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Pharmaco-Legal Issues in Drug Administration and Consumption

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Abstract:
In order to explain the layered sheath-like consumer protection against counterfeit, fake, adulterated and substandard drugs in modern pharmacy practice, this work designed a Drug Consumer Protection Model. It further explored the role of the law, practice and care in achieving a complete consumer protection based on the concepts of pre-exposure and post-exposure. Under the layers and sub-layers identified, the producer (pharmacist) is prone to an assortment of liabilities including criminal, civil and professional discipline. Nonetheless, having regard to the relative protection the law accords the producer through available defenses, this work advocates the need not to unduly fetter the discretion of the producer as a professional.

1. Introduction

It is expedient from the onset to state that whereas pharmaco-legal issues are easy to appreciate in general pharmacy practice, drug administration and consumption raise issues peculiar to health institutions. To properly situate consumer protection in the context of Drug Administration, therefore, working definitions have to be fashioned out for terms like drug administration, consumer protection, producer and consumer. The purpose is to see which terminologies under consumer protection as a concept can be accommodated by the pharmaco-legal issues raised in this work and those that require techno-juristic tinkering.

Next, this work treats consumer protection under Drug Administration in layers to correspond with the chain of activities culminating in drug consumption and even beyond. In this connection, it is possible to recognize three (3) layers of protection viz:

i. Consumer protection as a matter of law-1st Layer
ii. Consumer protection as a matter of practice-2nd Layer
iii. Consumer protection as a matter of pharmaceutical care-3rd Layer

It is pertinent to note that each layer creates the next one in the order stated to achieve a complete consumer protection.

Under the first and second layers of protection, it is again possible to recognize the concepts of pre-exposure (use) and post- exposure (use). Pre-exposure or use under the first layer is based on the philosophies of paternalism[i] and information or disclosure[ii] and anchored on the UN Guidelines for Consumer Protection[iii] and local legislation. The local legislation set out predominantly to prevent the consumer from getting in contact with counterfeit, fake, substandard and adulterated drugs by criminalizing certain activities of the producer or supplier with a view to protecting the consumer from harm. The concern of the law under this sub-layer is essentially deterrence. Post exposure or use under the first layer is based on the philosophy of individualism anchored on the notion of the individual's freedom to act, relies on voluntary and unhindered exchanges, sees the consumer as his best protector, and hence is represented by the *caveat emptor*[iv]. It must, however, be noted that since the relationship between the pharmacist, as a retailer and the consumer (patient), strictly speaking, is not that of a seller and buyer, the liability rule is not based on contract but tort, hence the remedy under this sub-layer is essentially tort-based.

Under the second layer of protection, which is consumer protection as a matter of practice, the pre-exposure (use) and post-exposure (use) concepts also exist as sub-layers. The pharmacist as supplier of medicaments under pre-exposure rely on the outcome of physical examination for details on expiry date, composition and address, use of cutting edge technologies as quality control, insistence on prescription sheets for certain drugs and non-disclosure of the names of certain drugs in ensuring that the consumer does not get into contact with counterfeit or fake drugs or drugs with addiction-forming and addiction-sustaining liability. The above-mentioned activities of the pharmacist are geared towards ethical practice, falling which; he would be accordingly disciplined by the Pharmacists Council of Nigeria (PCN). Where, however, the consumer, under the second sub-layer under the second layer actually uses the offending drug in question, the liability of the pharmacist (supplier) bifurcates-damages based on tort and professional discipline.

Consumer protection as a matter of pharmaceutical care as the third layer of protection is actually an off-shoot of consumer protection as a matter of practice (second layer). But because the former is about the protection of the consumer against his or her own unusual reactions to conventional drugs while the latter seeks to protect him/her against unethical practice by the pharmacist as a dispenser or supplier, this work treats them differently. The third layer of consumer protection as conceptualized by this work correlates with the emerging concept of pharmaceutical care[v] with pharmacovilance (Pv)[vi] as an integral part. Obviously, the liability of the pharmacist under the third layer of protection is limited to professional discipline for unethical practice, as he cannot be held liable in tort for injuries to the consumer occasioned by the consumer's idiosyncrasy[vii].

Finally, this work examines the producer's liabilities as outlined and attempt to tie them to the correlative consumer's remedies using a case study approach. According to Kanyip, if the liability rule is contract or tort-based, or is criminal base, or administrative or regulatory in nature, then the remedy would equally be contract or tort-based, or punitive or administrative as the case may be[viii]. Also, this last segment examines the possible qualifications, exemptions, exceptions, excuses and/or defenses to the consumer rights and remedies as a protection for the producer.

