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Legal aspects of providing naloxone to heroin users in the United States

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Abstract

Administration of naloxone hydrochloride is the standard treatment for heroin overdose. Naloxone is simple to administer, effective and has a very low risk of harm. Prescribing naloxone to heroin users for later use in case of need is a simple, inexpensive harm-reduction measure that has the potential to reduce mortality from heroin overdose. Some physicians in the USA may be discouraged from distributing naloxone, however, by legal concerns. A legal analysis finds that the legal risks are low. Prescribing of naloxone in the USA is fully consistent with state and federal laws regulating drug prescribing. The risks of malpractice liability are consistent with those generally associated with providing healthcare, and can be further minimized by following simple guidelines presented.

Keywords: Harm reduction; Drug users; Overdose; Heroin; Physicians; Prevention programs

Introduction

Heroin overdose deaths have increased dramatically in the United States during the past two decades. Overdose deaths are usually preventable. Most overdoses are witnessed, providing a window of opportunity for intervention. Naloxone hydrochloride, an injectable opiate antagonist, is routinely used by emergency medical personnel to rapidly and safely reverse opiate-induced respiratory depression. Programs instituted in various parts of the world, including the US state of New Mexico, have begun distributing naloxone hydrochloride to heroin users as a simple, inexpensive measure with the potential to reduce mortality from heroin overdose. Some physicians and health agencies in the USA may be discouraged from distributing naloxone, however, by uncertainty about its legality or the risk of malpractice suits, for naloxone distribution is a new intervention in

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a politically charged context. This article considers the legality of distributing naloxone to heroin drug users in the United States, and concludes that prescribing naloxone would not expose physicians to an unusual risk of legal liability. This article also recommends measures to minimize the risk of liability associated with naloxone distribution, while improving the potential to reduce overdose mortality.

Heroin overdose: a significant cause of preventable mortality in the United States

Mortality from heroin overdose

Overdose is a large and growing public health problem. The average annual mortality rate among regular heroin injectors is 2%, a rate between six and 20 times that for non-drug-using age-peers (Sporer, 1999). Half of this mortality rate is attributed to overdose (Sporer, 1999). Heroin overdose was implicated in more than 3800 deaths nationwide in 1993 (Heroin Abuse in the United States, 1997; Sporer, 1999), and rates of overdose, and overdose mortality are rising. Between 1990 and 1996, emergency room visits related to heroin doubled, from 33,900 to 70,500 (Greenblatt, 1997; Sporer, 1999). A recent study of overdose mortality in 25 American cities of various sizes found that between 1988 and 1997, the rate of overdose deaths from heroin increased from 8.7 per 100,000 population in 1988 to 13.8 in 1997. The number of heroin overdose deaths in these cities jumped from 2460 to 3780 (Drucker and Garfield, 2000).

Naloxone: an effective medical intervention

Death from overdose is usually the direct result of respiratory failure (Darke et al., 1996a). Heroin binds to the Mu_2 receptors in the brain stem, and renders it insensitive to the build-up of CO_2 in the blood, so that breathing mechanisms are not triggered (Sporer, 1999). Signs of overdose include diminished breathing, cyanosis (blue skin color), and loss of consciousness (Darke et al., 1996a; Darke and Zador (1996), Sporer, 1999). It is estimated that most victims die between 1 and 3 hours after injection, a time interval that allows for medical intervention (Manning et al., 1983; Darke and Hall, 1997; Sporer, 1999).

Treatment with naloxone can reverse respiratory failure within a few minutes (Darke and Hall, 1997; Physician's Desk Reference, 2000). Naloxone is an opiate antagonist, and is thought to displace heroin at the Mu_2 receptors. Physicians and emergency personnel treat patients suspected of heroin overdose by administering an initial dose of naloxone parenterally. While 2 mg is almost always sufficient to revive a patient, additional doses can be administered if the desired improvement does not occur, and smaller doses are often used to minimize the discomfort of sudden heroin withdrawal (Physician's Desk Reference, 2000). In adults, naloxone has a half-life of between 30 and 81 minutes (Physician's Desk Reference, 2000). Therefore, repeated administration could be necessary to reverse the effect of particularly large or long-lasting doses of heroin (Sporer, 1999; Physician's Desk Reference, 2000). In practice, however, a single 2-mg dose is almost always sufficient. If a patient has not taken opioids, naloxone has no pharmacological effect (Darke and Hall, 1997).

