

Medicinal Products Liability of the Pharmacists: An Overview of Some Emerging Legal Issues in Nigeria

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Abstract

There is no doubt that medicinal products are under strict control and regulation with the aim of protecting the consumers and hence promoting public health. However, there have been incidences in Nigeria where the use of some of these products have resulted to injury and even death. And in view of the alarming rate of adulteration of drugs and other related products and especially with the increase in the resort to numerous herbal products in Nigeria now, manufacturers, physicians, pharmacists as well as the consumers of medicinal products need to be abreast with their obligations, rights and remedies as the case may be. Also, the increased complexity and expanded role of the pharmacists in the drug-use process may bring about an increased exposure to liability as a result of injuries arising from their actions. This paper aims to highlight the potential liability of the pharmacist and educate the pharmacy community about product liability laws that have arisen from the expanded role of pharmacists in the healthcare delivery system.

Introduction

It is interesting to note that litigation prompted by consumer dissatisfaction with medicinal products and health practitioners has drastically increased over the years especially in the developed countries, with injured consumers and patients seeking compensation based on the available remedies in law.

Now that product-related bills in Nigeria are increasing and surveys are showing that many medicinal and regulated products are ineffective, fake, substandard or adulterated, the rights and remedies of the injured consumer need to be specified as does the liability of the manufacturer, medical professionals etc., for damages when the use of a defective product causes injury to a person or property. This will help to stabilize and improve people's lives and promote the sound development of the national economy.

Until recently, there was ample evidence of the poor state of regulatory activities in Nigeria. For example, the market was flooded with expired products, products with no expiry dates, products relabelled with the intention of extending their shelf life, toothpastes containing little or no fluoride, non-iodized or insufficiently iodized salt, improperly processed and unregistered packaged water (popularly called "pure water"), and beer and other alcoholic drinks containing high nitrosamines and with inappropriate labels that did not disclose the alcohol content.

Nigerian bakers continued to use potassium bromide as an enhancer (a product banned since the early 1990s for its implication in cancer, kidney failure and loss of hearing, as well as breakdown of vitamins). Others continued to deal in counterfeit cosmetics, banned chemicals, unsafe medicinal products and goods brought into the country as "export only" products. It is a fact that countries that produce such products do not actually distribute them to their own people. Thus, most importers (marketers who may be professionals or nonprofessionals) have become merchants of death in the quest to make quick money (Akunyili 2003).

Some Nigerians pay no attention to expiry dates, and storage conditions of medicinal and regulated products are so poor that even genuine products deteriorate. It is important to note that even when these medicinal and regulated products are properly stored they degenerate and the rate of spoilage is directly related to time.

The major problem in Nigeria is that of counterfeit or fake products. Every useful product can be faked or counterfeited, and consumers are either deceived into buying the counterfeits as the originals or out of financial constraints and sundry reasons, buy the counterfeits because they are cheaper (Erhun 2001).

Fake and counterfeit products occur in many forms, but the common denominator remains the suffering, injury, pain and even death that they cause to the consumers. Regulated products for the promotion of good health and safety now result to grave danger or even death of consumers.

The truth is that the evil of fake and counterfeit products is worse than the scourge of malaria, HIV/AIDS and armed robbery put together. Malaria can be prevented, HIV/AIDS can be avoided, armed robbery may kill a few at a time, but fake and counterfeit products kill en masse. Anyone can be a victim at any time because we all need these products in our day-to-day life. It is also important to note that the social problems posed by hard drugs (e.g. cocaine and heroine) cannot be compared with the damage done by fake drugs (Akunyili 2004).

Consumers who have been injured by using defective medicinal products or received substandard professional services can seek redress to enforce their legal rights and obtain remedies by taking courts actions. The injured consumer is entitled to have remedies flowing directly or indirectly from civil or criminal law. As far as civil law is concerned, the remedy may be for breach of contract against the professional (e.g. a pharmacist) who has not fulfilled obligations imposed upon him or her by law, or the remedy may be in tort for negligence to show a reasonable standard of care. Additionally, where the professional's activities involve a criminal offence (such as unlawful dealings with hard drugs) resulting in a successful prosecution, the consumer may seek compensation under criminal law.

Some medicinal products may be considered safe, and administered, but eventually result in injuries to potential consumers or patients, for example, saccharin (for its carcinogenic potential). Other examples include thalidomide (an otherwise excellent sedative drug) and diethylstilbesterol (or DES, a hormonal drug used to treat threatened abortion and to prevent habitual abortion) were administered to pregnant women and both caused birth defects (Harvey 1973).