2. Conceptual Clarifications

As noted in the introductory segment of this work, because of the technical nature of the aspect of consumer protection under consideration, a few key terminologies require clarification. The purpose is to make for easy understanding of the Pharmaco-Legal issues raised in this work.

2.1. Drug Administration

In the hospital setting, "Drug Administration" encompasses the roles of the doctor who prescribes drugs, the pharmacist who dispenses the drugs and the nurse who actually administers the drugs on the consumer (patient) in meeting his health need. They all qualify as producers for the purpose of liability to the consumer. However, since this work is to consider only Pharmaco-Legal issues, "drug administration" is restricted to the role of the pharmacist in this context. But pharmacist in this context also includes the one in community practice. This is the sense in which drug administration is used in this work.

2.2. Consumer Protection

It is the prevention or reduction of wrongs or injuries (occasioned by a producer), and the provision of redress for an individual purchaser, user or disposer of any product or service[ix]. This definition is adequate and therefore adopted by this work.

2.3. Producer

It should be noted that as important as the term is to the concept of consumer protection, it is not defined in the Consumer Protection Council (CPC) Act[x]. Textually, it is defined as a generic term which encompasses all those persons who stand in converse position to the consumer in respect of all contractual relations and they include "the manufacturers, the distributor, the wholesaler, the marketer, the seller, the importer, the retailer, the banker, the legal practitioner, the medical doctor, the insurer, the bailee and public utilities"[xi]. However, since we are dealing with pharmaco-legal issues for consumer protection, the producer is necessarily a pharmacist or a pharmaceutical company with legal personality.

Having regard to registration requirements for dealing in drugs in Nigeria, the former serves as a producer when he dispenses drugs either in the hospital, pharmacy or in retail outlet, whereas the latter qualifies as a producer if it is a manufacturer, importer or wholesaler. For the purpose of this work, therefore, the producer is the pharmacist acting either as a dispenser, manufacturer, importer or wholesaler. It is also significant to mention that Patent Medicine Vendors who sell only patent and proprietary medicines qualify as producers for the purpose of liability for the wrongs and injuries to consumers. But again, since we are concern with only pharmaco-legal issues for consumer protection in this work, no further mention will be made of them. Finally, the possibility of making a government agency that certifies drug a producer for the purpose of liability is to be examined later in this work.

2.4. Consumer

According to the CPCA[xii], a consumer means "an individual, who purchases, uses, maintains or disposes of products or services. But to Ajai, the use of the words "maintain" and "dispose" in the body of the CPC Act is "an unwitting, irrelevant, otiose and doctrinally unsound expansion of the ambit of the Act beyond the consumer[xiii]. Kanyip, on the other hand, while concurring with Ajai on the use of the word "maintain" held an opposing view with the use of the word "dispose"[xiv]. Having regard to the chain of activities involved in drug handling, the word "dispose" merely creates a cascade of consumers down the chain. For example, for drugs manufactured outside Nigeria, the word "dispose" as used in the Act makes the patient a consumer to the dispensing pharmacist who, in turn, is a consumer to the wholesaler, who, in turn is a consumer to the importer that is a consumer to the manufacturer. It is submitted that but for the use of the word "dispose", importer who receives counterfeit or fake drugs from a manufacturer as a pharmaceutical company may not be able to claim any compensation from the manufacturer by way of third party procedure if sued for damages by a wholesaler and a wholesaler sued by a dispensing pharmacist.

3. Layers of Consumer Protection

As noted under paragraph C, the producer in Drug Administration is either a pharmaceutical company with legal personality (manufacturer, importer or wholesaler) or a pharmacist in the hospital or community practice. In the paragraph, also, a somewhat descending producer/consumer relationship was established between the producers themselves before that between the producers and the consumer (patient). On the final analysis, the ultimate consumer is coated with different layers of protection based on different philosophies and the rules of liability. In fact, this work has designed a model for consumer protection in Drug Administration (hereinafter referred to as "Drug Consumer Protection Model".

