Mobile Health Liability without Fault

Tony Yang

INTRODUCTION

In the near future, it is likely that physicians will prescribe mobile health applications (commonly referred to as “apps”) as part of treatment, preventative care, or long-term monitoring of health. For example, a dermatologist could prescribe a consumer skin cancer application for monitoring skin conditions and possible melanoma. The application would decrease the frequency of doctor appointments for patients, while increasing the likelihood of catching skin cancer early. Applications, however, may not be completely reliable. The application might fail to catch possible skin cancer until it progresses to a much later stage. If the consumer, trusting in his or her prescribed application, dies from undiagnosed skin cancer, the question of liability for the failure to diagnosis arises. Likewise, this same kind of application, which allows individuals to use the camera on their smartphones to take a picture of a skin lesion or mole, stores those pictures. If the application is hacked, there is great potential for the leak of protected health information. Again, the question of who is liable for the leaked information exists. Obviously, the person responsible for the attack is liable for the leak, but to some extent, there could be liability for other actors, like the smartphone company or application developer.

The first question is about professional liability for failure to diagnose. Here, traditional concepts of tort law should allocate liability when the consumer’s injury results from
negligence. There is a possibility, however, that the consumer’s injury is not due to negligence. For example, an application could pass all FDA regulations and function properly as intended, but still not catch possible skin cancer. In that case, it is unclear whom, if anyone, should be liable from the physician to the application developer. The second question, where a hacker leaks consumer’s private health information, is about systematic liability. If the data breaches are the product of negligence, poor training, and inadequate compliance and testing, state tort and related consumer protection laws apply, and liability assigns accordingly. However, some mobile health companies are fully HIPAA compliant, and take additional steps to encrypt all of their data, back up all data securely, and train their employees to safeguard digital media and avoid attempts at social engineering. What if these companies that take all of the steps they can to protect consumer information are hacked? Increasingly, companies are subjects of sophisticated cyber-attacks, allegedly from North Korea, China, or Russia, among others. Not only are these companies’ systems often inadequate to prevent such penetrations, it is uncertain that any system, even the US federal government’s, will be adequate to prevent these hacks. When the company takes the necessary steps to prevent the harm, it is unclear who, if anyone, is liable for the harm.

When doctors decide whether to recommend or prescribe a mobile health application, they must exercise clinical judgment and balance the application’s potential benefits against its potential risks and the alternatives. Even when they appropriately prescribed, some applications will still injure the patient. In most circumstances, these patients are not entitled to compensation because their injuries are not due to the negligence or fraud of either the

---

manufacturer or provider. This paper proposes the use of a no-fault mechanism as a potential path forward in handling this issue when mobile health applications become mainstream sources of healthcare in the future. It examines concepts of ethics and economics and reviews the experience of relevant injury compensation mechanisms. Fundamental ethics and sound economics favor holding manufacturers of applications liable for injuries, unless there is clear negligence by another party. The creation of an administrative liability allocation system that would determine which claims are entitled to compensation and the amount of compensation is necessary.

LIABILITY ALLOCATION

Today patients are typically entitled to manufacturer compensation under tort liability rules only when injured due to the manufacturer's fraud, negligence or failure to disclose known risks. Most states have adopted the rule from Restatement of Torts § 402A.\(^3\) The comment K to § 402A makes an exception to the usual rule of holding manufacturers strictly liable for injuries resulting from defective products. Manufacturers, including the ones behind applications, can avoid liability for known risks by disclosing them to consumers. Generally, courts have held that a manufacturer fulfills its duty to warn when it discloses the risk on the label, package insert or to physicians, who act as an intermediary between manufacturers and patients. Since the start of direct-to-consumer advertising in 1995, the FDA has required that advertisements, including those for applications, provide information on risks, along with where to find more information about those risks.\(^4\) In addition to manufacturer liability for injuries caused by applications, medical injuries may also entitle patients to compensation for injuries due to the negligence of

---

\(^3\) Restatement (Second) of Torts § 402A, cmt. b (1965).
their treating physician, other medical providers or medical facilities. Injuries caused by administering an inappropriate application to a patient, failing to account for a patient's technology literacy, or inadequate application monitoring would be examples.

Currently, each consumer must bear the unavoidable risks of injury in order to obtain the benefits. However, it is not necessary for each individual patient to bear the financial consequences of injury. From an ethical perspective, mobile health application companies profit from the sale of applications, and it is unfair for them to make individual users who suffer harm bear the financial costs. In terms of risk allocation, the company should compensate those harmed. They are better able to bear that burden since they can more efficiently insure those risks and spread those costs across all application purchasers. The fairness of holding mobile health application companies responsible for harm is especially strong because they sell their applications to reduce risk for consumers of becoming ill and for treating and managing illness. It seems contradictory for firms that sell products to promote health to shift risks of injury to purchasers.