At times, pharmaceutical companies even push their products (e.g. Celebrex) into the market

before assessing their full side effects and subsequently become liable for damages. In Nigeria, 14 children died after receiving chloroquine phosphate injections in 1947 (Erhun 2001) and another 109 children died after taking paracetamol syrup (Daily Times 1990).

Recently, the Federal Government of Nigeria has instituted an action against Pfizer, Inc., a pharmaceutical company headquartered in New York, for the use of trovafloxacin mesylate (Trovan) in an impoverished region (Tudun-Wada) of Kano in northern Nigeria in 1996. In the study by Pfizer, 100 meningitis-infected children were treated with (Trovan) and another 100 children (used as control patients) received an approved antibiotic, ceftriaxone. It was reported that 11 of the children who received Trovan died, while others suffered physical disabilities and brain damage.

Although the pharmaceutical company is insisting that the drug was used to provide humanitarian relief, the investigation committee report indicted Pfizer for illegal experimentation by using an unapproved drug on human subjects. The Federal Government of Nigeria is asking for \$7billion US damages as compensation for damages (Wise 2001; Anaba 2007).

To avoid litigation and hence liabilities resulting from injuries caused by the use of medicinal products, pharmaceutical manufacturers, marketers of medicinal products and all health professionals who serve as learned intermediaries (one who takes into account the propensities of the drug as well as the susceptibilities of the patient and makes decisions regarding the usage of a drug), owe the potential consumers of these medicinal products a duty of care. Duty of care is an obligation to conform to a particular standard of conduct and ensuring that the person receiving care is given is not injured.

What Is Product Liability?

Product liability refers to the liability of any or all parties along the chain of manufacture of, and distribution (wholesale and retail) of any product, for damage caused by that product to a consumer. This includes the manufacturer of component parts (at the top of the chain), an assembling manufacturer, the wholesaler and the retailer (at the bottom of the chain).

Products containing inherent defects that cause harm to a consumer of the product, or to someone to whom the product was loaned, given, etc., are the subjects of product liability suits.

While products are generally thought of as tangible personal property, product liability has stretched that definition to include intangibles (e.g., gas), naturals (e.g., pets), real estate (e.g., houses), and writings (e.g., navigational charts). The term "product" is no longer limited to food and drink. It now includes cases in which the injurious element is not a foreign body but something intrinsically part of the product itself. It may cover areas in which there is no allegation that the product has been carelessly made, but that it is dangerous to use without proper warnings or instructions.

Therefore, products subject to the law cover a broad spectrum that includes food, drugs, appliances, automobiles, medical devices, blood and tobacco.

Product liability claims can be based on negligence, strict liability or breach of warranty of fitness, depending on the jurisdiction within which the claim is based. In any jurisdiction, one must prove that the product is defective.

When Is a Product Defective?

A product is defective if it does not provide the level of safety that the general public expects. Also, a defective product is the item that causes injury and, as such, an injured consumer can bring an action for damages against any party involved in the manufacture and distribution of the product.

Factors that determine whether a product is defective are:

- (1) Design defects that are inherent and exist before the product is manufactured. This type of defect affects every unit and includes provision of adequate warnings and instructions on using the product. The case of *Gall v. Union Ice Co.* involved the absence of sufficient warning labels on drums of sulphuric acid that eventually exploded. The Californian court held that the company was negligent in failing to place proper warning labels on their product (*Gall v. Union*

Ice Co. 1952). Similarly, in the case of *Toole v. Richardson*, the plaintiff's eye was damaged as a result of inadequate warning given with a prescription drug, MER/29. Justice Salsman found that the product was marketed without proper warning of its known dangerous effect (*Toole v. Richardson* 1967).

- (2) Manufacturing defects that occur during the construction or production of the item. Pharmaceutical industries are involved in the production of medicinal products and must avoid introducing defects during the manufacture of their products. Normally, there is an implied warranty (assumption) that a medicinal product is safe for what it is sold for. Manufacturing defects are limited in number and easy to prove, for example, improper sterilization of injectables.
- (3) Defects in marketing that result from improper instructions and failure to warn consumers of latent dangers in the product. Pharmacists are either direct marketers (wholesalers or retailers) of medicinal products or at least dispensers of medicinal products. Care must be taken to not introduce defects during repackaging, labelling or dispensing medicinal products. For example, where there is a representation that a packaged product is the same as that on the patient's prescription, then liability will be found against the pharmacist if the substituted product causes injury to the patient (*Jacobs Pharmacy and Co. v. Gibson* 1967).