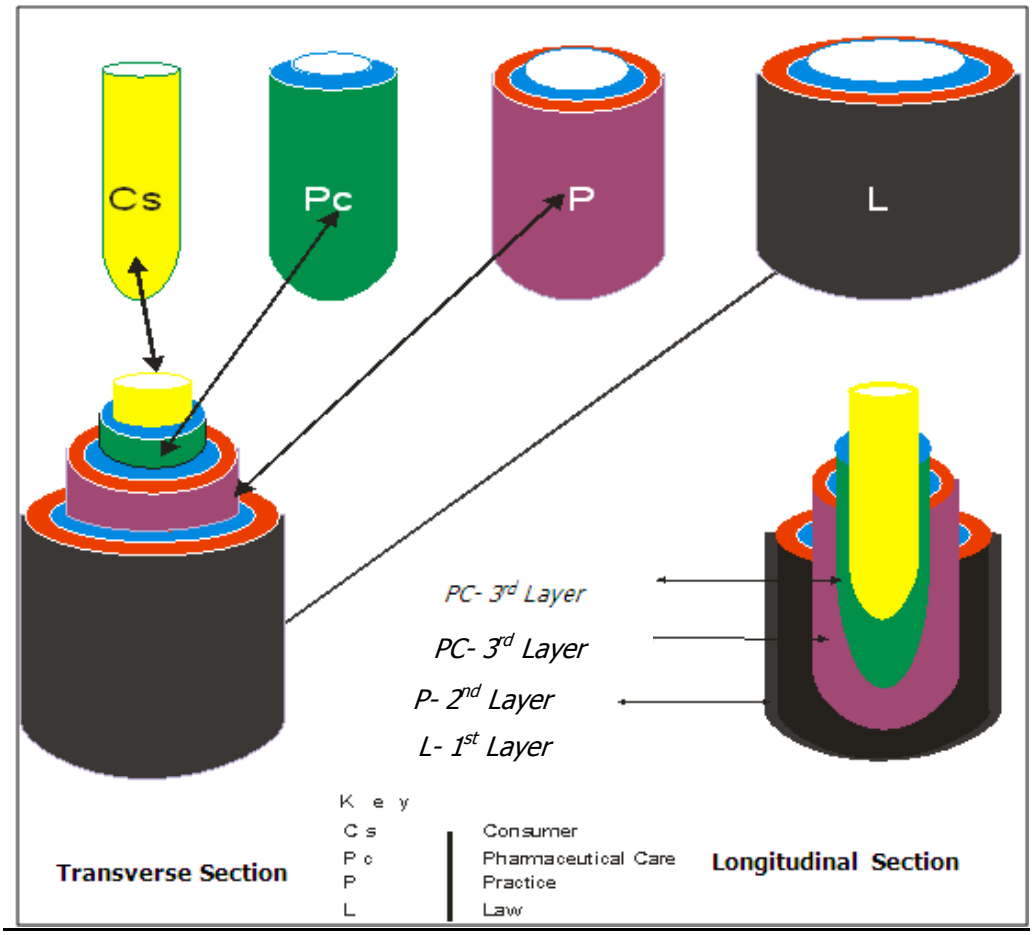

Figure 1: Drug Consumer Protection Model (DCPM)