Some argue that when a firm has expenses imposed on it, the firm passes those costs on to purchasers by raising prices. One could argue that it is fair to require all consumers to pay higher prices as a means to compensate individuals who suffer harm. However, firms are unlikely to pass the full costs on to consumers. If they do, higher prices remain fairer than having the financial burden fall on the harmed individuals alone. Application companies can absorb some or all of the costs by lowering their profits, and they may not be able to pass on those costs. Often firms set prices based on what the market will bear, which is much higher than the firm's costs, and a minimum necessary rate of return to attract investors. If the set-prices do not closely reflect their costs moderate increases or decreases in their operating costs do not
automatically lead to the firm changing its prices. If an application company earns high profits, despite increases in its operating costs, it can maintain prices at the current level. It is quite possible that application companies already set prices near the maximum that the market can bear, meaning these companies will be unable to raise prices much further.

Whether application companies raise prices will depend on many factors including: consumers’ perception of the application’s value; the amount that health insurers and third party payers are willing to pay for the application; whether individuals pay for applications mainly through health insurance or out of pocket; whether there are other applications in the same class that can be substituted for the application; and the consequences to consumers of forgoing use of the application. Even if application companies pass on the full cost of compensating for harm to purchasers, it would be a better outcome than having harmed individuals shoulder the economic burden alone. Since users share the benefits of applications, they should share the costs of the enterprise that produces those applications. Although users of applications do not know whether they will be among those users who suffer harm they should be willing to pay a slightly higher price to avoid that economic burden. Purchasers of applications already share the costs of virtually all aspects of the application, which are reflected in application prices and include application company compensation for harm due to their fraud or negligence. Application prices also include the application company’s cost for acquiring investment capital for new research and product development, costs of production, management, promotion, marketing, regulatory compliance, and legal expenses. There is no ethical argument that justifies making application users bear these other costs, but not the cost of unavoidable harm.

When mobile health applications impose harmful effects or excessive costs on consumers, economists refer to that effect or cost as a negative externality. Application
companies can over-produce harmful effects, because they do not pay for the cost of that negative externality. Consumers bear that cost. Rules that make the company pay for harmful effects encourage the company to take actions that prevent or reduce those effects. Making application companies pay for the harm caused by their applications creates incentives for them to reduce those harms. Of course, application companies cannot prevent unavoidable harms. Application companies, however, can still prevent many injuries and breaches even when they are not due to companies’ negligence or failure to disclose risks. Since application companies have more information on application risks than physicians or consumers, these companies can more efficiently obtain new information, alert physicians about risks, and influence prescriptions. Today, however, application companies lack economic incentives to market applications in a way that reduces inappropriate usage or improper prescribing. Rather, application companies have strong incentives to maximize the number of applications sold, even when doing so increases the risk of injuries. The more applications they sell the more they earn, and they bear no extra costs when applications are neither needed nor appropriate for the consumer. It is not surprising that application companies market applications in ways that increase harm or fail to take steps that would reduce its occurrence.

Making application companies liable for the cost of injuries would shift their economic calculation when they market applications by making it less profitable for firms to encourage overprescribing or high-risk prescribing. Heavy sales promotion would still be profitable for application companies, even when inappropriate, but they would have greater incentives than currently do to take measures to reduce harm. Furthermore, many injuries and breaches may be uncompensated even though tort lawsuits are supposed to provide a remedy. Even when an application company fails to disclose known risks or is negligent in other ways, injured
individuals often are unable to prove the application company’s negligence caused their injuries. They may not obtain enough evidence to support their negligence claim against the application company. In other cases, lawyers may refuse to take the case because they believe their efforts in pursuing a lawsuit, coupled with the risks of losing, are greater than the amount they are likely to earn. Application companies get a free pass for these injuries today, but under no-fault systems, they would compensate injuries unless they were clearly due to the negligence of some other actors.

Application companies can insure their liability or finance expenses more efficiently than consumers, which is another reason to make them liable for injuries and breaches. Application manufacturers have more options and can: (1) purchase liability insurance; (2) set aside funds to self-insure; or (3) spread these expenses across all purchasers. Application companies obtain insurance for injuries and breaches more efficiently than consumers, who are only able to insure themselves. In contrast to more than three-hundred million American consumers, there are a relatively small number of application companies. The administrative costs of having application companies purchase insurance would be much less than having virtually all individual Americans or households purchase insurance. Selling policies to a relatively small number of application companies would be relatively simple. To contrast, in order to sell policies to most consumers, insurance companies would spend enormous amounts to market, administer, and estimate variations in individual risk.

Application companies also have a reasonable basis for calculating the aggregated risks of injuries because they can employ experts to analyze risks. Those experts then monitor those

---

Calabresi G. The Decision for Accidents; An Approach to Non-Fault Allocation of Costs, Harvard Law Review. 1965;78:713
risks through post-marketing studies, using their knowledge about how many applications were sold and about the consumers who purchased. Conversely, most consumers would have great difficulty in assessing what level of coverage they need and determining a reasonable price to pay. Individuals cannot know the probability of their harm or its economic costs. It is not practical for them to change levels of coverage as their use of mobile health applications change. As a practical matter, it is also not realistic to rely on individuals to purchase such insurance for several reasons. First, there is no insurance market selling policies to individuals to cover mobile health application harm. Second, even if such a market existed, most people would not purchase such policies because they have many more immediate needs. If an application company does not want to purchase insurance, or self-insure, it can raise its prices to offset its increased expenses. Application companies can spread these costs over multiple applications and over several years. It creates a lesser burden on consumers to bear injury-related expenses through higher application prices than by purchasing injury insurance because consumer health insurance may not cover the price of mobile health applications.

