfunction. In particular, the scarcity of judicial cases and the complexity of tort law mean that software designers and manufacturers (and also health care professionals and patients) are working and living in a transitional period, in which it is only possible to speculate about what will happen if something goes wrong. Finding certain answers in this field at the intersection of health, law and technology is always difficult: only a comprehensive analysis of all the interdisciplinary aspects can help to achieve this task.

This paper aims to explore and clarify the legal issues related to computer software and expert systems in the medical field, taking into account United States legislation on the one hand, and more general and theoretical aspects on the other hand.

2. Introduction to Legal Issues: Product Safety Law and Product Liability Law

The development and use of computer software in the medical field and its consequences may be regulated by two similar but different areas of law: product liability law and product safety law. A central issue in both fields is establishing “how products should be classified as “excessively” or “unduly” hazardous, “unreasonably” dangerous, or “defective”. Both areas of law seek to reduce the toll of accidents from such hazards, to improve product safety. But there they begin to diverge” [Owen 2005].

Product safety law is regulatory law. It is made of rules established by the legislatures and administrative agencies of federal, state, and occasionally municipal governments to regulate the safety of products sold to the public. Product safety law operates *ex ante*, seeking to prevent product-caused accidents and diseases before they occur [Owen 2005].

In contrast, product liability law involves the responsibility of those who supply goods or products for the use of others to purchasers, users and bystanders for losses of various kinds resulting from defects in those products [Prosser 1984]. Product liability law operates *ex post*, after a product accident has occurred: it “concerns the consequences of modern science and technology gone awry – when products, or the interactions between people and their products, fail” [Owen 2005]. Damage can result from product defects and/or misrepresentations about a product’s safety or performance

capabilities¹. In the field of medical devices, liability may be imposed on manufacturers, sellers, hospitals, physicians, and other health care professionals or personnel [Miller 1985].

It will be seen that the federal regulation of product safety can have an impact on product liability litigation and sometimes pre-empt state law claims. With regard to the field of medical devices, the debate about FDA regulations and the eventual pre-emption of state law claims has been wide. However, the Supreme Court's 2008 *certiorari* in *Riegel v. Medtronic*² had a great impact on this issue, as will be shown.

3. The Regulation of Medical Devices

3.1 A Brief History of the Regulation of Medical Devices

Drugs have been regulated in the U.S. legal system since the enactment of the Food and Drugs Act of 1906 to protect consumers from the potential dangers of unregulated food and drug products. Only under the Federal Drugs and Cosmetic Act of 1938 (FDCA)³ the Food and Drug Administration (FDA) was authorized to act against manufacturers or distributors of medical devices that were not respondent to the law. However, there was no pre-market approval process for medical devices and so the FDA had to prove that each item was unsafe or misbranded. "Considerable agency time and resources were required to remove even relatively simple fraudulent products from the market, and, pending litigation, product seller could generally continue marketing" [Lafler 1989]. The provision of a pre-market approval process for new drugs was added to the FDCA only in 1962. During this process, the manufacturer was required to prove the safety and effectiveness of a product before marketing it.

In the following years, advances in medical device technology led to the creation of many new devices, and their safety and effectiveness became more of an issue and, strictly, the pre-market approval process was required only before marketing drugs, not medical devices. However, the FDA classified as drugs a number of products that were arguably devices and applied the pre-market approval requirements. Courts accepted this 'wide' interpretation of the FDCA rules, but it was obvious that an express regulation of medical devices was necessary. Therefore, to address many safety issues which arose in the seventies [see Cooper 1970], Congress enacted the Medical Device Amendments (MDA) to the FDCA in 1976, giving the FDA authority to regulate medical devices, "to provide for the safety and effectiveness of medical devices intended for human use."⁴ The FDCA was again amended with respect to the regulation of medical devices by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, the Food and Drug Administration Modernization Act of 1997 (the Modernization Act), the Medical Device User Fee and Modernization Act (MDUFMA) of 2002, and the Food and Drugs Administration Amendments Act (FDAAA) of 2007.

3.2 Definition of Medical Device

The definition of a medical device is contained in 21 U.S.C. § 321(h). It is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(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, or

¹ However, there is no monolithic product liability law in the United States, and there is probably no significant aspect of product liability which is precisely the same in all American jurisdictions [FRUMER 2004].

² *Riegel v. Medtronic, Inc.* (No. 06-179) 451 F. 3d 104.

³ 21 U.S.C. § 301 et seq.

⁴ Public Law No. 94-295 (preamble).

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes”⁵.

Thus, the legal concept of ‘medical device’ is wide and includes very simple mechanical products and quite complicated state-of-the-art medical technology [Green 2000]. Some commentators underline the fact that “medical devices are designed and can be modified to reduce or eliminate risk” [Green 2000], but in the case of very complex software and/or devices this may be not true, as the tragically famous Therac-25 showed in the worst way. (The Therac-25 was a computer-controlled radiation therapy machine whose malfunctions caused death and severe injuries; see [Leveson 1993]). In fact, “even small changes in critical software can have catastrophic effects” [Bovee 2001]⁶.

Software that meets the definition of 21 U.S.C. § 321(h) is considered a device subject to all applicable FDA medical device statutory and regulatory provisions. Software can be a device by itself or it can be incorporated into another device as a component, part, or accessory. Examples of software that fit the definition of device include hospital information systems, pharmacy prescription ordering systems, drug dosing calculators, expert medical decision support systems, etc. [Crumpler 1997].

3.3 Classification of Medical Devices

Medical devices are classified into three different classes, each one based on the risks that they pose to the public⁷:

(A) “Class I, general controls”: these are low risk devices, like examination gloves and bandages. They are subject to general controls⁸ (the baseline requirement of the FDCA). Most Class I devices are exempted from a pre-market review process (about 74%⁹), though in some cases a so-called 510(k) process (see *infra*) can be required. However, “all medical devices must be manufactured under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labeled, and have establishment registration and device listing forms on file with the FDA.”¹⁰

(B) “Class II, special controls”: these are moderate risk devices, like endoscopes and powered wheelchairs. General and special controls¹¹ are required for these device. Some class II devices are exempted from a pre-market review process and most of them are subject to the 510(k) process. Also, clinical data can be required before marketing some of these devices.

⁵ This definition of “device” is quite similar to the definition of “drug” (see 21 U.S.C. § 321(g)), but the key distinction is found in the fact that devices do not work primarily through chemical action or by being metabolized

⁶ Consider, also, that “the FDA’s analysis of 3140 medical device recalls conducted between 1992 and 1998 reveals that 242 of them (7.7%) are attributable to software failures. Of those software related recalls, 192 (or 79%) were caused by software defects that were introduced when changes were made to the software after its initial production and distribution” [CDRH 2002, 3].

⁷ See 21 USC § 360c (2004).

⁸ General controls include: establishment registration, medical device listing, manufacturing devices in accordance with Good Manufacturing Practices (GMP) in 21 CFR Part 820, labelling devices in accordance with labelling regulations in 21 CFR Part 801 or 809, and submission of a pre-market notification [510(k)] before marketing a device (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm>).

⁹ See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>.

¹⁰ See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm>.

¹¹ Special controls may include special labelling requirements, mandatory performance standards and post-market surveillance.

(C) “Class III, pre-market approval”: these devices present a potential, unreasonable risk of illness or injury, like heart valves and pacemakers. General and special controls are not sufficient to ensure the safety and effectiveness of these devices and so they should be subject to the stringent pre-market approval process (PMA, see *infra*). However, devices substantially equivalent to pre-1976 medical devices can go through a 510(k) process if the FDA does not call for a PMA.

3.4 Premarket Approval Processes for Class III Medical Devices

Market approval for a Class III medical device can be obtained in three ways:

1) The *premarket approval process* (PMA). This provides the FDA with information concerning the safety and effectiveness of the new device. During this process, the applicant must include sufficient information to prove that the device is safe and effective. The PMA process (and its review time) is much longer¹² and more expensive than the premarket notification process (PMN, see *infra*). In practice, clinical trials with the device must be conducted before submitting the PMA: devices will rarely be approved just on the basis of published literature and uncontrolled clinical experience. “PMA approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). [...] An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device.”¹³ “Unlike general labeling duties, pre-market approval is specific to individual devices. And it is in no sense an exemption from federal safety review – it *is* federal safety review. [...] It] is focused on safety, not equivalence.”¹⁴

2) The *510(k) premarket notification process* (510(k) process or PMN). Congress intended this exception for devices that are “substantial equivalents” to devices that were marketed before May 28, 1976 (the effective date of the MDA of 1976), in order to prevent makers of ‘grandfathered’ devices from retaining a commercial advantage over competitors struggling to obtain FDA approval through the lengthy PMA process: in fact, the PMN process is much less demanding than the PMA process.¹⁵ The “substantial equivalence” of a new device to a predicate device subsists if the first has the same intended use as the predicate device and has the same technological characteristics as the predicate device or has different technological characteristics that do not raise new questions of safety and effectiveness, and the sponsor demonstrates that the device is as safe and effective as the legally marketed device. Today (too) many manufacturers prefer to seek approval under the PMN process,¹⁶ trying to bring their devices to market more quickly than would be possible if they were subject to review under the PMA process [Scandaglia 2004] and so this ‘exception’ has become the rule, used as the predominant method for new devices to pass FDA scrutiny [Green 2000]: in one fiscal year, the Office of Device Evaluation (ODE) of the FDA received 37 original PMAs and 3,110 510(k)s [Ode 2004]! According to one commentator, the Congress, in enacting the MDA, did not foresee that substantial equivalence would play such an important role [Goldberger 2001].