Generally, product liability is considered a strict liability offense. Strict liability wrongs do not depend on the degree of carefulness by the defendant. Translated to product liability terms, a defendant is liable when it is shown that the product is defective. It is irrelevant whether the manufacturer or supplier exercised great care; if there is a defect in the product that caused harm, the defendant will be liable for it.

Who Is a Consumer?

A consumer has been defined as any person to whom goods and services or credit are supplied by another person for personal or household use (Section 32 of the Consumer Protection Decree No. 66; Ajai 1993).

There is always an imbalance between consumers and producers which often leads to the exploitation of the consumer. Being in a weaker position, the consumer is exposed to problems of product safety, fair trade practices, and product or services quality and ought to be protected. This was the position of Justice Aniogulu in the case of *Ngonadi v. Nigerian Bottling Co. Ltd.*

The aim of the manufacturer and entrepreneurs is to maximize profit, but they must be cautious and not cause injury to consumers. A manufacturer is required by law to take reasonable care to ensure that his or her products do not injure the ultimate consumer.

Who May Be Liable for Supplying a Defective Product?

Liability is not restricted to the ultimate supplier of a product, and this creates a liability chain and possibly increases the number of potential defendants to any claim.

It often becomes difficult to prove liability arising from the use of medicinal products, since so many people (manufacturer, distributors, prescribing doctor, dispensing pharmacists and even the nurse who administers the medicinal products) are responsible for the medicinal product reaching the patient. However, a pharmacist becomes liable if a medicinal product that is prescribed or dispensed by him or her causes injury to a patient.

From the above, four categories of persons may face liability for a defective product: the manufacturer, the importer, any person who holds or presents him- or herself out as the manufacturer and the person supplying the product to the victim.

The first three groups have primary liability, whereas the supplier of the product has a secondary liability. The supplying pharmacist should therefore ensure that he or she has adequate systems and records to identify with certainty the manufacturer of the medicinal products that he or she supplies.

This is because, unlike the general duty of care imposed on all vendors of goods, the pharmacist as an expert on and custodian of drugs, he or she is in a fiduciary relationship with the patient in respect of transactions involving pharmaceutical knowledge. Reliance is placed upon the special skill and knowledge of the pharmacist when manufacturing, selling, prescribing or dispensing medicinal products (Appelbe and Wingfield 1998).

The general duty of pharmacists when dispensing medicinal products involves product selection, recommendation of alternatives, counselling on the use of the product, monitoring drug therapies and evaluation of product utilization. It is important to state that the expanded role of the pharmacist resulting from the evolution of pharmacy practice to include clinical pharmacy and pharmaceutical care has also exposed pharmacists to liabilities arising from injuries caused by medicinal products.

Who Can Bring an Action?

Any consumer or patient who is directly or indirectly injured after using a product can institute an action of compensation in any court of competent jurisdiction. Second-generation injury enabled daughters of consumers of diethylstilbestrol (DES) to succeed in their claims even when it was their mother who had taken the drug. The drug caused impairment of their prospect of motherhood, propensity to develop cancerous tumours, malformation of bodily organs and some other effects that required lifelong monitoring and possibly surgery (Harvey 1973). It is important to note that the purpose of litigation is to compensate for injuries caused to an injured consumer of a product and then to forestall and prevent future occurrences.

What Type of Compensations Are Available?

The legal term for the type of award that an injured person can obtain after winning a law suit is “damages”. In product liability cases, damages are termed “compensatory damages.” They may be for economic loss (e.g., compensation for monies spent on medical bills and lost wages as a result of inability to perform usual duties) or non-economic loss, which includes monies awarded to compensate for the pain, suffering and inconvenience caused by the defective product.

Statutory Provisions and Case Law Position on Product Liability

In Nigeria, case law position on product liability is rare, and most court decisions are premised on foreign law positions as enunciated below. This is true where there is no legislation governing a specific matter or where ambiguity is occasioned and it may be necessary to have recourse to laws and practice elsewhere, especially English law and practice. Consequently, Nigerian product liability law cannot be discussed in isolation of the source and development of English law. English common law, doctrine of equity and statutes of general application were received into the Nigeria law by virtue of court ordinances. There are also international laws, conventions, agreements and treaties to which Nigeria is signatory, and they are increasingly having considerable impact on pharmacy laws in Nigeria.