While administration of naloxone may produce acute withdrawal symptoms in patients with heroin dependence (Physician's Desk Reference, 2000), the drug does not have long-term or life threatening adverse effects when it is administered at therapeutic

doses (Strang et al., 1996). Naloxone has been associated with complications such as seizures and arrhythmia (Physician's Desk Reference, 2000), but more recent research suggests that complications are exceedingly rare, that past reports of complications may have been erroneous (Goldfrank and Hoffman, 1995), or that complications occur, if at all, in patients with pre-existing heart disease (Goldfrank and Hoffman, 1995). Naloxone is not addictive, and has no psycho-pharmacological effects.

Overdose mortality and the failure to seek medical assistance

Individuals usually overdose in the presence of other users, often close friends, who ideally would be willing and able to contact emergency medical services for assistance (Darke et al., 1996b; Sporer, 1999; Strang et al., 1999). Studies indicate that most users are familiar with the signs of overdose (Darke et al., 1996b). While many deaths from overdose could be averted if medical assistance were solicited, users present at the scene of an overdose often refrain from calling for help. According to an Australian study, nearly half of heroin users who reported having witnessed a heroin overdose said that they did not call an ambulance (Darke et al., 1996b; Darke and Hall, 1997). In the case of fatal overdoses, companions sought medical assistance in only 10% of cases (Zador et al., 1996). Subjects in the study reported that a major factor that deterred them from seeking medical assistance was fear of police involvement, entailing confiscation of drugs or even arrest (Darke et al., 1996b). A Medline search yielded no comparable American studies, but an unpublished survey of 82 heroin users in the San Francisco area reported that only 51% called the emergency 911 number the last time they witnessed an overdose (90% reported trying various street remedies), and by far the most common reason was fear of law enforcement authorities (Seal et al., 2000). Anecdotal evidence suggests that American drug users also refrain from calling 911 out of fear of police intervention (Giuliano, 1999).

These fears are not far-fetched. In many states, drug users who call for assistance are subject not only to arrest for drug possession, but also to murder charges if they are suspected of supplying the drugs used in a fatal overdose (Rambo, 1986; Hull, 1998; Ariz Rev Stat Ann. §13-1105; Conn Gen stat. §53a-54b(6), Fla Stat Ann. §782.04; Nev Rev Stat. §200.010; Tenn Code Ann. §39-2-211(b)). Concerned with the problem, the California Medical Association passed a resolution in 2000 stating that law enforcement and emergency medical services agencies should adopt and publicize policies to encourage persons to call 911 in response to illicit drug overdose, and to minimize the risk of subsequent police involvement (Drug Treatment Reform Resolutions, 2000).

Take-home naloxone as an alternative means of treatment

Encouraging users to call 911 in case of overdose is an essential method of reducing mortality, for there is no substitute for trained medical attention. In many regions, police practices will have to change substantially before users may call 911 without risking legal repercussions. The longstanding distrust of heroin injectors toward public authorities is likely to present an additional obstacle. It may not always be feasible to obtain medical help immediately. Distributing take-home naloxone represents an alternative, and complementary strategy for reducing mortality from heroin overdose.

In a naloxone distribution program, health educators or physicians would train heroin injectors, individually or in injecting partnership pairs, to treat peers with naloxone in case of overdose. Injectors would also be trained in other resuscitation techniques, particularly rescue breathing and, if feasible, CPR. Injectors would be advised of the importance of calling 911, even after naloxone is administered, and trained on how to talk to 911 personnel so as to solicit assistance while minimizing the risk of police involvement. Physicians would then prescribe naloxone and syringes to injectors, and possibly supervise injectors as they prefill and store the syringes. Naloxone is also available in pre-filled syringes in the United States and many other countries.

There are no published evaluations of a naloxone distribution program, but preliminary studies and anecdotal reports are promising. In Italy, naloxone is distributed over-the-counter with no reported problems (Campana, 2000). In a London-based study of heroin injectors, Strang and colleagues estimated that two-thirds of the overdose deaths witnessed by their respondents could have been avoided if the users had been provided with a take-home supply of naloxone (Strang et al., 1999). The concept of naloxone distribution was acceptable to the drug users surveyed, 70% of whom stated that distributing take-home naloxone to reduce mortality from overdose was a "good" or "very good" idea (Strang et al., 1999).

