Negligence is carelessness. Ordinary human behavior is rife with careless actions, most of which cause no harm or do so little harm as to be easily forgiven. We have all received (and dialed) a wrong number phone call and excused the person who dialed it without thinking twice. It is only when the caller dials again that we become upset or when it becomes obvious the intrusion is somehow intentional that we take action to block the call. Ordinarily, as long as a behavior is not harmful or annoying and the person who was careless apologizes, negligent acts are forgiven and forgotten as part of our normal social structure, hardly causing a second thought.

The provision of health care is an error-prone human endeavor. As admirable as the oft-stated goal of eliminating all error might be, to avoid all error in health care would necessarily involve eliminating both the patient and the healthcare provider from the encounter. Arguably, health care today is safer than at any time in our history, despite the increased risk of harm associated with increased technology and disease intervention. However, as safety in healthcare practice has increased, so has the public expectation regarding safety, an expectation that is often racing ahead of what is possible to achieve. A bad outcome is first treated as a possible or probable mistake subject to proof otherwise, even in the mind of the professional responsible for the patient in some way. Malpractice case law is formed by the tension between acts that are a
possible cause of a treatment misadventure and acts that are a probable cause of a treatment misadventure. As it becomes more certain that any given act is the actual cause of an injury, liability for that act increases dramatically.\(^6\)

Ordinary negligence, per se negligence, gross negligence, and criminal negligence are degrees of carelessness divided by the probability of harm and the imputed mindset of the person causing that harm.\(^6\) It is important to note that the most extreme form of malpractice, criminally negligent malpractice, does not involve a premeditated intention to harm another person. Premeditation to harm is an essential element of a criminal act that defines attempted or actual murder—not negligence. Rarely, an ordinary part of the provision of health care can become a charge of homicide (or murder) if a motive toward profit or a desire to harm a patient can be imputed to the healthcare professional, but such a motive must be beyond extreme carelessness. Such acts are unusual in health care, as the following case describes.

**Case Presentation**

Dale McIntosh owns Cornerstone Pharmacy. Cornerstone has been at the same location, next to Mercy Hospital, since 1956. Many things have changed in the past 50 years, but most of the changes have occurred since he bought the pharmacy from his former partner 20 years ago. Dale has seen a successful business, based on professional service and community loyalty, gradually morph into a small compounding pharmacy, providing the few products not on the shelves of MegaPharm, the national chain pharmacy that moved into the area 18 months ago. After a sobering look at his books, Dale has realized what he has known for more than a year: unless he can do something drastic to improve his bottom line, he will soon be out of business.

Mercy Hospital recently opened a new international cancer treatment center, a service that has been very successful, drawing patients from a 3 state area. Dale tried to obtain the contract to provide premixed chemotherapeutic agents to the private oncology offices at Mercy, but he was outbid by MegaPharm. However, the annual renewal bidding process will begin next month, and Dale is desperate to win this time. He has spent hours in the medical library, and he thinks he knows how to undercut MegaPharm. He decides to dilute 3 of the 9 chemotherapeutic agents by 25% from the concentrations required in the contract, sell the solutions at 5% less than the MegaPharm price, and therefore make just enough profit to stay in business and cover his overhead. From all he can learn, Dale concludes that the 3 agents are almost as effective at the diluted strength as at the full strength and may even cause fewer adverse effects if diluted. While this step will require Dale to be deceptive, he is convinced that he will harm no one. Dale also received a call last week from "A New You," a group of 5 plastic surgeons who practice at Mercy. Their office manager was looking for a less expensive source for Botox injections than MegaPharm could provide and wondered whether Dale could help. Dale has made a number of contacts over his long career, including some less-than-reputable suppliers. As it happens, one of them had just told him how he could buy deeply discounted Botox from Mexico at a fraction of the price he would pay in the US. Seeing his opportunity, Dale placed an order. When the first shipment arrived, Dale recognized the package markings as irregular, suggesting that the source of the Botox was not the national pharmaceutical company printed on the label. When he called his supplier, he was told that the Botox was "good stuff" and that if he wanted more, he needed to adopt a "don’t ask, don’t tell" attitude. Dale decided he wanted more Botox.