3) The *investigational device exemption* (IDE). This permits a manufacturer to market a device prior to pre-market approval, “for the purpose of conducting investigation of that device.”¹⁷ Thus, an

¹² For comparison, in the fiscal years 2004 and 2007, the total average review time for original PMAs was respectively 288 and 275 days [ODE 2008].

¹³ See <http://www.fda.gov/cdrh/devadvice/pma/>.

¹⁴ *Riegel v. Medtronic, Inc.* (No. 06-179) 451 F. 3d 104.

¹⁵ In contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours [Medtronic v. Lohr, cit.].

¹⁶ “A company can normally obtain FDA acceptance without clinical trials, or, indeed, even without developing a physical prototype” [KAHAN 1984, 516].

¹⁷ 21 C.F.R. § 812.1.

IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a PMA application or a PMN submission to the FDA. Clinical studies are most often conducted to support a PMA.¹⁸ The FDA exempts IDE devices from certain MDA performance standards, including requirements regarding misbranding, PMN, and presentation of clinical testing results prior to market entry [Rieders 2004]. In the fiscal year 2008, the ODE received 216 original IDEs [ODE 2008].

3.5 Federal Pre-emption in the Medical Device Amendments Act and its Application by the Courts

It is widely known that when federal and state laws conflict, the latter must give way, but whether a federal statute pre-empts state law is a question of congressional intent. This intent is not perfectly clear in § 360 k(a) of the MDA, which attempts to define the relationship between the federal rule and other state and local laws:

(a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement:

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.¹⁹

Furthermore, “state or local requirements are pre-empted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device.”²⁰

The application of § 360k to real world cases has been widely debated for years and courts have been divided in deciding whether it pre-empts state law claims (negligent design, negligent manufacture, failure to warn, and strict liability claims) against the manufacturer of an allegedly defective device, with particular regard to Class III medical devices approved by the FDA after a PMA process. In 1995 the Supreme Court did not give a comprehensive answer to this difficult question: in fact, in the famous case *Medtronic v. Lohr*, the Court did not directly address this issue. However, this decision is still very important to a plausible interpretation of § 360k and the Court had the possibility of avoiding the question because the defective product, a pacemaker manufactured by Medtronic, was approved by the FDA through the PMN process and not through the PMA process. As noted by the Supreme Court, the § 510(k) process is focused on equivalence, not safety, and its determinations provide little protection to the public [Adler 1988]. “Neither the statutory scheme nor legislative history suggests that the § 510(k) process was intended to do anything other than maintain the status quo, which included the possibility that a device’s manufacturer would have to defend itself against state-law negligent design claims.”²¹ Thus, if on the one hand generalized FDA safety regulations are not pre-emptive, on the other hand, as affirmed by state courts, state law product liability claims should be pre-empted where the FDA’s regulations are exacting or specific to a particular product [Owen 2005]. The difference between the PMA and PMN processes, in fact, has been considered by the majority of federal courts: according to them, the PMA process constitutes a specific federal requirement and a certification of safety and effectiveness [Rieders 2004]. However, the Court of Appeals for the Eleventh Circuit²² and several federal district courts have held that the PMA process is

¹⁸ See <http://www.fda.gov/cdrh/devadvice/ide/index.shtml>.

¹⁹ 21 U.S.C. § 360k (2004).

²⁰ 21 C.F.R. §808.1(d) (2003).

²¹ *Medtronic v. Lohr*, 518 U.S. 470; 116 S. Ct. 2240; 135 L. Ed. 2d 700; 1996 U.S. LEXIS 4260.

²² *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).

not a specific federal requirement, and therefore does not trigger pre-emption of common law claims by § 360k(a) of the MDA [Rieders 2004].

Thus, federal and state courts are currently divided in determining whether § 360k(a) of the MDA pre-empts state common law claims against manufacturers of medical devices that have undergone the rigorous PMA process. One commentator argues that, under an accurate interpretation of the federal pre-emption provision, the PMA process is not a sufficiently specific federal requirement to trigger pre-emption [Rieders 2004]. In a basically similar perspective, another commentator points out that the PMA process should only have pre-emptive effect when it imposes a specific regulation upon a specific device. In this regard, the public can be assured that pre-emption of common-law claims is being traded for the sake of detailed regulation of a particular device, rather than for compliance with a programme that only assures minimal public safety [Allen 2001]. However, for another commentator, the “preservation of state product liability actions for injured Class III medical device consumers stands as the only pragmatic means to enhance product safety incentives” [Petrella 1996]. This view is traditionally justified by the assumption that the standards set by most product safety statutes or regulations generally are only minimum standards.²³ Green and Schultz point out that tort law may

assist in providing an incentive for manufacturers to take ameliorative action once a serious problem with a medical device is uncovered. The FDA has a number of tools for dealing with these situations, but all entail either a manufacturer’s voluntary compliance or legal action by the FDA, which requires expenditures of resources and delay. The financial consequences imposed by the tort system are considerably more acute than any that might result from regulatory enforcement and may assist the FDA in effectively managing risks that emerge after marketing [Green 2000].

According to another commentator, the confusion about the pre-emptive effect of the MDA when a device has been reviewed and approved under the PMA process should “be resolved in favour of pre-emption if the FDA’s regulatory authority and the goals behind the passage of the MDA are to be served. Without the safe harbour offered by federal pre-emption, the risk of inconsistent legal outcomes and liability threatens to discourage innovation, eviscerate the FDA’s power, and destroy the uniformity intended by Congress” [Scandaglia 2004].

In 2008, the Supreme Court stated that “State requirements are pre-empted under the MDA only to the extent that they are “different from, or in addition to” the requirements imposed by federal law §360k(a)(1). Thus, §360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case are “parallel,” rather than add to, federal requirements”²⁴.

This “erroneous” decision [Brennan 2009] could have a potential negative impact on product safety, because “the possibility of litigation for “failure to warn” or design defect served as a strong inducement for device companies to be vigilant about the safety of their products” [Curfman 2009]. It could be interesting to study the impact of *Riegel v. Medtronic* on a statistical and empirical basis, in order to determine if the number of accidents has risen since 2008 (also taking into account other factors, such as the number of new devices, and comparing it with previous years). In the meanwhile we can argue that this decision can have a potential negative impact on product safety because it is a disincentive to create safer medical devices, since manufacturers are less accountable than in previous years.

3.6 Federal Pre-emption in the Restatement (Third) of Torts

Before looking at the specific liability rules set out by both the Second and the Third Restatement of Torts, it is useful to look at the approach followed by the American Law Institute on

²³ For instance, see the “Health Insurance Portability and Accountability Act” (HIPAA), which only establishes a minimum federal floor for protecting privacy and providing access to medical records and so state laws “more stringent” than the federal rule can be enacted or, if already enacted, will remain in effect [Pub. L. 104-191, Sec. 264 (c)(2)].

²⁴ *Riegel v. Medtronic, Inc.* (No. 06-179) 451 F. 3d 104.

the topic of federal pre-emption of state law claims. The contribution of the Restatements to the evolution of the U.S. legal system is widely acknowledged and, as we will see *infra*, the Restatement (Second) of Torts on product liability has played a very important role in the evolution of the law of torts. About thirty years after the approval of the Restatement (Second), the ALI promulgated the Restatement (Third) of Torts on product liability because, among other reasons, it was clear that during the previous decades, the law of torts had become increasingly more complex and intricate and many subjects in tort law had become controversial: “no one can seriously argue that the law of product liability in any jurisdiction has evolved in a straight line from § 402A of the Restatement Second” [ALI 1996].

According to § 4 of the Restatement (Third) of Torts,

in connection with liability for defective design or inadequate instructions or warnings: (a) a product’s noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation; and (b) a product’s compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

As noted in comment (e) to § 4,

occasionally, after reviewing relevant circumstances, a court may properly conclude that a particular product safety standard set by statute or regulation adequately serves the objectives of tort law and therefore that the product that complies with the standard is not defective as a matter of law. Such a conclusion may be appropriate when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise [ALI 1996].

In many cases, reported in the same comment, most courts hold that compliance with product safety regulations is relevant and admissible on the question of defectiveness, but it is not necessarily controlling.²⁵

3.7 FDA Regulations and Software Used in the Medical Field

The FDA stated its software policy in 1987²⁶ and since then other documents have updated and expanded this policy. Its basis is the least burdensome approach in all areas of medical device regulation.