Naloxone is easy for injection drug users to administer, and poses little risk of harm. Some have expressed concern, however, that possession of naloxone may prove counterproductive by encouraging dangerous behavior. It has been suggested that individuals with access to naloxone may inject more heroin than they otherwise would, knowing that they have an immediate antidote, or that they may delay calling 911 when a companion overdoses. There is also concern that a user revived with a dose of naloxone will inject more heroin to overcome the sudden withdrawal effect, leading to an even more serious overdose when the naloxone wears off. Deaths have occurred, although rarely, after naloxone was administered in a non-hospital setting and the ambulance left (Vilke et al., 1999; Darke et al., 2000), which speaks to the need to ensure both good general education in a distribution program and for clear discussion of the effects of the medication after it has been administered, particularly if the patient is not to be hospitalized. Survey data indicate that few drug users would use more heroin if they knew naloxone was at hand, if only because of the unpleasantness of sudden withdrawal (Darke and Hall, 1997; Strang et al., 1999). Nor is premature re-injection a reported problem among overdose patients treated with naloxone by first responders and released without hospitalization (Vilke et al., 1999). All these risks can be addressed to some extent in the education component of the intervention, and should be monitored in any evaluation.

The low risk and likely value of naloxone availability have prompted health providers in Europe and the United States to begin providing take-home naloxone to heroin users. A British medical team is currently preparing to introduce an overdose fatality prevention program involving naloxone distribution (Strang et al., 1999). Some US physicians and public health workers have also initiated naloxone distribution programs. The first large-scale naloxone prescription program in the United States began early in 2001, when physicians began prescribing naloxone in pre-filled syringes to heroin-injecting patients in Rio Arriba

County, a sparsely populated rural area in northern New Mexico that has the highest heroin overdose death rate in the US. Prescription is preceded by patient education about administration, calling 911, and the half-lives of different drugs. The intervention was developed over a 9-month period by a heroin overdose task force convened by the state Secretary of Health. The task force met with and educated physicians, law enforcement officials and political leaders. Physician response was very positive, and implementation has so far proceeded without reported legal or medical problems (Katharine Huffman, Personal communication, 2001).

Although take-home naloxone is a promising intervention, concern about legal liability may discourage physicians from prescribing the drug for this use. As the remainder of this article will discuss, US physicians would not incur significant increased liability for prescribing naloxone to heroin users. The analysis may also provide a starting point for physicians in other jurisdictions to investigate their legal risks.

Legality of naloxone distribution in the United States

Current legal status of naloxone

Naloxone is currently approved by the Food and Drug Administration as a prescription drug (U.S.C., 1999; Physician's Desk Reference, 2000). Naloxone is not a controlled substance, i.e. a psychotropic substance whose distribution is subject to additional state and federal restrictions, including criminal penalties for improper prescription (Shulgin, 1992). Its FDA labeling clearly contemplates use in the hospital, under medical supervision (Physician's Desk Reference, 2000). At present, over-the-counter distribution of naloxone is prohibited under federal law (U.S.C., 1999).

Feasibility of over-the-counter licensing

The most effective route to providing naloxone to injectors at risk of overdose would be to have the Food and Drug Administration (FDA) reclassify naloxone as an over-the-counter medication. Over-the-counter distribution would make naloxone accessible to a broad segment of the user community, and would enable grassroots organizations to distribute the drug.

Naloxone could probably be shown to fulfill all the criteria set out under the Food, Drug, and Cosmetic Act for over-the-counter sale. The FDA licenses drugs for over-the-counter distribution if they are effective, not misbranded, and safe for consumer use without professional supervision (21 C.F.R. §330.10(a)(4)(vi, 310.200; F.D.A. Bulletin, 37 Fed. Reg. 16,503). The product must produce significant relief for a significant percentage of those who use it in accordance with a label bearing adequate directions and warnings. It must also produce a low rate of adverse reactions, and have a low potential for harm from possible abuse.