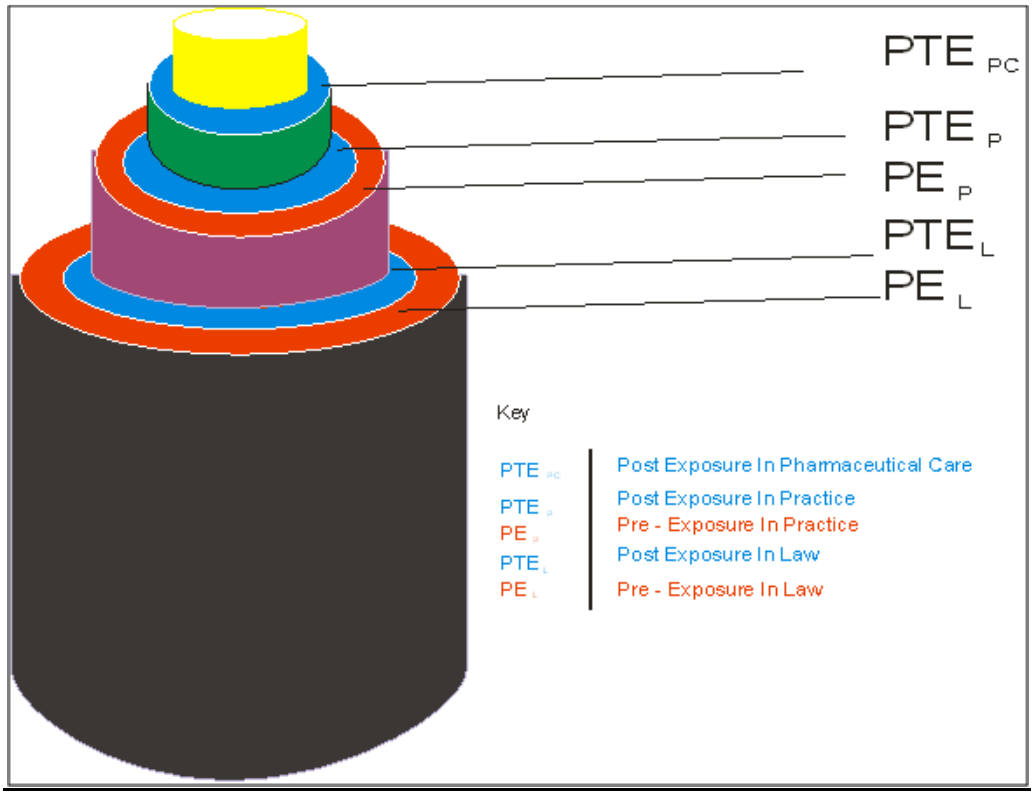

Figure 2: Drug Consumer Protection Model (DCPM)

From the diagrammatic representation of Drug Consumer Protection above, the law, as the base of the protection provides the framework for practice and pharmaceutical care. Under the 1st and 2nd layers, that is, law and practice, the range of the consumer protection is divided into pre-exposure (use) and post- exposure (use) sub-layers, which correspond to the different liability rules and the correlative consumer remedies. However, since the 3rd layer as at today is predicated on moral ground, the protection it affords the consumer is essentially at the post-exposure (use) sub-layer.

3.1. Consumer Protection as a Matter of Law (1st Layer)

If indeed consumer protection is about the adjustment of power relations between consumers and producers, then the law is the appropriate starting point in examining it. It is no wonder, therefore, that the Government of Nigeria, in living up to its social objectives under the Constitution has deployed the instrumentality of the law to the protection of consumers as citizens[xv]. In doing so, the Government is guided by the capitalist nature of the Nigeria's economy with its exploitative tendencies, as well as the predominantly illiterate consumer society. For effective drug consumer protection in Nigeria, the law takes up dual personality based on the philosophies of paternalism/disclosure and individualism. Based on the former philosophy, the law seeks to prevent the consumer from having any contact with counterfeit or fake drugs, pre-exposure (use) through criminal sanctions in various legislation. Under the latter, discussed as post-exposure (use), the law imposes liability based on the rules of tort.

3.1.1. Pre-exposure (use)

Under this sub-layer, we are concerned with how the law protects the consumer even before he gets in contact with counterfeit or fake drugs. Ideally, on a subject of this nature with international coloration, the mechanism for addressing issues arising there from is usually a mosaic of treaty provisions and local legislations enforced by an amalgam of local and international institutions. Such treaties lay down the framework within which local legislations are made and implemented. This approach would have been particularly effective for the issue of consumer protection against drug counterfeiting having regard to Nigeria's over reliance on foreign drugs. Unfortunately, the UN Guidelines for consumer protection unanimously adopted in its Resolution[xvi] still remains guidelines as at today. In general, the guidelines make provision in respect of the following matters:

a. that countries should adopt appropriate measures to ensure that products are safe for either the intended or normally foreseeable use;
b. that government policies should enable consumers obtain optimum benefit from economic resources, and achieve the goals of satisfactory production and performance standards;
c. that governments should formulate and promote the elaboration of standards at both national and international levels for the safety of goods and services and give them appropriate publicity;
d. that governments should ensure the efficient distribution of goods and services to consumers;
e. that governments should establish and maintain legal and/or administrative measures to enable consumers or relevant organizations to obtain redress expeditiously and inexpensively;
f. that governments should develop and encourage the development of general consumer education and information programmes and which should be an integral part of the basic curriculum of the educational system, preferably as a component of existing subjects;
g. that governments should adopt and maintain the standards of food security, safety and adequate supply laid down by the Food and Agriculture Organization (FAO), the World Health Organization (WHO) and Codex Alimentarius Commission;
h. that governments should ensure the supply and distribution of good and quality drinking water;
i. that governments should develop and maintain adequate standards and regulations for the supply of appropriate Medicare through a National Drug Policy; and
j. that governments should develop, review, maintain or strengthen appropriate mechanisms for the exchange of information on material policies and measures, in co-operation with other countries at the international level or among different tiers of government at the domestic level.