In particular, in 2002 the FDA issued the “General Principles of Software Validation; Final Guidance for Industry and FDA Staff” to describe “how certain provisions of the medical device

²⁵ See, among others, *O’Gilvie v. International Playtex, Inc.*, 821 F.2d 1438 (10th Cir.1987); *Sours v. General Motors Corp.*, 717 F.2d 1511, 1517 (6th Cir.1983); *Foyle v. Lederle Labs*, 674 F.Supp 530, 533 (E.D.N.C.1987); *Carlin v. Superior Court*, 920 P.2d 1347 (Cal.1996); *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 63 (N.M.1995); *Washington State Physicians Ins. Exch. & Assoc. v. Fisons Corp.*, 858 P.2d 1054, 1069 (Wash.1993); *United Blood Servs. v. Quintana*, 827 P.2d 509, 525 (Colo.1992); *Feldman v. Lederle Labs*, 625 A.2d 1066, 1070 (N.J.1993); *Plenger v. Alza Corp.*, 13 Cal.Rptr.2d 811, 819 n. 7 (1992).

²⁶ In 1987 the FDA formally stated its software policy in its “Draft Policy on the Regulation of Computer Products”; this document was followed by another draft policy statement (“FDA Policy for the Regulation of Computer Products”) in 1989. In 1996 the FDA called for new discussions on the same topic (among others, see [MILLER 1997a] and [MILLER 1997b]) and in 1997 it released another draft (“General Principles of Software Validation, Version 1.1”). In 2009 the FDA released a draft guidance on “Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions”.

Quality System²⁷ regulation apply to software and the agency's current approach to evaluating a software validation system" [CDRH 2002]: today, unless specifically exempted in a classification regulation, any medical device software product developed after June 1, 1997, regardless of its device class, is subject to applicable design control provisions.²⁸ However, if the software is developed by someone other than the device manufacturer, as in the case of off-the-shelf software,²⁹ the device manufacturer, and not the software developer, is directly responsible for compliance with FDA regulations [CDRH 2002].³⁰

Pre-market submission guidance is contained in the "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices,"³¹ issued in 2005 by the Office of Device Evaluation (ODE) of the Center for Devices and Radiological Health (CDRH) of the FDA. This guidance applies to all software that can be used as a medical device (we have already seen how broad the legal definition of "medical device" is); it distinguishes between three levels of concern: major (if a failure or latent flaw could directly result in death or serious injury to the patient), moderate (if a failure or a latent flaw design could directly result in minor injury to the patient or operator), minor (if failures or latent design flaws are unlikely to cause any injury to the patient or operator) [CDRH 2005].

Basically, these regulations are quite generic and so courts may consider compliance with them (and consequent approval from the FDA) as only compliance to minimum standards, not capable of pre-empting state law claims. Furthermore, it is clear that the intent of the FDA is just to provide guidance, but not exemption from liability, so these requirements should be considered what they are: necessary requirements to market a device, and no more.

4. Product Liability

4.1 General aspects

As we have seen, compliance with FDA regulations may allow manufacturers to market medical devices in the United States but they may still be held liable under the law of torts for harm caused by, or through, their products. This liability may extend to manufacturers of medical computer software. A tort is "a civil wrong, other than breach of contract, for which a remedy may be obtained, usually in the form of damages; a breach of duty that the law imposes on persons who stand in a particular relation to one another" [Garner 2004]. Thus, torts are neither crimes nor contract-based claims [Prosser 1984] and tort law sanctions wrongful acts.³² "The essence of tort is the defendant's potential for civil liability to the victim for harmful wrongdoing and correspondingly the victim's potential for compensation or other relief" [Dobbs 2001].

²⁷ 21 C.F.R. Part 820.

²⁸ See 21 C.F.R. § 820.30. "This requirement includes the completion of current development projects, all new development projects, and all changes made to existing medical devices" [CDRH 2002, 3].

²⁹ Its use in medical devices is regulated by another document: "Off-The-Shelf Software Use in Medical Devices", issued in 1999 by the Office of Device Evaluation of the CDRH [ODE 1999]; this superseded the "Guidance on Off-The-Shelf Software Use in Medical Devices" of 1997.

³⁰ The medical device manufacturer "bears the responsibility for the continued safe and effective performance of the medical device" [ODE 1999].

³¹ This document superseded two previous documents: the "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review" (1991) and the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (1998).

³² The law of torts is wide and complex. In this paper only the aspects necessary for the discussion will be analyzed.

For our purposes, a first distinction can be made between intentional torts,³³ negligence, and strict liability for defective products. Basically, the first concept regards harms intentionally caused by a person (e.g. a punch on the nose): the actor desires to bring about the consequences which follow or he or she knows that they are substantially certain to occur or he or she believes that they will occur [Prosser 1984]. The second concept focuses on the principle that everyone should exercise reasonable care when he or she acts, taking account of the potential harm they might foreseeably cause to other persons: the actor is required to do what the “reasonable man of ordinary prudence”³⁴ would be expected to do in his place under the same or similar circumstances (having regard, also, to the subjective attributes of the actor – physical attributes; mental capacity; age; superior knowledge, skill and intelligence). The third concept focuses on the product rather than on the conduct of the manufacturer, who may be held liable even in the absence of intent to injure or negligence.

Almost any injured human being can assert a claim for negligence or strict product liability: he or she must only be a foreseeable plaintiff [Frumer 2004]³⁵. This definition includes parties who are outside the purchasing line of a product, such as a repairman injured while cleaning elevator cables.³⁶ Today, “the requirement of privity³⁷ has been relaxed under modern laws and doctrines of implied warranty and strict liability, which allows a third-party beneficiary or other foreseeable user to sue the seller of a defective product” [Garner 2004].

A contractual relationship still exists between the health care professional (hospital, physician, etc.) and the computer software manufacturer. However, Article 2 of the Uniform Commercial Code (UCC) applies only to “transactions in goods.”³⁸ While transactions involving hardware are usually considered as Article 2 transactions [Lamkin 1994], it is not clear whether software is a good under this rule. Indeed, the definition of “goods” is wide: it “means all things (including specially manufactured goods) which are movable at the time of identification to the contract for sale other than the money in which the price is to be paid.”³⁹

If the sale involves both hardware and software, courts categorize the sale as one of goods, while if the contract is purely for the provision of customized data processing services, courts usually categorize the transaction as one of services. However, when the contract is only for the provision of software, the courts are divided in determining if the transaction is in goods or services [Lamkin 1994]. “In numerous cases, the courts have held not only that software is a product, but that the limitations of vendor liability expressly contained in standard software licensing agreements are valid and enforceable” [Ballman 1996]. In fact, contractual liability can be successfully limited in the contract itself, and, in such cases, patients, who presumably have no contractual relationship with the manufacturer, are unable to sue the latter on a contract basis.

4.2 Product Defects

‘Defect’ is the core concept upon which product liability turns [Fischer 2002]. There are three types of product defects:

³³ The most basic elements of the common usage of the term “intent” “are that (1) it is a *state of mind* (2) about *consequences* of an act (or omission) and not about the act itself, and (3) it extends not only to having in mind a purpose (or desire) to bring about given consequences but also to having in mind a belief (or knowledge) that given consequences are substantially certain to result from the act” [PROSSER 1984].

³⁴ This person is fictitious, he or she is “the personification of a community ideal of reasonable behaviour, determined by the jury’s social judgement” [PROSSER 1984].

³⁵ Before 1916, a plaintiff could recover for injuries caused by negligently manufactured products only if he or she was in privity of contract with the defendant. In *MacPherson v. Buick Motor Co.* [217 N.Y. 382, 111 N.E. 1050 (1916)], Justice Cardozo held that the privity rule is not applicable to any product that is dangerous when defective.

³⁶ *Sikora v. AFD Industries, Inc.*, 319 F. Supp. 2d 872, 875-876 (N.D. Ill. 2004).

³⁷ Privity is “the connection between two parties, each having a legally recognized interest in the same subject matter [GARNER 2004].

³⁸ UCC §2-102.

³⁹ UCC §2-105(1).

- 1) *Manufacturing defects*: basically, a product has such a defect if it is improperly made. Therefore, in a negligence action based on this type of defect, a plaintiff must prove that the manufacturer did not use reasonable care in its manufacturing, construction, and assembly processes, until the products left his or her hands [Frumer 2004]. In a strict liability action based on a manufacturing defect, the plaintiff must prove that the product did not perform in a manner intended by the manufacturer or that it was different from the condition intended by the manufacturer [Fischer 2002].
- 2) *Design defects*: a product that has a defective design meets the manufacturer's draft specification, but raises the question of whether the specifications themselves created an unreasonable risk. Therefore, the problem is found not in the single product, but in its design, and thus refers to an entire line of products [Frumer 2004]. The risk will be deemed to be unreasonable if the presumable risk of harm posed by the design could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or distributor: it is clear that the requirement of reasonableness introduces a *de facto* element of negligence into the question of strict liability related to design defects [Brannigan 1981].
- 3) *Warning defects*: manufacturers must properly warn the user of the product about the risks associated with the it, providing instructions to use it safely or warning of product-related dangers that cannot be eliminated. However, if a product is marketed only to professionals, who are aware of its dangers and how to deal with them, they may reasonably give a much less detailed warning than they would have to give to members of the general public.