Although these foreign laws operate in Nigeria, Nigerian cases, by their own nature, reflect the Nigerian interpretation and application on peculiarly Nigerian facts and situations. For example, Section 303 of the Nigerian Criminal Code imposes a duty of care on health professionals for the health of their patients, while Section 304 imposes duty on persons in charge of dangerous things, which include drugs as poisons. Section 305 states that a person who undertakes a duty, is so held to owe it, so that a pharmacist who dispenses medicinal product inexcusably owe a standard duty of care to patients based on his or her training.

As stated before, there are a number of overlapping counts upon which an injured party can bring an action in product liability law. These counts are negligence, breach of warranties (implied or express) and strict liability (Pasley 1969).

Some drug products undoubtedly cause harm and the initial law that governed the use of products was the English common law that devolved from the position of *caveat emptor* – let the

buyer beware. But currently, the position of the law offers considerable protection to even the most unwary buyer, and indeed, some would argue that it has reached the point of *caveat venditor* rather than *emptor* in developed societies.

Traditionally, a consumer or patient may have remedy in contract if the terms, (express or implied) have been breached. A good example is the famous old case of *Carlill v. The Carbolic Smokeball Company*, in which the defendant manufacturers of a product “The Carbolic Smoke Ball” (price 10/-, refills 5/-), issued an advertisement in which they offered to pay £100 to anybody who succumbed to influenza after using the smoke ball in the specified manner for a specified period. They added that they had deposited the sum of £1000 with the bankers “to show their sincerity.”

The plaintiff, Miss Carlill, relying on the advertisement, bought and used the smoke ball as prescribed but caught influenza nonetheless. She sued for her £100. The defendant company predictably and vigorously defended itself by arguing ingeniously that the claim was a bet within the meaning of the Gaming Act that the offer was a mere advertising “puff” never intended to create a binding obligation, that there was no offer made to an individual person and that, if there were, Miss Carlill had failed to notify the company of her acceptance (*Carlill v. The Carbolic Smokeball Company* 1892).

The Court of Appeal, upholding the decision of the trial judge (Justice Hawkins), found no difficulty in rejecting the argument that an offer cannot be made to the world at large. In that case Lord Justice Bowen stated that:

It is an offer made to the world which is to ripen into a contract with anybody who comes forward and performs the condition. Although the offer is made to the world, the contract is made with the limited portion of the public who comes forward and performs the condition on the faith of the advertisement (*Carlill v. The Carbolic Smokeball Company* 1892: 484).

None of the judges, however, saw fit to comment on the peddling of bogus or ineffective medical products, and it was only on a narrow contractual point that Mrs. Carlill was able to obtain satisfaction. Now, however, the tortious liability of regulated products has become a relevant concept when a consumer suffers damages or sustains injury occasioned by the use of a product.

It was not until 1932, with the House of Lord’s landmark decision in *Donoghue v. Stevenson*, that a general duty of care was actually formulated and generally accepted. The facts in the *Donoghue v. Stevenson* case were as follows. The defendant (a manufacturer of ginger beer) had supplied his products in a sealed, opaque glass bottle to a retailer who ran a café in a park in Paisley, Scotland. In August 1928, the plaintiff and a friend visited the café and Miss May Donoghue’s friend bought the bottle of ginger beer to be served with a slab of ice cream. The ice cream was served up in a tumbler; the ginger beer was poured over it. Miss Donoghue drank some of the concoction, and her friend was topping up her glass with the remaining ginger beer when the remnant of a decomposed snail floated out of the bottle. The plaintiff was upset and claimed that she suffered shock and gastroenteritis. She sued for damages from the manufacturer of the ginger beer but was not able to sue the café owner in contract owing to the rules of “privity” of contract, as her friend had bought the drink. She claimed that the defendant was in breach of the duty of care, which he owed her (*Donoghue v. Stevenson* 1932).

The manufacturer denied liability, as there was no contract between himself and the plaintiff. But the House of Lords ruled by a narrow majority of 3:2 that the defendant was liable for negligence on the grounds of a breach of legal duty of care owed the plaintiff as the ultimate consumer of his products. The case has formed the common law basis of our developing consumer law and gave rise to Lord Atkin’s famous statements (*Donoghue v. Stevenson* 1932).