In practice, however, changing the status of a drug from prescription to over-the-counter entails a lengthy application procedure. Gathering data to support the switch can cost millions of dollars. Because the patent has expired, no pharmaceutical company has the financial interest in making this investment. Furthermore, over-the-counter licensing might be politically volatile, and public reaction might further complicate the licensing process. In the immediate future, distribution by prescription

is probably more practical than switching the licensing status of naloxone.

Legality and feasibility of distribution by prescription

Although the requirement of a prescription may limit access, it also provides physicians with a propitious opportunity to ensure that users are educated about safe methods of administration, as well as to offer counseling and testing for HIV and hepatitis C, prescribe sterile injection equipment (Burris et al., 2000) and offer referrals for drug treatment and other services. If a drug is distributed by prescription, a physician is responsible for complying with federal and state medical practice and drug-distribution rules. To avoid liability for malpractice, the physician must also refrain from causing injury to a patient by failing to observe professional standards of care.

Compliance with federal law on prescribing drugs for off-label uses

The FDA-approved label indicates that naloxone was licensed with the expectation that it would be administered under physician supervision in a clinical setting. (In practice, it is routinely given by paramedics in the field, operating under standing orders from physicians who are neither on site nor directly supervising.) There is no legal bar, however, to prescribing drugs for uses not specified on the label. Federal law affords physicians considerable discretion to prescribe drugs for off-label uses, and such prescriptions are a routine part of medical practice (F.D.A. Bulletin, 37 Fed. Reg. 16,503; United States v. Evers, 1981). In the absence of any explicit prohibition on prescribing naloxone for home use, physicians should be free to do so as far as federal law is concerned.

Compliance with state prescription laws and regulations

State laws usually do not explicitly limit the power of physicians to prescribe drugs other than controlled substances. There is virtually no case-law discussing physicians' general authority to prescribe drugs and devices, which probably reflects the fact that physicians' discretion is broad, well-established and rarely contested. State laws specifically regulating the prescription of controlled substances, and the laws governing medical licensure, however, do provide insight into prescription practices considered legitimate, and provide a standard for assessing the legality of naloxone prescription. Prescribing naloxone to a heroin injector at risk of overdose would not violate state law as long as the physician acts (1) in good faith; (2) in the course of professional practice; and (3) for a legitimate medical purpose.

To meet the good faith standard, the physician must have an honest, bona fide medical purpose, and must prescribe the drug out of concern for the patient's well-being, rather than with the goal of profiting, or of harming the patient (People v. Nunn, 1956; People v. Goldberg, 1975; In the Matter of DiLeo, 1995). A physician demonstrates good faith in providing naloxone to heroin injectors, if he or she does so with the sincere aim of preventing mortality from overdose.

A prescription dispensed "in the course of professional practice" is dispensed to further the medical treatment of a patient (People v. Nunn, 1956; Anderson v. State, 1973; People v. Goldberg, 1975). In determining whether a prescription arises within the usual course of professional practice, courts normally consider such indicia as whether a bona fide physician–patient relationship existed, whether other care was provided, whether proper records were kept of the encounter,

whether the prescription was based on a proper history or individualized assessment of the patient's risk factors, efforts to provide other harm reducing services, follow-up and so on.

A legitimate medical purpose is one that accords with accepted treatment principles, and one that is consistent with techniques and approaches endorsed by a responsible segment of the physician population (Commonwealth v. Possinger, 1979; Commonwealth v. West, 1979). Unanimity among the medical community as a whole is not required (Glover v. Board, 1991). The therapeutic value of naloxone in reversing the effects of overdose is clearly established (Sporer, 1999; Physician's Desk Reference, 2000). Although prescribing naloxone to heroin users constitutes a new intervention, a segment of the medical and public health communities does support naloxone prescription as a means of reducing fatality from heroin overdose (Strang et al., 1996; Physician's Desk Reference, 2000).

Risk of malpractice liability

In order to win a tort suit, a plaintiff must prove that (1) the physician's failure *to meet the professional standard of care* (2) *caused an injury*. The plaintiff must also establish that the defendant physician (3) had a *duty* to avoid harming the plaintiff, and must negate any defenses to liability the defendant may raise.