The traditional refusal by courts to impose tort liability for defective designs of prescription drugs or medical devices entails a unique set of risks and benefits. What may be harmful to one patient may be beneficial to another. Litigation raising the issue of design defects in medical devices has been the subject of appellate review in relatively few cases. Most of the cases that have addressed the issue have held that medical devices that require a medical provider's description are subject to the same rules that apply to prescription drugs [ALI 1996].

However, it may be difficult to distinguish the design phase from the production phase in computer programs and it may not be possible to determine whether an error is due to a design defect or to a production flaw [Brannigan 1981].

4.3 Breach of Warranty

A breach of warranty is "a breach of an express or implied warranty relating to the title, quality, content, or condition of goods sold" [Garner 2004]; for some plaintiffs who have suffered only economic loss it can be the only way to recover [Frumer 2004]. Three kinds of warranties are recognized by Article 2 of the UCC: express warranty, implied warranty of merchantability, and implied warranty of fitness for a particular purpose. While an express warranty is limited to the terms expressly agreed to in the contract, implied warranties impose non-contractual duties on the seller of goods. An implied warranty of merchantability covers damages that arise from a failure to conform to the trade standard associated with goods of the same class. An implied warranty of fitness for a particular purpose covers damages that arise from the buyer's reasonable reliance on the seller's knowledge and judgment when purchasing the good. Under the UCC, disclaimers for express and implied warranties are allowed, provided they are conspicuous to the buyer and follow UCC guidelines; therefore, by using an effective disclaimer, manufacturers may avoid liability, even for physical injuries. In addition, breach of warranty is still affected by the concept of privity.⁴⁰

⁴⁰ Privity of contract is "the relationship between the parties to a contract, allowing them to sue each other but preventing a third party from doing so" [GARNER 2004, 1237].

Generally, in a breach of warranty claim, “a plaintiff must prove that the defendant made an express warranty, or circumstances that support the imposition of an implied warranty; that the product breached the warranty at the time of sale; the existence of damage as a result of the breach; and that the breach was the legal and factual cause of the damages” [Frumer 2004].

4.4 Liability for Negligence

Negligence is the failure to exercise the standard of care that a reasonably prudent person would have exercised under similar circumstances: it denotes culpable carelessness [Garner 2004] and it is a matter “of recognizable danger of injury” [Prosser 2004]. The traditional elements of negligence are:

- 1) a duty recognized by the law, requiring the person to conform to a certain standard of conduct: generally, the defendant owes a duty of care to all persons who could foreseeably be endangered by his or her conduct [Scott 2005];
- 2) breach of that duty, that is a failure on the person’s part to conform to the standard required;
- 3) a reasonably close causal connection between the conduct and the resulting injury (“legal cause” or “proximate cause” [Scott 2005]);⁴¹
- 4) actual loss or damage resulting to the plaintiff [Prosser 1984]. Damages include personal injuries, property damage, and (in some States) pure economic losses.

Thus, actionable negligence requires unreasonable conduct that is both a cause in fact and a legal cause of damages. The plaintiff must prove that a reasonable person in the position of the defendant, before the alleged negligent act, would have recognized that the act would create a risk of harm to others, and that this foreseeable risk was unreasonable, so it was not justified by the benefit gained by taking it [Fischer 2002]. Thus, negligence must be proved, even by means of circumstantial evidence (for instance, see the doctrine of *res ipsa loquitur*⁴²).

Product manufacturers are held to the standard of a reasonable manufacturer of the particular product, which means that they should keep reasonably abreast of scientific research and developments in the field. Purchasers, foreseeable users, and bystanders can recover damages suffered, while manufacturers and dealers may be the liable parties. Recoverable damages include personal injury, property damage, and punitive damages [Nguyen 1994].

Providers of computer hardware or software may be liable for negligence if the plaintiff can prove the existence of a duty on the part of the defendant to conform to a specific standard of care, breach of that duty, that the breach was the actual and proximate cause of the alleged injury, and provable damage [Savage 1998]. In particular, in the case of medical expert system developers, the duty of care may be compared to that of other software developers with the same professional skill, knowledge, and experience [Nguyen 1994].

It is interesting to note that, according to Cupp and Polage, jurors respond more favourably (in terms of both the likelihood of success and verdict size) to plaintiffs whose claims are based on

⁴¹ The defendant’s negligence must have been the cause-in-fact of the plaintiff’s injury, so the latter must show that without the defendant’s negligence the injury would not have occurred, or that the negligence was a substantial factor in bringing about the injury. Also, the plaintiff must prove that his or her damages were a foreseeable result of the defendant’s negligent act [SCOTT 2005].

⁴² Literally, “the thing speak for itself”. There are three conditions usually required for the application of this principle: “(1) the event must be of a kind which ordinarily does not occur in the absence of someone’s negligence; (2) it must be caused by an agency or instrumentality within the exclusive control of the defendant; (3) it must not have been due to any voluntary action or contribution on the part of the plaintiff” [PROSSER 1984].

negligence rather than strict liability [Cupp 2002]: “the doctrine of negligence is both a vital and powerful theory of recovery in product liability” [Owen 2004].

4.5 Liability for Professional Malpractice and for “Computer Malpractice”

Malpractice is an instance of negligence or incompetence on the part of a professional. The standard of a reasonable practitioner of the profession (doctor, lawyer, engineer, etc.) is the basis for professional malpractice. Thus, “professional persons in general, and anyone who undertakes any work calling for special skill, are required not only to exercise reasonable care in what they do, but also to possess a standard minimum of special knowledge and ability” [Prosser 1984].

In recent decades, more and more cases of professional malpractice have concerned doctors and health care professionals, but it is widely known that there are areas in which even experts will disagree and where there are different (but recognized) schools of medical thought⁴³ and alternative methods of acceptable treatment. Thus, the doctor will not be liable if he/she has exercised reasonable care in ascertaining the operational facts upon which his or her diagnosis is based [Prosser 1984].

In particular, an action for computer malpractice would essentially be an action against the defendant for professional liability. A heightened standard of care from the defendant would be expected [Desai 2002], but a similar tort should not be recognized until educational or licensing standards for computer professionals are set [Ganske Graziano]. According to one commentator, a patient injured by a physician’s reliance upon a medical expert system may have a cause of action against the physician if the physician unreasonably (from the standard of the reasonable physician) relied upon the information provided by the system in treating or diagnosing the patient [Lamkin 1994].

A real opportunity for a malpractice claim against a manufacturer exists when a medical information system malfunctions, causing the doctor or health care provider to make an incorrect diagnosis or to choose improper treatment which may cause injury to the patient. However, a plaintiff alleging professional malpractice against the manufacturer of a medical information system will not have an easy road to recovery: to date, courts have been very reluctant to create a cause of action for computer malpractice [Lamkin 1994]. In fact, “the novel concept of a new tort called “computer malpractice” is premised upon a theory of elevated responsibility on the part of those who render computer sales and service”, but “simply because an activity is technically complex and important to the business community does not mean that greater potential liability must attach.”⁴⁴

4.6 Strict Product Liability: General Aspects

Strict liability is imposed on an actor who has not departed in any way from a reasonable standard of care: so it also called “liability without fault”. It is imposed for abnormally dangerous activities (e.g. nuclear energy) and for defective products.

Strict product liability requires neither privity of contract nor proof of negligence by the product manufacturer, and it is not subject to the disclaimers or the requirement of notice that are applicable to warranties under the Uniform Commercial Code [Fischer 2002]. It was adopted in 1963 in the famous case *Greensman v. Yuba Power Products, Inc.*⁴⁵ and in 1965 into § 402A of the Restatement (Second), which was adopted by almost all States, wholly or in part, so its rules are generally applied by courts, though in different ways depending upon the jurisdiction [Frumer 2004].

The wide debate about this type of liability is due to the fact that it is a doctrine more favourable to plaintiffs than negligence, and because it is easier to prove and susceptible to fewer defences [Frumer 2004]. Moreover, different policy justifications have been advanced by courts and

⁴³ “It must be the line of thought of a respectable minority of the profession” [PROSSER 1984].

⁴⁴ *Chatlos Systems, Inc. v. National Cash Register Corporation*, 479 F. Supp. 738; 1979 U.S. Dist. LEXIS 9030.

⁴⁵ 59 Cal.2d 57, 27 Cal.Rptr. 697, 377 P.2d 897 (1963).

scholars: compensation (or loss spreading);⁴⁶ deterrence;⁴⁷ encouraging useful conduct; resolving proof problems;⁴⁸ the protection of consumer expectations; and cost internalization [Fischer 2002].

4.7 The Restatement (Second) of Torts and its Applicability to Medical Computer Software

According to § 402A⁴⁹ of the Restatement (Second) of Torts on product liability:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and
(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller [ALI 1965].