Lord Atkin in the course of his speech stated

The duty which is common to all cases where liability is established must logically be based upon some elements common to cases where it is found to exist. In English Law, there must be, and is,

some general conception of relations giving rise to a duty of care, of which the particular cases found in the books are but instances. The liability for negligence ... is no doubt based upon a general public sentiment of moral wrongdoing for which the offender must pay. But acts or omissions which any moral code would censure cannot in the practical world be treated so as to give a right to every person injured by them to demand relief. In this way, rules of law arise which limit the range of complaints and the extent of their remedy. The rule that you must love your neighbour becomes, in Law, you must not injure your neighbour; and the lawyer's question: Who is my neighbour? receives a restricted reply.

You must take reasonable care to avoid acts or omissions, which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law is my neighbour? The answer seems to be persons who are closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question (Donoghue v. Stevenson 1932: pp. 580).

Lord Atkin also established and enunciated the manufacturer's duty of care in the following words:

A manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products, will result in injury to the consumer's life or property, owes a duty to take reasonable care (Donoghue v. Stevenson 1932).

Therefore, Lord Atkin reduced the concept of the consumer of products to what has been described as the "neighbour principle," consumers being persons who are closely and directly affected by the acts or omissions (negligence) that are called in question. He did not consider the relationship of the consumer and the manufacturer as arising only through contract but focused on the impact of the product on the consumer.

The duty of care according to the neighbour principle is an obligation to which law will give recognition and effect; to comport to a particular standard of conduct toward another, one must conform to legal standards of reasonable conduct in the light of apparent risk. A duty of care will be owed whenever, in the circumstances, it is foreseeable that if the defendant does not exercise due care, the plaintiff will be harmed.

In a negligence claim, a plaintiff must show that a manufacturer, seller, wholesaler or other party involved in the distribution chain had a duty to exercise reasonable care and failed to fulfill that duty, resulting in injury to the plaintiff. Negligence consists of doing something that a person with normal degree of prudence would not do under the same conditions, or of failing to do something that a person of normal prudence would do under the same conditions or circumstances. This may include negligence in drawing up plans for a product, in maintaining the machines that make the component parts of the product, in failure to anticipate probable uses of the product, in failure to inspect or test the product adequately, in issuing no warnings or instructions or adequate warnings or instructions, in releasing the product into the stream of commerce where due care is not used, and so forth.

The foreseeability test established by Lord Atkin in the celebrated case of *Donoghue v. Stevenson* and known as the neighbour principle is very important. The greater the likelihood that the defendant's conduct will cause harm, the greater the amount of caution is required (Donoghue v. Stevenson 1932).

Needless to say, if the condition of a product changes so as to render the product unreasonably dangerous after it has left the control of a defendant, that defendant cannot be held liable unless the change was reasonably foreseeable within the scope of the product's intended use.

To succeed in a claim of negligence, the plaintiff will have to prove that the injuries or damages sustained were reasonably foreseeable at the time, and any claim will be judged by reference to prevailing standards of knowledge and practices, i.e., the state-of-the-art.

The leading English case of *Roe v. Minister of Health* illustrates the protection that the state-of-the-art defense offers. TA patient, Mr. Roe, was admitted to hospital for a minor operation. An anesthetist injected his spine with nupercaine that had been stored in glass ampoules that were kept in a jar of phenol. Unfortunately, and unknown to the anesthetist, the glass ampoules had developed visually undetectable cracks through which the phenol seeped and contaminated the nupercaine. Mr Roe sued for negligence, but failed, because the dangers were not at that time appreciated by doctors (*Roe v. Minister of Health* 1954: 66).

As Lord Denning pointed out, the evidence at trial was that this risk was first pointed out in 1951 and would not have been appreciated by an anesthetist in 1947: “Nowadays it would be negligent not to realize the danger, but it was not then.” (*Roe v. Minister of Health* 1954).

However, under the breach of warranty and strict liability counts, while a plaintiff need not prove negligence, proving medical causation of injury is a crucial element. Under the warranty count, a plaintiff was required to be in “privity” of contract with the defendant, meaning that a contractual relationship had to be established between the injured party and the defendant sought to be sued. When viewed from the angle of the warranty theory, a pharmacist will be held liable if he or she takes steps without the consent of the patient. But where a patient is notified about, for example, a generic substitution and he consents to it, no liability will lie against the pharmacist. Under the strict liability theory, a plaintiff is not required to prove negligence or that he was in privity of contract with the manufacturer or the other seller. The strict liability was introduced with a California Court decision in the case of *Greenman v. Yuba Power Products, Inc.*, where the plaintiff was not required to prove negligence or privity of contract (*Greenman v. Yuba Power Products Inc.* 1963).