Everything went well for the next 2 years until one afternoon when one of the plastic surgeons called Dale, panicked and distraught. A young woman he had injected with Botox from Cornerstone had just been admitted to the emergency department with nausea, vomiting, and shortness of breath. She had quickly developed severe respiratory distress and cardiac arrest and had died. The physician wanted to know whether the Botox he had used had anything to do with his patient’s death.

When the coroner’s report confirmed the death to be due to a massive dose of botulinum toxin, an investigation ensued. The problem became evident quickly. The discounted Botox Dale had received in the most recent shipment was 100-fold more concentrated than expected and of a crude grade. Dale had simply assumed the shipment was the same as in the past and had labeled it as he usually did. What Dale did not know was that this formulation of Botox came from a small, backroom repackaging operation in Brownsville, Texas, and that the material used there was not approved by the Food and Drug Administration for human use in the US.

Dale has been arrested and charged with negligent homicide. An investigation of his pharmacy records has also revealed his fraudulent formulation of the chemotherapeutic solutions. The district attorney has turned this finding over to the Cancer Treatment Center and to the Centers for Medicare and Medicaid (CMS). He has asked the hospital to investigate the possibility of any excess morbidity and mortality during the time they had been using Cornerstone for their pharmacy needs and for CMS to investigate the possible violation of any federal laws (ie, whether Dale had defrauded the government by selling diluted medications to Medicare/Medicaid patients).

Finally, Dale has been served (along with the plastic surgeon) in a wrongful death malpractice suit by the husband of the woman who died from the Botox injection. Dale is concerned by something his attorney has just told him: his
malpractice insurance policy does not cover willful or intentional misconduct. The malpractice carrier has notified Dale’s attorney that it is considering denying coverage based on the outcome of the felony charge.

Dale understands that he has been sloppy in his business practices, possibly even negligent, but he maintains that he has not intentionally hurt anyone, that he was deceived like everyone else by the supplier of the illegal Botox, and that no one was actually hurt by his practice of diluting the 3 chemotherapeutic drugs. Dale does not understand how anyone could accuse him of homicide.

**Negligence Defined**

The case presented above is based, in part, on 2 actual cases and is, in part, fictionalized. It raises a number of important issues concerning negligence that require a more detailed discussion.

The definition of professional negligence most familiar to healthcare providers is the definition of ordinary negligence. As commonly phrased, ordinary negligence is the failure to exercise the degree of care that a careful or prudent practitioner would have exercised under like circumstances. Such definitions involve the exposure of a patient to an unreasonable risk of harm, as judged by a jury (or judge) after expert testimony has been given to establish the ever-changing standard of care. Negligence can occur due to something we do or do not do if the act we fail to do was necessary to prevent an injury.

In the US, common law and statutory law form an interlocking and complementary set of rules and standards that define all of the forms of negligence, including professional negligence. Common law is case law or rules and standards determined by previous decisions in specific cases. Statutory law is law made by the legislature of any given state and is intended to codify or to make certain principles embodied in case law. Most statutory malpractice law merely reflects or enforces previous findings by judges and juries and does not create new liabilities for practitioners. However, statutes can also be a reaction to a finding by juries and does not create new liabilities for practitioners. Merely reflects or enforces previous findings by judges and law (that is, per se).