The concept of strict liability focuses on the product rather than the conduct of the manufacturer [ALI 1996], making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product. As noted by Prosser (the ‘godfather’ of § 402A of the (Second) Restatement of Torts), strict liability “means liability that is imposed on an actor apart from either (1) an intent to interfere with a legally protected interest without a legal justification for doing so, or (2) a breach of duty to exercise reasonable care, i.e. actionable negligence” [Prosser 1984]. However, “the defendant is not an insurer” [Fischer 2002], and strict liability applies only where the product is, at the time it leaves the seller’s hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him, so the seller is not liable when he delivers the product in a safe condition, and subsequent mishandling or other causes make it harmful by the time it is consumed [ALI 1965]. “Ordinarily, the party that complies with federal standards applicable to the manufacturing or marketing of a product enjoys a reputable presumption that the product is not unreasonably dangerous” [Johnson 2005].

The rationale for imposing strict liability is based on the fact that the supplier of a defective or dangerous product is in a better position to reduce potential hazards caused to users of the product, negligence would be difficult to prove, and the supplier is in a better position than the users to ensure against such risks. To establish a case of strict liability, the plaintiff must show causation and resulting damages [Owen 2005]. In other words, the plaintiff tries to prove that the defendant’s defective product was the legal cause of his or her accident in order to obtain compensation for damages suffered. Therefore, the main historic advantage of strict liability has been that the plaintiff can recover without a showing of fault [Fischer 2002].

However, not every product is subject to § 402 A: in fact, as we read in comment *k* to § 402 A, “there are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. [... In the case of] many new or experimental drugs [...], because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and the use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to be strictly liable for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an

⁴⁶ Losses are spread over all consumers because manufacturers will raise the price of their products to pay for the losses or insure against them.

⁴⁷ The imposition of liability on manufacturers could be an incentive to avoid losses by marketing safer products.

⁴⁸ Usually plaintiffs lack the necessary information and expertise to prove a product defect.

⁴⁹ “Special Liability of Seller of Product for Physical Harm to User or Consumer”.

apparently useful and desirable product, attended with a known but apparently reasonable risk” [ALI 1965]. According to Dreier, this comment is “incomprehensible”: “it proclaimed both liability and exoneration under the rubric of an unavoidable lack of safety” [Dreier 1999].

§ 402A is applicable to computer software used in the medical field only if the said software is a “product”, not a “service”, sold by the defendant. The same product must reach the injured party without substantial alteration, it must be defective and the defect must be the source of injury. One commentator points out that courts recognize that it is usual for software to contain errors, but how many errors render a program defective or unreasonably dangerous [Wilson 1995]?⁵⁰ Miller et al. argue that, probably, “strict liability will be applied to a program’s use the more incidental the use of that program is in accomplishing a given medical task and the greater the extent to which that medical task is a service. By contrast, when little discretion on the part of a program’s user is involved, the program is more likely to be characterized as a product than a service” [Miller 1985]. Also, if the software is mass produced, then presumably it will be considered as a good rather than a service,⁵¹ while “where software is tailor-made for a particular user, it is very unlikely strict liability would apply” ([Wilson 1995]; see also [Mortimer 1989] and [Prince 1980]).

4.8 Medical Devices in the Restatement (Third) of Torts

Drugs and medical devices are considered in § 6 (c) of the Restatement (Third) of Torts: “A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients”. In fact, “imposing liability for unforeseeable risks can create inappropriate disincentives for the development of new drugs and therapeutic devices” [ALI 1996].

It is impossible to know if, in the near future, § 6 (c) will be followed by the courts, but, as noted by one commentator, “the principle of inertia suggests that courts for many years will continue to apply principles of negligence to design and warning defect issues while purporting to apply the accumulated “strict” liability spawned by § 402A” [Owen 2005].

For now, we can easily see that this new rule has been widely debated by many commentators. The majority of them criticize the approach followed by ALI, because this system “demands less than reasonable care from the manufacturers of medical devices. Its declaration that manufacturers of medical products need not make a safer product if the existing product does more good than harm reverses thirty-five years of safety-advancing product-liability law” [Conk 2000]. According to Vandall, this Restatement is a “wish list from manufacturing America” [Vandall 1997] and the distinction between drugs (and medical devices) and other products is “artificial and arbitrary” [Vandall 1997].

However, for another commentator, § 6 (c) “strikes the proper balance between a plaintiff’s interests and the interests of drug or medical device manufacturers” [Dreier 1999], because liability is subject to a risk-utility balancing analysis and the standard of judgment is that of a reasonable health care provider [Dreier 1999]. It is important to note that the Restatement (Third) of Torts is not an exemption of liability for manufacturers; rather, it focuses liability on the duty to disclose risks and benefits to the prescribing professional [Dreier 1999]. According to Henderson and Twerski, Reporters for the criticized rule, “plaintiffs may establish defectiveness by showing that safer alternative drugs were available on the market that reasonable health care providers would have prescribed in place of a defendant’s drug for all class of patients” [Henderson 2001]; the same reasoning could be extended to advanced medical devices.

⁵⁰ According to the ODE, “software failures are systematic in nature” and “engineering risk management for medical device software should focus on the severity of the harm that could result from the software failure” [ODE 1999, 2]. This consideration regards the use of off-the-shelf software in medical devices, but is quite generic and so could express another point of view of the agency.

⁵¹ See *Saloomy v. Jeppesen*, 707 F.2d 671; 1983 U.S. App. LEXIS 28100.

4.9. Strict Product Liability and Medical Computer Software

The application of liability rules to computer software manufacturers has been debated for many years ([Conley 1987], [Freed 1976], [Freed 1977], [Gemignani 1981], [Nimmer 1986]). Basically, as we have seen, strict product liability applies only to physical goods, not to services, so a software manufacturer can be held liable only if software is considered a good and not a service. Brannigan and Dayhoff point out that if programs are seen as products, their manufacturers will almost surely be held strictly liable for injuries caused by program defects, while if they are seen as services, the theory most likely to be applied will be negligence. However, multifaceted medical computer programs do not fall neatly into either category and so courts' choices are likely to be based on policy considerations [Brannigan 1981].

An obstacle to the general application of strict liability rules can be found in the circumstance that most States allow recovery only where there has been personal injury; obviously, medical computer software may cause personal injuries or death if something goes wrong, so this profile is not an obstacle to the application of strict liability rules in such cases. Nevertheless, as noted by Owen, whether manufacturers of computer software should be subject to product liability for personal injuries caused by defective software is an intriguing question. Even if the case law is as yet nonexistent, commentators widely favour the application of product liability theories in such situations.

It is possible to distinguish between two different hypotheses: if the defect lies solely in the substantive information fed into the program, then strict liability rules should not apply; but, if the defect is due to the software program design, then it is possible to find an analogy with navigational chart cases and so a producer should be subject to strict responsibility for any resulting harm [Owen 2005].

Aeronautical chart cases are quite enlightening because they highlight the difference between facts and ideas⁵². In *Aetna Casualty v. Jeppesen*⁵³, the defendant, Jeppesen, manufactured aeronautical charts, one of which presented two different views of the approach to an airport but not drawn to the same scale. The plaintiff argued that the chart was a defective and an unreasonably dangerous product because pilots using the chart might reasonably conclude that the two views were drawn to the same scale: as noted by the Court, the purpose of the chart was to translate the information provided in tabular form by the Federal Aviation Administration (FAA) into an instantly understandable graphic representation, and this was what gave the chart its usefulness. Due to the reliance created by Jeppesen on the graphical portrayal of data, the court applied strict liability to the manufacturer.

According to Lamkin, a computer program, like a navigational chart, converts data into a more accessible or usable form, the results of which may be passed on to a physician, or to a pilot, for professional evaluation. The professional must be able to rely on the accuracy of this information if he or she is to benefit from the mechanization or special compilation of the data [Lamkin 1994]. However, a professional must always exercise his or her judgment even when he or she uses a complex system (or even a simple device).

Lanoue argues that the increasing diffusion of computer programs in many different fields will lead to physical injuries to people from defective computer programs and the principles and policies of strict liability for defective products should be applied to computer-caused injuries; in fact all the policy reasons that led to the adoption of strict product liability should apply to the computer industry. Also, when one compares the courts' reactions to other intangible items (such as electricity) that cause injury, and the reception of computer programs in other areas of the law, there is a tendency by the courts to relax the traditional rigid definition of "products" [Lanoue 1983].

According to Lawrence, applying strict liability may encourage greater manufacturer accountability through prolonged testing of the software, but it would also unnecessarily prolong human suffering by denying a needed medical application or by delaying its use. So, a negligence standard should be used in the case of medical software because it is extremely beneficial to society, and yet it poses an inherent and substantial risk that is unavoidable at the time of distribution because software, due to its nature, cannot be made completely safe [Lawrence 1987].

⁵² See also *infra*, 7.

⁵³ 642 F.2d 339; 1981 U.S. App. LEXIS 14149.

Brannigan and Dayhoff note that only certain types of programs are likely to fall into the category of strict liability. To them, ordinary programming errors are likely to be considered production defects, as well as those with design defects that inflict injury, especially when the defective program directly operates a machine that inflicts injury on a patient. Conscious design choices, on the other hand, are likely to be judged according to a negligence standard [Brannigan 1981].