Paragraphs (e) and (i) of the guidelines appear to be the more relevant to this work. However, it does not enjoin member nations to prohibit activities capable of bringing consumers in contact with counterfeit or fake drugs. To that extent, it is unhelpful to the consumer at the pre-exposure (use) layer of protection. Moreover, the guidelines, not having been transmuted into a treaty is of limited value to consumer protection for want of enforcement.

In Nigeria, the law, through various legislation prohibits the activities of the manufacturer, importer, wholesaler and the dispensing pharmacist capable of occasioning wrongs and injuries to the consumer (patient). Notable amongst the legislations and relevant to this work are:

i. Poisons and pharmacy Act[xvii], (PPA)
ii. Consumer Protection Council Act[xviii] (CPCA)
iii. Food and Drugs Act[xix] (FDA)
iv. Food, Drugs and Related Products (Registration, etc.) Act[xx] (FDRA)
v. Counterfeit and Fake Drugs and Unwholesome Processed Food Act[xxi] (CFDA)
vi. National Drug Formulary and Essential Drugs List Act[xxii] (NDFA)
vii. National Agency for Food and Drugs Administration and Control Act[xxiii] (NAFDAC).

viii. Price Control Act[xxiv] (PCA)

With the above enactments in mind, it is expedient to start with the nature of consumer protection afforded by the CPCA, which has assumed a motherly role in its penal provisions. The following provisions of the CPCA are significant in this regard:
Any person who issues or aids in issuing any wrong advertisement about a consumer item, is guilty of an offence and liable on conviction to a fine of N50,000 or to imprisonment for a term of five years or to both such fine and imprisonment[xxv].
Any person who, in contravention of any enactment whatsoever for the protection of consumer:

a. sells or offers for sale any unsafe or hazardous goods; or
b. provides any service or proffers any information or advertisement thereby causing injury or loss to a consumer, is guilty of an offence under this Act and liable on conviction to a fine of N50,000 or to imprisonment for a term of five years or to both such fine and imprisonment.[xxvi]

Ideally, the penal provisions, in the context of this work are meant to protect the consumer at the pre-exposure (use) sub-layer through deterrent of the producer. However, from the nature of the provisions, it is submitted that the CPCA is a generic enactment with no life of its own, for at least two reasons. One, it has neither defined nor listed consumer items. Two, it depends on the existence of other enactments on consumer protection for its applicability. Even at that, there is the problem of which penalty applies – (a) the omnibus penalty under the CPCA[xxvii] or (b) the one provided by the contravened enactment for the sale of any unsafe or hazardous goods and so forth. It is, therefore, submitted that the CPCA has not added any value to the protection of consumers by deterring the producers beyond arousing their consciousness to the fact that they are protected by some enactments.
In considering the contributions of the other listed legislation to the protection of the consumer, only a few representative samples of the penal provisions and their deterrent effects will be demonstrated. Notable provisions in this regard are found in the:
CFDA – Notwithstanding anything to the contrary contained in the Constitution of the Federal Republic of Nigeria, 1979, as amended, or any enactment or law, any person who –

a. produces, imports, manufactures, sells, distributes or is in possession of; or
b. sells or displays for the purpose of sale; or
c. Aids or abets any person to produce, import, manufacture, sell, distribute or display for the purpose of sale, any counterfeit, adulterated, banned or fake, substandard or expired drug or unwholesome processed food, in any form whatsoever, commits an offence under this Decree (Act) and shall, accordingly be punished as specified in this Decree (Act).[xxviii]