Standard of care

A physician is required to practice his or her profession in a reasonably competent manner. Particular conduct is assessed by reference to the customary behavior of the relevant segment of the profession under the same or similar circumstances, which is said to establish the "standard of care" (Paintiff v. City of Petersburg, 1986Restatement (Second) of Torts, §282, 1993). Because physicians often behave differently in the same or similar circumstances, the standard of care is not unitary. Practices adopted by a "respectable minority" of physicians are routinely found to meet the standard of care (Di Filippo v. Preston, 1961; Chumbler v. Mclure, 1974; Bellomy v. United States, 1995; Gala v. Hamilton, 1998). In all cases, the essence of the inquiry is whether the physician's treatment decisions were reasonable and consistent with accepted medical principles, considering all the circumstances. The medical standard of care is established by "expert testimony" from other physicians.

Newly emerging forms of treatment do not fit neatly into the usual analysis, because by definition their use does not represent the custom of the profession. Naloxone, of course, is unquestionably the drug of choice for overdose, but the question is whether prescribing the drug for self-administration is reasonable. Assuming that the patient is at risk of a fatal overdose, and is properly instructed in the administration and risks of the drug, a simple risk–benefit analysis would suggest that the physician's decision to prescribe was reasonable and not negligent (The T.J. Hooper, 1932). The reasonableness of the decision would be supported by the public health and clinical literature discussing take-home naloxone (Strang et al., 1996, 1999), and, in an actual case, by expert testimony from clinicians and public health experts. The case would get stronger as clinical and research evidence supporting safety and efficacy mounted; conversely, the prudent physician prescribing naloxone would be attentive to evidence that the practice was unsafe and would reconsider prescribing should such evidence appear. If the prescription of naloxone is reasonable, there can be no tort

liability even if the other elements of the case are established.

Injury caused by the physician

Every tort claimant must establish that he or she suffered an injury that was actually caused by the physician. The injured party may be the patient to whom the naloxone is prescribed, or a third party to whom the patient or another administers the drug. A suit may be brought by the individual who overdoses, if he survives on behalf of a deceased individual, or by an immediate family member, whose injury consists in the loss of consortium with the deceased or injured individual.

Naloxone administration in overdose can be associated with injury, though the risks of adverse effects from naloxone are small. A patient may suffer one of the rare side effects from the drug. If a user's companion improperly treats the user, and then fails to seek medical assistance in reliance on naloxone, brain damage or death may follow. Alternatively, a user may overdose after being revived with naloxone if the naloxone wears off and is not readministered, or if the user then injects more heroin. A plaintiff could also allege that the provision of naloxone led to delay or failure to summon medical help, leading to the "loss of a chance" to receive medical care (Martin v. East Jefferson Gen Hospital, 1990).

The analysis of causation in tort law mixes factual and value judgments. As a factual matter, tort doctrine requires the plaintiff to prove that the injury would not have occurred "but for" the defendant's unreasonable behavior. This will often be difficult to establish where the injury results from overdose, because at the moment naloxone was administered serious injury was already quite likely to happen. Where the injury is caused by side effects of naloxone, the causal connection is still somewhat tenuous: the behavior of the injured party, in overdosing on heroin, was an important causal factor that necessitated treatment with the drug. Injury was likely to be as severe, if not more so, had naloxone not been administered. It is not considered malpractice to prescribe a drug that carries a low risk of side effects, particularly if the patient is informed of the risk. Moreover, any judgement against a physician would be offset by past benefits that accrued to the plaintiff from the prescription, such as a prior successful overdose treatment (Restatement (Second) of Torts, §920, 1993).

Even in cases in which "but for" factual causation is established, the doctrine incorporates considerations of fairness, proportionality and common sense. A mere logical contribution to the injury is not enough to establish liability; the physician's actions must represent a major contributing factor to the injury (Murdoch v. Thomas, 1981; Roemer v. Martin, 1989). It is hardly fair to blame a physician for a harm primarily caused by a patient's decision to inject heroin, and indeed, courts have usually applied the rule of "superseding cause" to hold that people who voluntarily use dangerous or intoxicating drugs cannot blame others for the harm the drugs cause (Speer v. U.S., 1981; Hobart v. Shin, 1998). More broadly, judges may be concerned about the policy implications of blaming the physician, including the potential that it would encourage fraudulent claims, and deter physicians from providing medical services to drug users (Shepard v. Redford Community Hospital, 1986).