Negligence per se (statutory negligence) is behavior that “can be said without hesitation or doubt that no careful person would have committed.” Some states have defined certain acts or omissions to be negligence as a matter of law (that is, per se). Committing an act defined by such statutes effectively eliminates the plaintiff’s need to prove negligence. Operating on the wrong part of the body or leaving surgical equipment inside the body are classical examples of negligence per se. However, a minority of states define violations of a statute to be evidence of negligence—not negligence itself. Such evidence is still left to the court to weigh and to either accept or reject. Ordinary negligence does not include reckless or intentional behavior. It also does not include the legal concept of a battery, which is defined as an unpermitted touching, with or without an injury. Until the middle of the 20th century, many successful malpractice cases included some aspect of a charge of battery, especially cases raising what we now know as informed consent issues. A battery occurs only in the absence of any consent. Under current law, it is possible for a patient’s consent to be so defective as to be nonexistent, but such a finding is very unusual.

Healthcare professionals are frequently charged with reckless behavior in the initial complaint or summons in a case that actually involves only ordinary negligence. This is often done to allow the plaintiff’s attorney to later argue that the facts support a charge of gross negligence. Gross negligence is a matter of degree, defined as behavior that shows a “wanton or reckless indifference to the safety of others.” For example, it is certainly gross negligence and reckless behavior for a pharmacist to fill a prescription or formulate a medication while intoxicated, but it is not necessarily negligent or reckless to perform the same practices while sleep-deprived. If carelessness of an extreme degree can be shown, punitive damages can be sought. Punitive damages are difficult to obtain, because they are both defined (and limited) by statutory law and are given for a type of behavior that is unusual among competent providers. Because the purpose of punitive damages is to teach the responsible party a lesson they and others will not easily forget, the court reserves such damages for the most culpable individuals.

There is no clear or bright line between ordinary negligence and gross negligence. It is usually possible to characterize a sloppy practice as either ordinary or gross negligence. However, reckless or wanton behavior (essential to a finding of gross negligence) has important characteristics. It is behavior that involves a known or obvious risk of harm. It is done with a conscious indifference to the welfare of another such that it is the close equivalent of a willingness that the harm will occur. Such behavior does not require the proof of an actual motivation, but if a secondary motive (eg, profit or personal fame) can be shown, recklessness is far easier to prove. Any motive other than the general welfare of the patient can be enough to turn an inattentive error into a charge of recklessness. Finally, and possibly most important, negligence that is both offensive and of a type that a nonprofessional juror would consider reckless, without the help of expert testimony to establish that it is reckless, will often be found to be gross negligence.
Criminal negligence by a healthcare provider is defined as a reckless act with battery (unpermitted touching). In the circumstance of gross negligence, as opposed to criminal negligence, a patient has consented to treatment after being properly informed of the risks and benefits of a therapy, that is, after informed consent has been obtained. However, informed consent is not a permission slip to behave irresponsibly. No person can legally permit another to intentionally cause them harm. If an injury is the certain or foreseeable outcome of a behavior and the harm far outweighs any other intended benefit, no amount of informed consent can legally permit the act. Simply put, one cannot avoid criminal or civil liability for a person’s death by obtaining that person’s consent to kill them, even if that person believes that their death has some benefit to them. In the same sense, even though death is a possible unintended outcome of an act, no one consents to actually die when death is made probable by recklessness. Reckless or indifferent behavior can completely destroy the protection against criminal negligence afforded most healthcare providers by informed consent creating instead a battery. Because a battery that causes harm is a criminal act (felony or misdemeanor), it is a short step from gross negligence to an act that is prosecuted under the criminal law. Prosecution for criminal negligence associated with health care is at the discretion of the public prosecutor who often looks for (1) patterns of behavior or a single behavior that (2) offends all public decency and is an (3) offense described by the criminal statutes of the state.

Case Analysis

Most of the issues raised by the case presented here are probably evident after consideration of the various levels of negligence, but it is useful to look briefly at the behavior of Dale McIntosh in some detail, as an example of actions to avoid.