Any person who commits an offence under Section 1 of this Decree (Act) is liable on conviction to a fine not exceeding N500,000 or imprisonment for a term of not less than 5 years or more than 15 years or to both such fine and imprisonment[xxix]
PPA – Under Part VI on control of sale of patent and proprietary medicines, the PPA punishes non-disclosure of compositions of medicine upon conviction with a fine of twenty pounds for first offenders and one hundred pounds or imprisonment for a term of three months or to both such fine and imprisonment for subsequent convictions[xxx]
FDA - This Act prohibits the sale of any drug which is adulterated, or which was manufactured, prepared, preserved, packaged, or stored under insanitary conditions[xxxi]
PCA - This Act prohibits the sale of pharmaceutical products otherwise than in accordance with a resale price maintenance agreement or arrangement entered into by the manufacturer, importer or distributor on the one hand, and the seller (whether a wholesaler or retailer) on the other[xxxii].
FDRA – This Act prohibits the advertisement of any drug in Nigeria unless it has been registered in accordance with the provisions of the Act or regulation made under it[xxxiii].
The above penal provisions, together with the ones in the other listed enactments are meant for the protection of the consumer under the pre-exposure (use) sub-layer of the 1st Layer. The sub-layer insulates the consumer from contact with the counterfeit or fake drugs through deterrent policies aimed at the producer. By the aggregation of the provisions, it is hoped that only conventional drugs get to the consumer, hence he is well protected from wrongs and injuries by the producer.

3.1.2. Post-exposure (use)

Once the consumer gets into contact with the counterfeit or fake drug, either by purchase, use or disposal, the protection the law affords becomes expanded, direct and proximate. Unlike the protection afforded the consumer under the pre-exposure (use) sub-layer, which is purely hinged on public law, under the post-exposure (use) sub-layer, the protection is rooted in both private and public law. Here, the protection is exacted through administrative/regulatory provisions, contract law and tort law.
An example of an administrative provision for consumer protection under this sub-layer is found in the CPCA[xxxiv], which provides as follows:
Whereupon an investigation by the Council or State committee of a complaint by a consumer it is proved that –

a. the consumer's right has been violated; or
b. that a wrong has been committed by way of trade, provision of services, supply of information or advertisement, thereby causing injury or loss to the consumer, the consumer shall, in addition to the redress which the State Committee, subject to the approval of the Council, may impose, have a right of civil action for compensation or restitution in any competent court.

Clearly, by this provision, the law empowers the CPC to redress the wrongs or injuries suffered by the consumer. Regrettably, no such provision is contained in the NAFDAC Act to enable it deal with the myriad of complaints lodged before it daily. This means it has only criminal proceedings as an option for redressing the injuries caused a consumer, which remedy is of no direct benefit to the

affected consumer. This is because, unlike the CPCA[xxxv], the NAFDAC Act contains no provision mandating the court to, in addition to the penalties for any offence to make compensation order in favor of the consumer. It is submitted that the power to redress wrongs or injuries to consumers administratively by NAFDAC is most desirable in view of the uncertainty of criminal proceedings in Nigeria and the absence of a provision on compensation order in the NAFDAC Act.

A consumer who either purchases or disposes counterfeit or fake drugs is under contract with the producer; therefore, the liability rule is contract. The consumer here is not the patient who uses the drug in question but the pharmacist or pharmaceutical company that acts as a wholesaler or importer. This category of consumers comes under the protection of the numerous warranties contained in the Sale of Goods Law like the Kaduna State Sale of Goods Edict (KSSGE)[xxxvi] as well as the remedies available under contract. Some of the notable warranties under the KSSGE are:

1. Obligations as to title[xxxvii]
2. Obligations as to quantity[xxxviii]
3. Obligations as to quality[xxxix]
4. Obligations as to description[xl]
5. Obligations as to merchantability[xli]
6. Obligations as to fitness for purpose[xlii]
7. Obligations as to sample[xliii]

Against these obligations on the producer (seller) the law (KSSGE) grants the consumer (purchaser/disposer) or buyer two principal remedies – the right to repudiate the contract[xliv] and the right to claim for damages[xlv]. Additionally, damages for misrepresentation and breach of contract avail the consumer.

Having regard to the KSSGE[xlvi], the definition of contract of sale of goods as, "a contract by which the seller transfers or agrees to transfer the property in the goods to the buyer for a money consideration called the price" covers the relationship between the producer and consumer under the consumer protection regime with drugs as the goods. However, this work is limited to Pharmaco-Legal issues arising from consumer protection; hence it cannot accommodate a detailed discussion of contractual issues hinged on sale of goods. This is in recognition of the fact that pharmacy, as a profession, has ethical practice and not business as the underlining consideration. It is in this regard that a pharmacist is said to dispense and not sell drugs. For the purpose of this work, therefore, the issues of manufacturers, importers and wholesalers as pharmaceutical companies and pharmacists as producers and on the reverse, importers, wholesalers and pharmacists as purchasers and disposers, and therefore consumers are treated as side issues for clarity.