Strict liability theory holds suppliers of defective products liable for injury caused to consumers, especially where the product left the manufacturer and was expected to reach the consumer without any substantial change in condition. The liability is strict because it exists even when the supplier of the product has exercised reasonable care.

In the case of *Grant v. Australian Knitting Mill Ltd*, the Privy Council held that the defendant manufacturers were liable to the ultimate purchaser of the underwear that they had manufactured and that contained a chemical that gave the plaintiff a skin disease when he wore them (*Grant v. Australian Knitting Mill Ltd* 1936).

In *Osemobor v. Niger Biscuits Company*, the plaintiff purchased a packet of biscuits manufactured by the defendants. While eating a biscuit, she felt something hard in her mouth and it turned out to be a decayed tooth. The Court held the manufacturers liable (*Osemobor v. Niger Biscuits Company* 1973).

In the case of *Kubach & Anor v. Hollands & Anor*, a schoolgirl was injured while carrying out an experiment with chemicals supplied by her chemistry teacher. Under normal circumstances, the experiment would have been harmless. The teacher had brought the chemicals from the second defendant who had purchased them from a third party. The second defendant was held liable in negligence because a distributor or retailer may be liable for defects in products in appropriate cases (*Kubach & Anor v. Hollands & Anor* 1937). The law treats both the manufacturer and distributor/retailer as joint tortfeasors and holds them liable, as in the dictum of Judge Pemu in *Dumuje v. Nigerian Breweries Plc.* (Pemu 2000).

As part of this duty of care, a manufacturer must supply adequate information with those products, including any relevant warnings, and failure to do so will amount to negligence if the manufacturer knew or ought to have known of any latent dangers inherent in the product. There is a continuing duty on the part of manufacturers and suppliers of medicinal products to monitor their safety and to ensure that they are fit for their purpose and are reasonably safe. On occasion, a medicinal product or a particular batch of the product may have to be recalled, and/or there may be a duty to issue further warnings or information about the product in the light of emerging

knowledge and surveillance data.

Only in exceptional cases are products defective due to design and that is why the product liability rule focuses not only on the manufacturer, but on all those who are interposed between manufacturers and the ultimate consumers. In the case of drug products, health workers such as physicians, pharmacists, nurses and others who are termed “learned intermediaries” make the decisions on product use or application.

A learned intermediary is the expert who can take into account the propensities of the drug as well as the susceptibilities of the patient. He or she takes the risk of weighing the benefits of medicines against their potential dangers. The choice is an informed one, an individualized medical judgement based on knowledge of the patient and of drugs (Ovbiagele 2000).

In the case of a prescription drug, the manufacturer is required to convey warning information to an intermediary and not necessarily to the consumers or patients, while for over-the-counter (OTC) drugs, the information is conveyed directly to consumers.

Applying the learned intermediary rule, the burden on the manufacturer is discharged once a responsible intermediary has been informed, as in the case of *Holmes v. Ashford* (Holmes v. Ashford 1950).

A doctor or pharmacist who fail to provide a patient with adequate information or omits to convey important warnings may be found liable in tort for negligence. This is because consumers will, of course, expect that drugs prescribed to them by doctors and dispensed by pharmacists will be reasonably safe to take as illustrated by the case laws below.

In the American case of *Kaiser v. Suburban Transportation System*, a bus driver fell asleep while driving his bus and a passenger was injured in the resulting accident. The passenger sued the doctor who had prescribed Pyribenzamine (a sedating antihistamine) to the driver and had failed to warn him of its side effect - a tendency to cause drowsiness. After taking the first dose of the medication the following morning, the driver went to work and fell asleep while driving. The injured passenger sued the doctor, and would have been able to sue the manufacturers of the drug if they had not fulfilled their duty of care by informing the physician of the dangers. In this case, the Washington Supreme Court held that the doctor was liable for negligence because he was considered to be a person with knowledge of both properties of the medication and the relevant characteristics of the patient (*Kaiser v. Suburban Transportation System* 1965).