ORDINARY NEGLIGENCE AND PER SE NEGLIGENCE

One of the most important issues being addressed at the state and national level by lawmakers and healthcare professionals is the lack of uniform standards of care for outpatient, office-based care and the various professions that support that care. Free-standing plastic surgery centers and oncology treatment centers are among the several areas that have drawn attention. State statutory law mandates elaborate protections for free-standing treatment centers, and federal law expands those protections through Medicare and Medicaid regulations. However, unless a facility directly bills CMS or falls within the state guidelines of the definition of a surgical center, remarkably little statutory law applies to either the physician’s office or any of the services that support a physician’s office. Dale’s privately owned pharmacy was therefore not subject to any significant amount of state or federal oversight beyond the ordinary business laws that govern commercial transactions.

The public often assumes a level of safety in a pharmacy that is not present in all situations. Therefore, the only protection commonly afforded patients who received medications from Cornerstone Pharmacy would be the post-event recovery possible under Dale’s malpractice insurance policy, combined with any restraint Dale might feel based on either the threat of a malpractice suit or on his personal professional/ethical standards. Most malpractice suits are brought due to ordinary negligence. The proof of ordinary negligence is a fact-intensive enquiry, subject to the judgment of a jury based on all of the facts at hand. Dale’s carelessness in the purchase of the Botox and his failure to ensure normal product quality would be the central issues for the jury to consider.

GROSS NEGLIGENCE

The essential element of a finding of gross negligence is the determination of a willful or wanton disregard for the safety of others. Dale noticed a difference in the packaging of the Botox that he purchased from Mexico, suggesting to his trained eye that repackaging or fraudulent packaging was being done. Repackaging or intentional mislabeling exposes the consumer to an unpredictably high risk because it ignores the normal safeguards. By ignoring this risk to make a profit, Dale willfully disregarded the safety of the patients who received the Botox that he sold. He will almost certainly be found liable for gross negligence.

CRIMINAL NEGLIGENCE

Dale sold the Botox to a physician who represented the risk to his patients, based on the reputable use of the product. Since the patient’s informed consent to the use was obtained without knowledge of Dale’s misrepresentation (a fraud), no actual informed consent was obtained. Therefore, the physician committed a battery by injecting the Botox, but the battery was perpetrated by Dale’s fraud, with the physician taking the position of an involved but innocent party. A battery that causes death is a homicide, with or without a specific intent to harm. Dale faces a difficult task to prove his innocence.

MEDICARE FRAUD

Medicare and Medicaid law consists of a complex volume of regulations and case law, well beyond the scope of this discussion on negligence. However, Dale’s misrepresentation of the strength of the 3 chemotherapeutic agents will probably constitute Medicare fraud. Simply defined, it
is fraud to receive payment for a product or service provided to a Medicare recipient that is significantly other than the product or service billed. Diluted, altered medications would fall under this definition. Even if the diluted drugs did not harm anyone, Dale would be liable for Medicare fraud and subject to severe fines and penalties. Dale’s malpractice insurance would not cover this liability.

Discussion

Because ordinary negligence is carelessness, and since all humans are sometimes careless, it is impossible to defend against all human error. It is therefore impossible to provide health care without error, despite our personal sense that we are doing so on nearly all occasions. The illusion that our practice is (nearly) error-free is exactly that: an illusion. Careful studies of human error and, specifically, error in health care, point out that the source of most error is not a lack of personal concern or care, nor of skill or training, but of systems failures, largely out of the control of the healthcare provider. It is literally true that most error cannot be solved by the personal resolve and concerted effort of an individual provider to do well. As essential as professional integrity and training are, those qualities will not solve the ongoing problem of error in the provision of health care.

A number of strategies for avoiding error, limiting liability, and surviving a malpractice suit have been proposed. The literature on these issues is voluminous and impossible to summarize easily. That said, 2 thoughts come to mind. Experience has clearly shown the value of such personal counseling but has also documented its underutilization by most practitioners. Help may be available with a simple phone call and can dramatically help us survive malpractice.