Obviously, in the health care sector, the contemporary age provides the possibility of creating an ever-increasing number of sophisticated medical devices, but these devices may have malfunctions due to their complexity. “The public has the right to expect innovation, and development efforts should not be unduly hampered by litigation threats. There needs to be a correct balancing of the risks and benefits, requiring courts to analyze the federal intent to balance the goal of patient protection against the need for innovation” [Senft 2001].

Finding the correct balance is not an easy task. However, as noted by the Supreme Court in *Medtronic v. Lohr*, the safety of those who use medical devices was the primary issue motivating the MDA’s enactment and the intent to protect the industry was manifested primarily through fewer substantive requirements under the Act. In this perspective, it is possible to argue that when a medical device - including computer software that is classified as a medical device - is marketed only after a long process that ensures the safety and effectiveness of the said device, supported by clinical evidence, then state law claims should be pre-empted or – at least – strict product liability rules should not be applied. On the other hand, however, if the manufacturer chooses to use a much faster and less safe market approval process, then pre-emption should not be possible; furthermore, strict product liability rules should apply. In this way, it is possible to strike a balance between a correct incentive to the progress of the industry and the interests of consumers.

4.10 Product Liability and Medical Expert Systems

Medical expert systems may be regulated by the FDA as medical devices with provisions that are able to pre-empt state law claims. However, even if they are classified as Class III devices and subject to the PMA process, state law claims may still be possible and even strict product liability could be applied.

According to one commentator, the use of expert systems can raise three kinds of liability: (1) liability when the expert systems furnishes incorrect information; (2) liability because the user unjustifiably relied on the system; and (3) liability because an expert system was not consulted [Kutten 2004].

In the first case, we must remember the distinction between facts and ideas. If the system provides erroneous information because it is defective (for instance, has a bug), the manufacturer may be sued for negligence; strict liability rules may be also applied if the system is mass produced, but “the fact that medical expert systems are, at present, primarily custom-designed weighs against the use of strict liability” [Lamkin 1994]. As we have seen with regard to professional malpractice, there are areas in which alternative methods of acceptable treatment exist, so in these cases it seems fair to evaluate the reasonableness of the expert system’s “behaviour” under the negligence theory.

In the second hypothesis, it is obvious that a doctor who relies on the system’s advice should exercise his or her professional judgment [Forester 1994] because these systems are not a replacement for physicians, but just new and powerful tools that can be used to improve the quality of care [Cole 1990]. In fact, a patient is cured by the doctor, not by the system. In particular, strict liability should not be used in order to exempt physicians from liability, even without arguing for the protection of medical expert systems under the First Amendment [see *infra*]. One commentator argues that since expert systems are designed to function only within narrow domains, the developer can only be held liable for the system’s output within the context of its domain. In the case of medical expert systems, he notes that the domain is limited to that of a consultative role vis-a-vis the physician, not “final medical judgment.” As a result, the patient cannot bring a product liability claim against the system manufacturer, since the patient’s reliance on any information or advice given by the system is outside of the system’s domain [Cole 1990]. However, the central point is that the health care professional

must use his or her professional judgment: even a very advanced and complex expert system is a support, not a substitute.

The third case is not very important, but probably in the near future it may become more “popular” if medical expert systems become widely used. “The theory behind this potential liability is based on the claim that such a failure constitutes a breach of the obligation (duty) to use reasonable care [...]. The key element in finding such a duty would be whether in such circumstances there was a custom or usage in the industry to use a computer” [Scott 2005].

After all,

in pursuing traditional tort claims, the injured plaintiff’s best bet may be a medical malpractice claim against the physician for improper use of an expert system, as the medical malpractice cause of action is well-established. While there is a danger that forcing plaintiffs to rely on claims against their doctors when they are injured by defective expert systems will lead to hesitancy on the part of physicians to make use of new technology, these concerns are mitigated by two factors. First, a plaintiff could only assert a successful claim against the physician if the physician unreasonably relied upon the expert system, a problem that is unlikely to be widespread. Second, the physician, being in a contractual relationship with the developer of the system, is better positioned to pursue an indemnity claim against the manufacturer than a plaintiff is to pursue a tort claim. While relying on such indemnity would perhaps add to an already overcrowded court docket, it does go a long way towards eliminating concerns over suits against physicians for misuse of expert systems [Lamkin 1994].

Obviously, if expert systems ‘close the loop’ and directly cure the patient, professional malpractice rules, and not strict liability rules, should apply, because the application of the latter could bring about a difference between ‘human’ and ‘artificial’ health care providers, thus making product manufacturers ‘more liable’ than physicians and other professionals.

5. Medical Expert Systems and the First Amendment

Communications that have serious literary, artistic or scientific value, and political speech, are protected under the First Amendment. The extent to which medical information systems provide scientific communication and expression that is protected by the First Amendment has yet to be addressed, but manufacturers of medical information systems and medical expert systems are in some form providing the public with knowledge and their products and systems are in some ways expressions of thoughts and ideas, so it is possible to see an analogy between medical expert systems and books or other means of expression of human knowledge. One commentator has noted that people purchase expert systems not for the information the system contains but for the way in which it processes that information and makes it available in a useable format. Thus, expert systems closely resemble informative books and manuals, especially “how-to” books, which are generally purchased not for the aesthetic value of the print or the binding, but rather for the information contained in them [Lamkin 1994].

Courts have already addressed the question regarding the protection of ideas expressed in books. In particular, in one case, a nursing student treated herself for constipation using the instructions published in a medical textbook and suffered injury. The instructions published were defective and the nursing student sued the publisher.⁵⁴ The Court made a correct distinction between facts and ideas. In fact, as we have seen, courts have applied strict liability to the narrow area of published maps or charts,⁵⁵ assuming that a nautical chart or an airline chart is similar to other instruments of navigation such as a compass or radar finder which, when defective, can prove to be dangerous. However, “no case has extended Section 402A to the dissemination of an idea or

⁵⁴ Jones v. J.B. Lippincott Co., 694 F. Supp. 1216; 1988 U.S. Dist. LEXIS 10334; 15 Media L. Rep. 2155.

⁵⁵ Brocklesby v. United States, 767 F.2d 1288 (9th Cir. 1985); Saloomey v. Jeppesen & Co..

knowledge in books or other published material. Indeed to do so could chill expression and publication, which is inconsistent with fundamental free speech principles.”⁵⁶

One commentator argues that, like handbooks for physicians, medical expert systems are used to prescribe treatment for a known disease and so regulating medical expert systems chills expression and therefore violates the fundamental right to free speech [Nguyen 1994]. Obviously, this reasoning cannot apply to system malfunctions, like bugs that cause injuries to patients: in that case, product liability rules may apply. Moreover, we should point out that in a complex system, we must distinguish between “data” and “reasoning”, and only products involving the latter could find protection under the First Amendment. However, Lamkin notes that, “while First Amendment concerns are important and vital in the area of publisher liability generally, the special nature of expert systems makes First Amendment concerns in that area unwanted,” arguing that they “do not generally add to the store of knowledge and thus encourage the free flow of ideas, but rather provide an efficient means of processing information that already exists” [Lamkin 1994].

6. Potential issues

The unknown is always a source of fear. Perhaps this is the reason why so many people predicted catastrophes in the early years of computing. Fortunately, recent history has shown that the number of terrible accidents caused by defective computer systems is not high, especially if compared with the number of systems in use; we should learn, however, from the experiences of the past years. In fact it is clear that, today as in the past, problems arise not from bad ‘thinking machines’ that could rule the world and take control of our lives, but, simply, from bad products. Therac-25 is one of the ‘best’ examples in the medical field: the deaths and injuries caused by this machine could have been avoided through a serious and extensive testing process. The upshot is that the general attention toward (too) stringent liability rules, such as product liability, is not justified because it is missing the point. The false fear is that, without really strong *ex post* rules, people’s safety could be at risk. However, the manufacturer of Therac-25, which was not scared by the possible application of strict product liability rules, could easily have been sued for negligence to pay for its mistakes. Paying too much attention only to the application of strict product liability for defective medical devices is not useful enough. Currently, attention should be mainly focused on rules that prevent damage from happening in order to save as many human lives as possible; if these rules fail, or they are not respected, than compensation for damages should be possible in most cases, even without applying strict product liability.

In any case, it is clear that bad products, whether simple or complex, may be dangerous; however, even good products, outdated, misused or used for purposes for which they were not initially contemplated, may be dangerous too. The case of the failure of the U.S. Patriot missile system during the Gulf War, which led to the deaths of 28 U.S. servicemen, showed that the ‘defective’ part of the system was developed in the Sixties and that the intended use of the system was to shoot down aircraft, not missiles [Forester 1994]. This example teaches us that we must be very careful when looking at responsibilities: “the poor old computer gets the blame on these and other occasions, although frequently something else is at fault” [Forester 1994].