The pharmacist as an expert on drugs is expected not only to advise the patient but also to provide drug information for the physician. In *Dooley v Everett*, the Tennessee Court of Appeal found a violation of a pharmacist’s duty of care when the defendant pharmacy gave no warning to the physician or patient that a drug it dispensed was contraindicated for asthma medication the patient was taking (*Dooley v Everett*, 1990). Also, a pharmacist was held liable for failing to instruct or counsel a patient on the maximum dosage and possible risk of exceeding that dosage (*Riff v. Morgan Pharmacy* 1986; *Lasley v Shrake’s Country Club Pharmacy Inc.*, 1994).

In the case of *Dwyer v. Roderick* in the United Kingdom, a woman who suffered gangrene in both feet required extensive surgery as a result of receiving an overdose of Migril that has been prescribed for migraine. She was awarded £100,000 (\$200,000 US) damages in a High Court in London. The court tried to apportion blame for the error between the doctor who prescribed the drug and the pharmacist who dispensed it. The doctor admitted negligence by agreeing that the dose of Migril prescribed was wildly incorrect. He added, however, that the liability should be equally shared with the pharmacist because pharmacist’s duty to the patient is as strong and clear as that of the doctor. The doctor argued that the pharmacist even visited the patient three days after she had started the course of drugs and should have checked the drugs the patient was taking. After proving the negligence of the pharmacist, Justice Stuart-Smith held the pharmacy liable for 45% (£45,000 or \$90,000 US) of the damages awarded. The premise was that the pharmacist owed a duty to the patient to ensure the drugs were correctly prescribed and that the pharmacist should have spotted the doctor’s error and queried the prescription with the prescriber. It is therefore clear that a pharmacist has both a legal and a professional duty to query prescriptions with the prescriber

and should not be deterred by any adverse response or resentment on the part of the prescriber, because the pharmacist can be held as a joint tortfeasor if the dispensed product causes injury to a patient (Dwyer v. Roderick 1982).

In another case, *Prendergast v. Sam Dee Ltd*, a patient was prescribed Amoxil for a chest infection, but the pharmacist misread it as Daonil mistaking the “A” for “D” and the “x” for “n.” The patient took the drug and suffered irreversible brain damage. Mr. Justice Auld of the London High Court, in awarding £139,000 damages (75% against the pharmacist and 25% against the doctor), said that even assuming the prescription was unclear, the pharmacist should have been alerted to the fact that Daonil was being recommended in the wrong dosage. It was not enough for the pharmacist to blindly dispense drugs without giving it a second thought (Prendergast v. Sam Dee Ltd. 1988).

Although the doctor has a duty to his or her patient to write a prescription sufficiently legibly to avoid its being misread by the busy and careless pharmacist, the pharmacist is also under duty to give some thought to a prescription he or she is dispensing, and to refuse to dispense such a drug if there is any ambiguity, until satisfied that it was the correct one.

It is also important to note that the pharmacist may or may not be liable for injuries resulting from product selection, depending on whether he or she chose the product with or without the consent of the patient and physician. In the American case of *Ullman v. Grant*, a pharmacist substituted a generic drug as equivalent, and the doctor had not prohibited substitution. The court held that the pharmacist was not negligent since it was not proved that the product dispensed was defective and inferior to the other brands. However, where a physician prohibits generic substitution, a pharmacist be in breach of duty and hence will be held liable (Ullman v. Grant 1982).

From the foregoing, the liability when a consumer suffers damages or sustains injury occasioned by the use of any medicinal products could be that of the manufacturer or entrepreneur, or the distributors or retailers, as well as the learned intermediary. However, if the consumer fails to adhere to the instructions provided by the manufacturers and the learned intermediaries, the consumer has voluntarily undertaken the risk. The position of the law is that no wrong is done to one who consents. Consent renders a person “*volenti*” and gives a defence of *volenti non fit injuria*, which means, that to which a person assents is not regarded in law as injury; therefore, the learned intermediaries will be protected from liability.

Another major act of negligence especially in the developing countries, is predicated on the failure of pharmacists to observe the pharmacy laws by leaving their pharmacies (stores) in the sole charge of an unregistered person such as clerks. Obviously, this is a charge of statutory negligence and were the unregistered person a clerk dispenses and drug that injures a defendant, the pharmacist will be held liable (Goodwin v. Rowe 1913).

The Government versus Pfizer lawsuit

Initially, three bereaved Nigerian families were given permission by the Kano High Court in March 2001 to sue Pfizer after 11 children died; the families sought \$1,000,000,000 US as compensation. In May 2007 (11 years after the completion of the clinical trial), the Government instituted a criminal charge (FHC/ABJ/CR/47/07) against the pharmaceutical firm at the Federal High Court in Abuja.