Duty to the plaintiff

There is no question that a physician owes a duty of reasonable care to the patient, but

the case is different when the plaintiff is a third party with no direct connection to the physician. In such instances, courts usually refuse to allow the physician to be liable for injuries caused by negligence unless the physician had good reason to foresee the harm to the third party, and some means of ameliorating it (DiMarco v. Lynch Homes, 1990; Bradshaw v. Daniel, 1993; Restatement (Second) of Torts, §908 (2), 1993). This stringent test normally shields physicians from third-party liability. With take-home naloxone, there is a clearly a foreseen risk to third parties: the physician knows that the patient may well be in a position to administer the drug to someone else in distress. Likewise, the physician can reduce this risk by ensuring that the patient understands the proper use and the risks of the drug. Under these circumstances, a court could well find a physician liable to a third-party injured by naloxone, but only if the physician had negligently failed to provide proper instructions for its use.

"Defenses"

Even when the plaintiff in a malpractice case can establish the basic elements of the case against the physician, the defendant doctor can still defeat the claim by raising "affirmative defenses" alleging that the plaintiff's own misconduct caused or significantly contributed to the harm. These defenses are claims that mitigate or negate liability even if the court accepts the claim asserted by the plaintiff.

The defense of "comparative fault" allows the court to compare the defendant's and the plaintiff's negligence and to assign liability accordingly. Generally, each party is assigned a percentage of the fault, and the plaintiff's gross damages are reduced by his or her percentage of fault. In most states, plaintiffs who are deemed more than 50% at fault recover nothing. Given the fact that naloxone related injuries will nearly always start with voluntary drug use, comparative fault (and the similar defense of "assumption of the risk") will present significant barriers to plaintiffs.

Insurance coverage

Medical insurance should cover costs associated with malpractice suits for naloxone, even in the unlikely case of a judgement against the physician. Insurance policies generally require the insurer to pay for the cost of defending against malpractice claims, for amounts of money paid in settlement, and for the amount of verdicts entered against the physician. Typical exclusions from insurance coverage are for sexual misconduct, alleged impairment by drugs or alcohol, alleged criminal activity, and false imprisonment. Prescription of a new drug is not one of the items typically excluded from insurance. While punitive damages are often excluded from medical insurance claims, a conscientious naloxone prescription program could never constitute the type of willful or reckless conduct that meets the standard for punitive damages (Hirshfeld and Hattie, 1991).

Additional considerations regarding the risk of liability

Any analysis of malpractice liability would be misleading if it did not take into consideration what we know about actual behavior in the tort system. Data show first, that the vast majority of people who are injured by medical accidents and mistakes do not sue (Weiler et al., 1991). While it is also true that a substantial proportion of suits are filed by those whose injuries

were not caused by malpractice (Brennan et al., 1996), social attitudes can constitute significant barriers to litigation. Both juries considering taking on a case, and jurors deciding it, may be unwilling to blame a well-intentioned physician for the death of a voluntary drug user. The very social alienation that makes drug users so vulnerable to the risk of harm from their drug use would work to their further disadvantage in a malpractice suit.

Measures to shield physicians from liability and improve program efficacy

Several practices would help shield physicians from liability while maximizing the efficacy of naloxone distribution programs. Physicians can pursue and document rigorous patient assessment, and ensure that patients are competent to administer naloxone properly. The physician, or another health-care provider, can also provide comprehensive training on methods for administering naloxone.

Comprehensive monitoring, and follow-up counseling would also contribute to effective treatment. Patients should be encouraged to contact emergency medical services after naloxone is administered. They should be trained in methods of effective communication with 911 personnel so as to obtain medical assistance, while minimizing the risk of police involvement. Finally, naloxone prescription should be provided in conjunction with a broad harm reduction program including needle exchange or prescription, information on safer sex and injection, instruction in resuscitation techniques (particularly rescue breathing), and referrals for drug counseling and detoxification services (United States Public Health Service, 1997; Drucker et al., 1998; Burris et al., 2000).

Conclusion

Take-home naloxone has the potential to save thousands of lives per year, with little risk of injury to the patient or liability to the physician. Prescribing naloxone for take-home use could be particularly effective if initiated in conjunction with a comprehensive harm reduction program. Physicians may contribute to such a program without exposing themselves to a significant risk of increased liability for violation of federal or state law, or for malpractice.

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