Still under the post-exposure (use) sub-layer, the liability rule of tort affords the consumer a reasonable level of protection. Remedies for the tort of deceit, product liability and negligence avail a consumer who has actually used a counterfeit or fake drug. Negligence of the nature of the sale of expired drugs also amounts to both an offence[xlvii] and professional misconduct. Besides the criminal sanction for such negligence, the consumer is at liberty to either pursue the recovery of damages in civil suit or apply to an administrative tribunal set up under the PCN Act[xlviii] for disciplinary measures against the pharmacist (producer) or both. Where the pharmacist (producer) is adjudged guilty of infamous conduct as a result of the negligence, the Tribunal is empowered to give a direction reprimanding him or ordering the Registrar of the Pharmacists Council of Nigeria (PCN) to strike his name off the relevant part of the register[xlix].

3.2. Consumer Protection as a Matter of Practice

This second layer of protection deals with the roles of the PCN and NAFDAC as regulatory bodies in pharmacy profession and the pharmacist in ensuring the safety of the consumer of drug products. The regulatory activities, as well as the exercise of professional judgment by the pharmacist under this layer also fall within the legal framework for the profession. Based on the remedies available to the consumer under this layer, it is possible to recognize yet two sub-layers – pre-exposure (use) and post-exposure (use).

3.2.1. Pre-exposure (use)

The objective here is the same with pre-exposure (use) under para. IIIA1, that is, pre-contact protection of the consumer. However, while the liability rule in the former is criminal, that in the latter is administrative or regulatory in nature.

In ensuring that only qualified persons handle drugs and that consumers get in contact with only conventional drugs, the PCN under the PCN Act[l] is charged with the general duty of:

a. Determining the standards of knowledge and skill, to be attained by persons seeking to become registered members of the pharmacy profession (in this Decree referred to as the "the profession") and reviewing those standards from time to time as circumstances may require;
b. Securing in accordance with the provisions of this Decree, the establishment and maintenance of registers of persons entitled to practice as members of the profession and the publication from time to time, of lists of those persons;
c. Reviewing and preparing from time to time a statement as to the Code of Conduct which the Council consider desirable for the practice of the pharmacy profession;
d. Regulating and controlling the practice of the profession in all its aspects and ramifications;
e. Performing such other functions as may be required of the Council under this Decree.

No doubt, these duties, if properly carried out by the PCN will serve as consumer protection in drug administration. Unfortunately, due to Government's lack of appreciation as to how drugs should be handled, as evident in its drug policies, lack of political will to

address the chaotic drug distribution channels and other hidden considerations, the PCN has been unable to act decisively. The obvious consequence is that, as at today, drug products are handled like any other household item by quacks to the detriment of consumer protection. It is submitted that unless and until the Government of the day wakes up to its responsibility by streamlining the extant chaotic drug distribution channels, no meaningful consumer protection is achievable.

On the part of NAFDAC, the most visible drug regulatory body, its diagnosis and approach to the issue of drug counterfeiting and faking leaves much to be desired with respect to drug consumer protection. Its exploit in the regulation of the manufacture, importation, exportation, distribution, advertisement, sale and use of food and drugs has earned it the self-acclaimed slogan, "Safe-Guarding the Health of the Nation". The latest in its game plan is the introduction of cutting edge technologies such as truscan machine and stropxil technology. According to NAFDAC, Nigeria is the first country in the world to deploy these technologies into checking counterfeit and fake drugs, even though the technologies are foreign. It claims that with these technologies, the power to detect counterfeit and fake drugs has been transferred to the consumer.

The operation of the truscan machine is indeed simple and easy. With it, a pharmacist, in the comfort of his office can use it to detect which drug in the pharmacy is a counterfeit or fake. NAFDAC has further modified the technology to enable a consumer in the floor of the pharmacy to confirm the authenticity of drugs before obtaining them from the supplier by scratching a silver panel on the packet to reveal a number with which to call the Agency for information on the drug. The result of the information search is either, "correct and genuine" or "fake, don't use".

Obviously, these technologies have a place in the detection of counterfeit and fake drugs and, *a fortiori*, consumer protection but their value is greatly limited by the Nigeria's situation. The pharmaco-legal issue here is whether it makes sense to allow counterfeit and fake drugs from foreign nations to flood the Nigerian market only to attempt to erect a barrier between the drugs and the consumer? In other words, is it not better to intensify the fight against the importation of the drugs in the first place? Here lies the incorrect diagnosis of the problem by NAFDAC.