Furthermore, the example just given shows that only “the poor old computer” is expected to work without any problem for decades, even if it is used beyond its capabilities. In fact, the common perception of the age appears to differ for different categories of products: nobody would seriously argue that a car built in the Sixties is safer and more effective than a car built in the Nineties and that the former should still work just as well after forty years. Why should different expectations apply to software and computer systems? This is even stranger when we consider that the evolution of computer science has been incredibly rapid in the past few decades, even in sectors like artificial intelligence in which the high expectations of the Sixties have not been realised. Several years ago, and sometimes still today, the major interest was in substituting - not merely supporting - people generally and health care professionals specifically. In this sense, the role of computers was understood as them replacing the human doctor with a ‘computer doctor’, replacing the human judge

⁵⁶ Jones v. J.B. Lippincott Co..

with a 'computer judge' and so on. It was too early. Even today, technology still has a long way to go to reach these difficult, fascinating and – at the same time – frightening goals; this step is still too big and “instead of one giant step forward, computerization may occur in a staged manner” [Bodenheimer 2003]. However, whereas some years ago the fear was of catastrophes resulting from the (future) over-high intelligence of computer systems, it now seems that the fear is of dangers stemming from their stupidity: as many businesses have learnt to their own expense since the Sixties, “computers are not the solution to every problem” [Miller 1985].

Another constant fear regards the fact that software cannot be made totally reliable, which is true; however, it can be made *reasonably* reliable. Thus, products that might endanger people's safety should be extensively tested and include backup options in case something goes wrong. The more dangerous a product, the more extensive and complete the testing of it should be, and the more sophisticated and extensive its backup functions.

7. Open questions

Advanced medical computer programs and expert systems may help health care professionals to respect the principles of beneficence (i.e. doing good) and non-maleficence (i.e. avoiding doing harm), but computer programs should only be used in medical practice if they improve the quality of care at an acceptable cost in terms of time or money, or if they maintain previous standards of care at a reduced cost in time or money [Szolovits 1979]. The criteria proposed by Miller et al. provide a useful point of reference for defining the concept of “improved quality of care”: “improved diagnostic accuracy”, “improved therapeutic results”, “a better patient sense of well-being”, “easier and more rapid access to patient information via better record-keeping systems”, “better representation of facts in medical records and better documentation of the reasons for physicians' actions” [Miller 1985].

However, putting these principles into practice is not always easy, partly because the advance of technology sometimes blurs the borderline between benefits and harms: for instance by reducing errors but slowing the time of certain operations. In addition, many choices will remain ones of policy, which is the province of policy makers: throughout the world, even in rich countries, the health care sector suffers from a general lack of funds, and so advanced technologies that can save many lives cannot be widely adopted if they are too expensive.

In fact, money is one of the great problems in health care, and the fear of lawsuits can discourage serious innovations and/or raise costs, particularly because today, even after extensive testing, it is impossible to predict the legal consequences of malfunctions, real or presumed, of new technologies. This uncertainty works against the interests of both health care professionals and consumers more than against manufacturers. This is not a paradox. Manufacturers are not charity organizations: if they can make money without risking too much, they will be happy to continue with a slow development process in the field of medical devices, waiting for the first “innovative” step of their competitors. Health care professionals, on the other hand, stand to benefit greatly from their work by making fewer mistakes and reducing the outrageous number of cases of medical malpractice. Finally, consumers can benefit from an improved quality of health care. However, politicians are unlikely to make choices that could easily lead to their unpopularity, especially in these troubled years, and so the situation is unlikely to change until the courts have the opportunity to create the law for such cases.

In the meanwhile, it is easy to claim that health care should be modernized and more computerized through reliable software and devices. However, much investment is needed to do this. The lack of standards does not help achieve this task and the necessity of common standards is clear; the problem is that many different and advanced machines are not capable of communicating and working together. In simple words, they just do not speak the same language. Obviously, the more complex the machines, the more complicated it will be to make them cooperate. Connections between different systems have been a giant step for the spread of computing: it is difficult today to think to a world without Internet and without the other types of connection that enable many different devices (computers, PDAs, cell phones, mp3 players, etc.) to communicate. In the near future, a highly complex “smart” system could greatly improve health care: if many different systems can work

together and interact, many tasks can be made fully automatic. Hopefully, we will not have to wait long to have minimum standards in this field.

Another hope is that the FDA approval process for Class III devices be changed: as has been shown, the 510(k) process is not sufficient to ensure the safety and effectiveness of new devices and the possibility of selling potential Class III devices via this process is no longer acceptable. As Adler notes, “consumers will face unnecessary risks from devices that may have reached the market using twenty- or thirty-year old technology” [Adler 1988]. However, this change requires providing the FDA with more funding: its resources are not sufficient to properly investigate all the submissions it receives, and this brings us back to the field of politics. This change is necessary: uncovering the existence of defects in medical computer software can be very difficult; furthermore, the complexity of new systems requires more careful testing before their use, so policy needs to be changed and the pre-market approval processes need to become less bureaucratic and more effective.

8. Conclusion

Safety has a cost. On the one hand, manufacturers of medical devices who choose the easiest, fastest and cheapest methods should be strictly liable for damages that their defective products may cause. On the other hand, manufacturers of medical devices that follow legal and professional rules to ensure the safety and effectiveness of their products should not be liable under section 360 (k) of the MDA. This middle-of-the-road approach could be a good way of protecting both manufacturers and consumers, by striking a correct balance between their interests. A case-by-case analysis is probably the best way to ensure the best balance and, also, negligence may still be a good way to hold manufacturers liable for their defective computer programs. Their conduct should be compared with the conduct of a reasonable manufacturer of that particular type of product. Obviously, a margin of uncertainty will always remain, but hopefully it will not be as huge as it is today.

References

- [ADLER 1988] Adler R., The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction. *Food Drug Cosmetic Law Journal* 1988; 43(3):511-532
- [ALI 1965] American Law Institute, Restatement of the Law Second, Torts 2d. St. Paul, MN, American Law Institute Publishers, 1965
- [ALI 1998] American Law Institute, Restatement Third, Torts: Product Liability. St. Paul, MN, American Law Institute Publishers, 1998
- [ALLEN 2001] Allen A.S., *Weiland v. Telectronics Pacing Systems, Inc.*: Illinois Reexamines Medical Device Preemption. *Indiana Law Journal* 2001; 76:443-463
- [BALLMAN 1996] Ballman D.R., Software Tort: Evaluating Software Harm by Duty of Function and Form, *Connecticut Insurance Law Journal* 1996; 3: 417
- [BODENHEIMER 2003] Bodheneimer T., Grumbach K., Electronic Technology. A Spark to Revitalize Primary Care?. *Journal of the American Medical Association* 2003; 290(2):259-264
- [BOVEE 2001] Bovee M. W., Paul D.L., Nelson K.M., A Framework for Assessing the Use of Third-Party Software Quality Assurance Standards to Meet FDA Medical Device Software Process Control Guidelines. *IEEE Transactions on Engineering Management* 2001; 48(4):465-478
- [BRANNIGAN 1981] Brannigan V.M., Dayhoff R.E., Liability for Personal Injuries Caused by Defective Medical Computer Programs. *American Journal of Law & Medicine* 1981; 7(2):123-144
- [BRANNIGAN 1987] Brannigan V., The Regulation of Medical Expert Computer Software as a "Device" under the Food, Drug, and Cosmetic Act. *Jurimetrics* 1987; 27(4):370-382
- [BRENNAN 2009] Brennan D., Federal Preemption of all State Law Tort Claims in Riegel v. Medtronic: A Need to Undo a Serious Wrong. *Western State University Law Review* 2009; 36:137-171.
- [BRONZINO 1990] Bronzino J.D., Smith V.H., Wade M.L.. Medical Technology and Society: An Interdisciplinary Perspective. Cambridge, Massachusetts – London, England, MIT Press, 1990
- [CDRH 2002] Center for Devices and Radiological Health, General Principles of Software Validation; Final Guidance for Industry and FDA Staff. 2002 <http://www.fda.gov/cdrh/comp/guidance/938.html>
- [COLE 1990] Cole G.S., Tort Liability for Artificial Intelligence and Expert Systems. *Computer Law Journal* 1990; X(2):127-231
- [CONK 2000] Conk G.W., Is there a design defect in the Restatement (Third) of Torts?. *Yale Law Journal* 2000; 109(5):1087
- [CONLEY 1987] Conley J.M., Tort Theories of Recovery Against Vendors of Defective Software. *Rutgers Computer & technology Law Journal* 1987; 13(1):1-32
- [COOPER 1970] Cooper T et. al. (Study Group on Medical Devices), Medical devices: a legislative plan. Rockville, MD, U.S. Department of Health, Education, and Welfare, 1970
- [CRUMPLER 1997] Crumpler E.S., Rudolph H., FDA Software Policy and Regulation of Medical Device Software. *Food and Drug Law Journal* 1997; 52(4):511
- [CUPP 2002] Cupp R.L. Jr., Polage D., The Rhetoric of Strict Products Liability Versus Negligence: An Empirical Analysis. *New York University Law Journal* 2002; 77(4):874
- [Curfman 2009] Curfman G.D., Morrissey S., Drazen J.M., The Medical Device Safety Act of 2009. *The New England Journal of Medicine* 2009; 360(15):1550
- [DESAI 2002] Desai et al., Information Technology Litigation and Software Failure. *The Journal of Information, Law and Technology* 2002(2): http://www2.warwick.ac.uk/fac/soc/law/elj/jilt/2002_2/desai/
- [DOBBS 2001] Dobbs D.B., The Law of Torts. St. Paul, MN, West Group, 2001
- [DREIER 1999] Dreier W.A., Manufacturer's Liability for Drugs and Medical Devices Under the Restatement (Third) of Torts: Products Liability. *Seton Hall Law Review* 1999; 30(1):258-264
- [FISCHER 2002] Fischer D.A. et al., Products Liability. Cases and Materials, West Group, St. Paul, MN, 2002