The legal significance of the word “negligence” varies with the behavior that is being described, ranging from ordinary negligence to criminal negligence. Health care in the US is highly regulated and is under increasing public scrutiny. As the public expectations of health care and research science increase, the legal standards that define negligent actions become more stringent. More than ever, healthcare professionals need to adhere to the highest levels of ethical and professional behavior to avoid liability beyond ordinary negligence.

Golden Rules of Negligence

Six practical Golden Rules describe malpractice law and the principles used to evaluate our behavior.

1. Ordinary negligence is common in all human behavior.
2. The best protection against ordinary negligence is error prevention through risk management strategies, not legal strategy or risk prevention.
3. Negligence per se (statutory negligence) is uncommon in healthcare malpractice suits, and the effect of such negligence varies from state to state.
4. Gross negligence is commonly alleged but rarely proven. It is the basis of punitive injury claims.
5. Good informed consent is an important defense against any claim of negligence but is especially important to disprove gross negligence.
6. Criminal negligence is charged for rare, egregious behavior and is based on reckless and wanton acts outside of normal professional ethics and practice.

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7. KAC v Benson, 527 N.W. 2d 553 (Supreme Court Minnesota 1995).
8. Miller v HCA, Inc., 118 S.W. 3d 758 (Supreme Court Texas 2003).

EXTRACTO

OBJETIVO: Revisar la práctica/principios legales del derecho sobre negligencia y proveer créditos de educación continua para el dominio de esos principios.

RESUMEN DEL CASO: Se presenta un caso ilustrativo ficticio, basado en parte en hechos obtenidos de casuística real. Un respetado farmacéutico, enfrentado con la pérdida financiera de su negocio, decide involucrarse en dos esquemas creativos pero no éticos para aumentar su margen de ganancia. Al hacerlo, violó la ley federal de Medicare y colocó a un número de los pacientes que utilizaron sus servicios en riesgo significativo de complicaciones médicas.

DISCUSIÓN: El derecho sobre negligencia ha evolucionado durante los últimos 30 años en una forma que aumenta significativamente la responsabilidad legal del farmacéutico practicante, por acciones tanto de negligencia ordinaria como de negligencia criminal. Además, la última década ha visto tal expansión de la Ley de Fraude y Abuso de Medicare que ahora esta representa un área de creciente alto riesgo para cada proveedor de servicios médicos, incluyendo al farmacéutico.

CONCLUSIONES: La práctica profesional en los Estados Unidos es altamente regulada, gobernada tanto por el derecho casuístico como por el derecho estatutario. Cada farmacéutico practicante debe estar alerta a la ley que gobierna su conducta para evitar responsabilidad legal tanto civil como criminal.

Ana E Vélez

RÉSUMÉ

OBJECTIF: Revoir les principes de lois et de pratique sur la négligence professionnelle et offrir des crédits de formation continue visant à maîtriser ces principes.

RÉSUMÉ DU CAS: Un cas fictif est présenté à partir de faits basés sur de véritables cas de loi. Un pharmacien respecté, faisant face à la perte de son entreprise pour des raisons financières, décide de s’engager dans deux stratégies créatives mais non éthiques visant à augmenter ses marges de profit. Ce faisant, il a violé la loi fédérale du Medicare et mis un nombre de ses patients à risque de conséquences médicales majeures.

DISCUSSION: La loi sur la négligence a évolué depuis les trente dernières années vers une augmentation significative de la responsabilité du pharmacien pratiquant quant aux fautes commises, qu’elles soient banales ou criminelles. De plus, il y a eu des changements importants dans les lois sur l’abus et la fraude du Medicare qui créent un risque plus élevé pour chaque prestataire de soins médicaux, incluant le pharmacien.

CONCLUSIONS: La pratique professionnelle aux États-Unis est fortement réglementée par le droit législatif et la jurisprudence. Tout pharmacien pratiquant devrait être aux fait des lois qui régissent ses comportements pouvant avoir des responsabilités civiles et criminelles.

Nicolas Paquette-Lamontagne