**Proposed Solutions**

There are two main ways to make application companies liable for injuries caused by the use of their applications in absence of fault. First, liability rules could change to strict liability, while continuing to rely on litigation before courts to prove causation and determine damages.\(^6\) Second, the government could develop an administrative plan to determine consumer eligibility for compensation and the amount required. Using the first approach, legislatures or courts could make application companies liable for all injuries caused by the use of their applications that are

---

not clearly due to the negligence of other parties. In states that have adopted the Restatement of Torts Section 402A, implementing this rule would require legislation. Alternatively, Congress could enact legislation that preempts state tort law and creates a federal liability regime for mobile health application injuries. The second way to make application companies liable for injuries is to create an administrative compensation plan as an alternative to tort litigation. Administrative plans have advantages and disadvantages when compared to tort litigation. On the negative side, the administrative plan staff members might not obtain all the relevant facts in the absence of an adversarial system. This could cause some individuals to receive no compensation or less compensation than if they prevailed in a lawsuit. On the positive side, administrative plans have the potential to reduce the high transaction costs, long delays, and uncertainty of tort litigation. Using administrative plans, employees can specialize in reviewing claims, which is likely to produce more consistent decisions than having different judges and juries review claims. Administrative plans can also spread the compensation costs across all the relevant parties rather than only on individuals.

Ideas are one thing but putting them into practice is another, and a compensation plan for mobile health injuries may not be feasible. However, the United States and several other countries have successfully created compensation plans in other health-related fields, like established compensation plans for vaccine injuries. Additionally, several countries have no-fault plans to compensate medical malpractice. Currently, nineteen countries, including the United States, have vaccine injury compensation plans. Vaccine injury compensation plans respond to an important need in public health. Most vaccine injuries are not due to negligence,

---

7 National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 USC § 300aa-22(b)
so typically, tort law does not provide compensation. Proponents of compensation for vaccine injuries argue that since vaccinations produce public health benefits for the community, it is unfair to have only injured individuals shoulder its costs. Vaccine compensation plans represent an expression of what people in these nations refer to as social unity for those injured. Manufacturers also often prefer the creation of compensation plans as a means to preclude their risk of unlimited liability, and some manufacturers said they would stop producing vaccines unless legislation created a compensation plan that capped their liability.

The United States should implement a no-fault administrative plan that would supplement but not limit existing tort remedies. Application manufacturers would compensate injuries through an administrative plan when injured individuals demonstrate that there is at least a 50 percent probability that their injury was due to their use of one or more applications sold in the United States. The administrative plan, however, would not pay compensation if the plan or a court found that the injury was clearly due to the negligence of a party other than the application company. The administrative plan should follow the lead of America's National Vaccine Injury Compensation Program. The program pays reasonable attorneys’ fees for all those who file a claim. Without such funding, many individuals would lack the ability to file a claim or to develop the best evidence in support of a claim. Studies demonstrate that most people with grievances do not file legal claims, in part due to transaction costs and in part due to social, cultural, and administrative factors. A compensation schedule, established by regulations and indexed for inflation, should include payments for: (1) death of the individual; (2) permanent disabilities: (with payments based on the level of payments made by private disability insurance); (3) unreimbursed medical expenses; (4) personal care expenses for individuals

---

unable to care for themselves; (5) out-of-pocket expenses incurred directly due to the injury; and (6) lost income up to a cap. The administrative plan should also follow the National Vaccine Compensation Program and create an official table of injuries found to be caused by mobile health applications. Following this table would facilitate making decisions. The plan would presume that individuals with injuries listed on the table would be eligible for compensation, while the plan would require that evidence from medical literature supported other injuries. The compensation plan should also specify the criteria it would use to decide whether claims merit compensation. To reduce the number of claims mistakenly paid or denied, the compensation plan should employ persons trained in medicine, epidemiology, engineering, and related fields so that competent people evaluate individual claims. Individuals who decide claims should make public their reports explaining the basis for their decision, much like public record for court decisions.

**CONCLUSION**

Although it’s currently extremely rare that mobile health applications injure consumers, as our smartphones are fast becoming the ATM of health, it could be more commonplace to see injuries associated with using mobile health applications. This paper provides an ethical and economic rationale for creating a no-fault administrative plan to compensate all mobile health injuries that are not due to negligence. Congress, however, may be reluctant to enact large-scale legal changes, even when the legislation does not increase taxes or commit the federal government to spend funds. There are ways that the government could implement compensation

---


plans to satisfy concerns of Congress. Incremental reforms will reduce concerns about how much the no-fault compensation plan will cost application companies and consumers.