The government alleges that the drug makers did not seek the consent of the children’s parents, did not explain to the families that the antibiotic was experimental and that they could refuse treatment for their children, did not explain to them that other medicines were available and did not allow the parents of the children into the wards during the administration of the drug. The government alleges that the researchers administered Roche-made ceftriaxone, used as the control drug, in dangerously low doses to make Trovan look more effective, and, after the completion of the trials, that Pfizer took all medical records and obliterated any evidence. The government also claims that the approval letter obtained from a Nigerian ethics committee was falsified. They summarize that these acts violated Nigerian laws, the International Declaration of Helsinki (Declaration of Helsinki 1964) and the UN Convention on the Rights of the Child.

Pfizer on their part has vehemently denied the allegations of misconduct surrounding the drug trial and claims that the suit has no merit, is frivolous and is a gross abuse of court process. They argue that at the time of the Kano clinical trial, Trovan, which was in the last stage of development, had been tested clinically in more than 5000 patients and showed excellent activity against all meningitis pathogens. Pfizer said they used the best medical knowledge available at the time and acted in the best interest of the approximately 200 children involved in the trial. They also claim that they sought and obtained all necessary approvals from relevant federal and state government agencies in Nigeria and that an approval letter was obtained from the National Agency for Food and Drugs Administration and Control (NAFDAC) in March 20, 1996.

A US federal court had dismissed a previous lawsuit filed against Pfizer in 2005 concerning the Kano clinical trial, but the trial Judge (Justice Anwuri Chikere) in Abuja has refused to dismiss the case as submitted by the Counsel to Pfizer.

Use of Trovan was severely restricted by the US Food and Drug Administration agency in 1999 because the drug was associated with reports of liver damage and deaths. European regulators also banned the drug.

In my view, a pharmaceutical company should be able to accept responsibility for the efficacy and safety of its product and the clinical investigations used to justify that the therapeutic value of the product outweighs the foreseeable inherent risks to the subjects or others. The question that comes to mind, even after fulfilling all ethical obligations is whether legal issues can arise from a particular action. In the treatment of a sick person, one is free to use a new therapeutic measure if, in one's judgement, it offers hope of saving life, re-establishing health or alleviating suffering. There is also the need for clear protocols, procedures and supervision in trial stages. The effect of inadequate protocol and proper duty of care was observed at a Liverpool inquest in 1984, where there was evidence that during a trial for oral morphine tablets given following a routine gynecological operation, a woman had died of unexpected side effects. The researchers were held liable (Brahams 1984).

Conclusion

Pharmacists have a duty to fill prescriptions correctly and to warn patients or notify prescribing physicians of an excessive dosage or of obvious inadequacies in prescribing that creates a substantial risk of harm to the patient.

It is hereby recommended that statutes and regulations such as the Nigerian Consumer Protection Act and other laws relating to product liability be updated to reflect the contemporary pharmacy practices and to provide stricter liability provisions as well as additional basis for a claim for damages for personal injuries to an action in negligence (tort) or contract. Although it is argued that truly strict liability would seriously hamper the development of new products, it is important to safeguard the health of the Nigerian public especially since most of these products are imported.

In the Pfizer case, the main issue is to establish if it was actually Trovan that caused the death and/or damages to the children involved in the Kano clinical trial. To not be prejudicial, this paper will only raise some questions that will need to be addressed. These are as follows: Before the Kano clinical trial, had Pfizer tested the drug in children with meningitis? Is there evidence that the drug (and not the disease) played a part in the death of the children? Did the experimentation conform to generally acceptable scientific principles such as dosage in children (e.g., compliance with *Bolam v. Friern Barnet HMC 1957*)? Did the experimentation conform to the laws and regulations of the country in which the research was performed? Was the research carried out by scientifically competent personnel following approved procedures? Was a higher standard of care required in the situation? Are there inherent risks associated with the use of the drug, and what procedures were followed to warn patients and what procedures were taken to manage those risks? Are the reasons (e.g., illiteracy) for not obtaining consent tenable? Is the allegation of malpractice in the dosage of ceftriaxone (Rocephin) used true?

Answers to these questions are necessary, and evidence should be examined to establish a link between the alleged breach of the duty of care and the resulting harm before liability can arise.

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