- [FORESTER 1994] Forester T., Morrison P., Computer Ethics. Cautionary Tales and Ethical Dilemmas in Computing. Cambridge, Massachusetts – London, England. MIT Press 1994
- [FREED 1976] Freed R.N., Computers and Law. A Reference Work. Powers & Hall, Boston, MA, 1976
- [FREED 1977] Freed R.N., Products Liability in the Computer Age, *Jurimetrics* 1977; 17:270
- [FRUMER 2004] Frumer L.R., Friedman M.I.. Products Liability. Newark, NJ. Matthew Bender, 2004 (1960)
- [GABLE 2001] Gable J.K. An Overview of the Legal Liabilities Facing Manufacturers of Medical Information Systems. *Quinnipiac Health Law Journal* 2001 5:127-151
- [GANSKE GRAZIANO 1991] Ganske Graziano S., Computer Malpractice – A New Tort on the Horizon?. *Rutgers Computer and Technology Law Journal* 1991; 17(1): 177-187
- [GARNER 2004] Garner B.A. (editor), Black's Law Dictionary. Thomson West, St. Paul, MN, 2004
- [GEMIGNANI 1981] Gemignani M.C., Product Liability and Software. *Rutgers Computer & technology Law Journal* 1981; 8(2):173-204
- [GOLDBERGER 2001] Goldberger B.A., The Evolution of Substantial Equivalence in FDA'S Premarket Review of Medical Devices. *Food and Drug Law Journal* 2001; 56(3):317-337
- [GREEN 2000] Green M.D., Schultz W.B., Tort Law Deference to FDA Regulations of Medical Devices. *Georgetown Law Journal* 2000; 88(7):2119-2145
- [HENDERSON 2001] Henderson J.A. Jr., Twerski A.D., Drug Designs Are Different. *Yale Law Journal* 2001; 111(1):151-181
- [JOHNSON 2005] Johnson V. R., Gunn A.. Studies in American Tort Law. Durham, NC, Carolina Academic Press, 2005
- [KAHAN 1984] Kahan J.S., Premarket Approval versus Premarket Notification: Different Routes to the Same Market. *Food Drug Cosmetic Law Journal* 1984; 39(4):510-525
- [KAHAN 2009] Kahan J.S., Medical Device Development: Regulation and Law. Parexel and Barnett, Needham, MA, 2009
- [KOHN 2000] Kohn L.T., Corrigan J.M., Donaldson M.S. (editors). To Err is Human: Building a Safer Health System, Washington, DC, National Academy Pres, 2000
- [KUTTEN 2004] Kuten L.J.. Computer Software. Protection/Liability/Law/Forms. Thomson West, St. Paul, MN, 2004
- [LAMKIN 1994] Lamkin B.H., Medical Expert Systems and Publisher Liability: a Cross-Contextual Analysis. *Emory Law Journal*, 1994; 43: 731-770
- [LANOUE 1983] Lanoue S., Computer Software and Strict Products Liability. *San Diego Law Review* 1983; 20(2): 439-456
- [LAWRENCE 1987] Lawrence D.B., Strict Liability, Computer Software and Medicine: Public Policy at the Crossroads. *Torts & Insurance Law Journal* 1987; 23(1):1-18
- [LEFLAR 1989] Leflar R.B., Public Accountability and Medical Device Regulation. *Harvard Journal of Law & Technology* 1989; 2: 1-84
- [LEVESON 1993] Leveson N., Turner C.S., An Investigation of the Therac-25 Accidents. *IEEE Computer* 1993; 26(7): 18-41
- [MCLEAN 2002] McLean T.R., Cybersurgery – An Argument for Enterprise Liability. *Journal of Legal Medicine* 2002; 23:167-210
- [MILLER 1985] Miller R.A., Schaffner KF, Meisel A. Ethical and Legal Issues Related to the Use of Computer Programs in Clinical Medicine. *Ann Intern Med.* 1985; 102:529 36
- [MILLER 1989] Miller R.A., Legal Issues Related to the Use of Medical Decision Support Systems. *International Journal of Clinical Monitoring and Computing.* 1989; 6:75 80
- [MILLER 1997a] Miller R.A., Gardner R.M., Summary Recommendations for Responsible Monitoring and Regulation of Clinical Software Systems. *Ann Intern Med.* 1997. 127(9):842-45
- [MILLER 1997b] Miller R.A., Gardner R.M., Recommendations for Responsible Monitoring and Regulation of Clinical Software Systems. *J Am Med Inform Assoc.* 1997. 4(6):442-457
- [MORTIMER 1989] Mortimer H., Computer-Aided Medicine: Present and Future Issues of Liability. *Computer/Law Journal* 1989; 9(2):177-203

- [NGUYEN 1994] Nguyen F.D., Regulation of Medical Expert Systems: a Necessary Evil?. *Santa Clara Law Review*, 1994; 34: 1187-1206
- [NIMMER 1986] Nimmer R., Krauthaus P.A., Computer Error and User Liability Risk. *Jurimetrics* 1986;26(2):121-137
- [ODE 1998] Office of Device Evaluation, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, 1998
- [ODE 1999] Office of Device Evaluation, Off-The-Shelf Software Use in Medical Devices, 1999 <http://www.fda.gov/cdrh/ode/guidance/585.pdf>
- [ODE 2004] Office of Device Evaluation, Annual Report. Fiscal Year 2004. <Http://www.fda.gov/cdrh/annual/fy2004/ode/2004.pdf>
- [ODE 2005] Office of Device Evaluation, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, 1995 <http://www.fda.gov/cdrh/ode/guidance/337.pdf>
- [ODE 2008] Office of Device Evaluation, Annual Performance Report. Fiscal Year 2008. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM199014.pdf>
- [OWEN 2000] Owen D.G., Madden M.S., Davis M.J., Madden & Owen on Products Liability. West Group, 2000
- [OWEN 2005] Owen D.G., Products Liability Law. St. Paul, MN, Thomson West, 2005
- [PRINCE 1980] Prince J., Negligence: Liability for Defective Software. *Oklahoma Law Review* 1980; 33(4):848-855
- [PROSSER 1984] Prosser W.L., Keeton W.P., Prosser and Keeton on Torts. St. Paul, MN, West Publishing Co., 1984
- [RIEDERS 2004] Rieders S.B., State Tort Law Claims and the FDA: Proposing a Consumer-Oriented Prescription in Medical Device Cases. *Cardozo Law Review* 2004; 25(3):1159-1202
- [SAVAGE 1998] Savage D.W., Avoiding Tort Claims for Defective Hardware & Software. 1998 <http://library.findlaw.com/1998/Oct/1/128551.html>
- [SCANDAGLIA 2004] Scandaglia G.J., Tully T.L., Express Preemption and Premarket Approval Under the Medical Device Amendments. *Food and Drug Law Journal* 2004; 59(2):245-264
- [SCHWARTZ 1970] Schwartz W.B., Medicine and the Computer. The Promise and Problems of Change. *New England Journal of Medicine* 1970; 283(23):1257-1264
- [SCHWARTZ 1987] Schwartz W.B., Patil R.S., Szolovits P., Artificial Intelligence in Medicine: Where Do We Stand?. *New England Journal of Medicine* 1987; 316:685-688
- [SCOTT 2005] Scott M.D., Scott on Computer Law. Aspen, New York, 2005
- [SENFT 2004] Senft D.M., Surgically Implanted Medical Device Liability: Will the New Restatement Help the Unraveling Shield created by *Medtronic, Inc. v. Lohr*?. *University of Baltimore Law Review* 2001; 30(2):389-429
- [SHAPO 2001] Shapo M.S., The Law of Products Liability. Chicago, IL, CCH, 2001
- [SZOLOVITS 1979] Szolovits P., Pauker S. G., Computers and clinical decision making: Whether, how, and for whom?. *Proceedings of the IEEE* 1979; 67:1224-1226
- [TUMIDOLSKY 1998] Tumidolsky R., How *Medtronic v. Lohr* Has Redefined Medical Device Regulation and Litigation. *Defense Counsel Journal* 1998; 65(2):268-276
- [VANDALL 1997] Vandall F.J., Constructing a Roof Before the Foundation is Prepared: the Restatement (Third) of Torts: Products Liability Section 2(b) Design Defect. *University of Michigan Journal of Law Reform* 1997; 30(2/3):261-279
- [WILSON 1995] Wilson C.H.Jr., Winning Techniques for: Computer and High Tech Litigation. The Growth Field of the Information Age. Lawyers & Judges Publishing Co., Tucson