If the current statistics that over 70% of the drugs consumed in Nigeria are imported, then any meaningful fight against drug counterfeiting must of necessity be targeted at the manufacturers of the drugs. Otherwise, the present situation where NAFDAC relies solely on local legal regime to fight an international problem is an exercise in futility. Elsewhere, this writer has recommended the domestication of the United Nations Convention against Transnational Organized Crime [li](Palermo Convention) as a means of stemming the conspiracy between the foreign manufacturers and their Nigerian collaborators. With the offence of conspiracy and the forfeiture regime under the Palermo Convention, NAFDAC would be properly positioned in law to deal with the menace of drug counterfeiting thereby enhancing consumer protection.

Lastly, the pharmacist, as a producer, has over the years in the course of his practice enhanced consumer protection through:

a. The practice of dispensing certain drugs only on prescription
b. Consumer (patient) counseling
c. Non-disclosure of the names of certain drugs to the consumer

These practices evolved over the years, are meant to protect the consumer from the misuse and abuse of certain drugs. They serve to prevent the consumer from contact with the drugs except under certain conditions. Although these practices are largely based on the professional judgment of the pharmacist, they emanate from the legal framework for the dispensing of drugs.

Unfortunately, attempts have been made to convert the pharmacist's discretion to dispense certain drugs on prescription to a legal requirement. In the recent murder saga involving one Miss Cynthia Akosogu, the issue of dispensing Rohypnol (flunitrazepam) tablet without prescription was over stretched. The pharmacist who sold the Rohypnol with which Cynthia was drugged before been murdered was charged along with the murder suspects for conspiracy, rape, murder and administering obnoxious substance.

Earlier, Ediru[lii], in making clarifications on the charges submitted that no law exists in Nigeria under which a pharmacist can be charged for dispensing any drug without prescription; moreover, no law lists the drugs to be dispensed on prescription. On the restriction on the sale of poisons, rohypnol inclusive, he further drew the attention of the public to the provision of the PPA[liii], which states that, "No selling dispenser or chemist shall sell or deliver any poison (Rohypnol) included in part 1 of the first schedule to this Act, to a person unless that person is known to the seller or introduced by some person known to the seller to be a person to whom the poison may properly be sold".

Still on the issue of dispensing drugs without prescription, Ediru, maintained that the written order or prescription by a medical doctor serves as an introduction of the patient to the pharmacist as a person, to whom the poison may properly be sold, but that if the patient is known to the seller (pharmacist), such introduction becomes otiose. Also, he submitted that a pharmacist's professional judgment whether or not to dispense a drug on prescription is not automated by a doctor's prescription. According to him, this point has been successfully canvassed by his humble self in a case[liv] decided by Badamasi Maina J (as he then was) on the 30th day of July, 2009 in the Nasarawa State High Court 2.

Writing the next day, through the same medium and in support of Ediru, Amalu, posits:

Now if the police bothered to find out what the drug Rohypnol (flunitrazepam) is, as clearly explained by the pharmaceutical society of Nigeria (PSN), then unless there are other acts of complicity to ground conspiracy, charging Osita who allegedly sold the drug to the confessed felons for the offence of murder; instead of dragging him to the pharmaceutical society for breach of professional ethics is preposterous.

From the position of the two commentators, it is clear that the practice of dispensing certain drugs on prescription is in the domain of the pharmacist's discretion and meant to protect the consumer and that a breach by the pharmacist attracts professional discipline and not criminal liability.

Counseling as an integral part of pharmacy practice is not simply providing information to the consumer; rather, a counseling session is an opportunity for information exchange. It is based on the correlative assumptions that the pharmacist (producer) is the expert on drug therapy but the patient (consumer), the expert on his daily routines, how he understands the illness and its treatment, and whether he anticipates any problems taking the medication as prescribed. Counseling is both a pre-exposure and post-exposure service aspect of the practice aimed at helping the consumer to adhere to treatment regimens.

For counseling to be effective and to serve as consumer protection its content is very essential. It must be such as to secure consumer's compliance with treatment regimens with the overall goal of meeting his drug need. In this connection, a checklist[lv] with the following items has been developed.

1) Pharmacist introduces self.
2) Identifies patient or patient's agent.
3) Asks if patient has time to discuss medication.
4) Explains purpose and importance of counseling session.
5) Asks patient what physician told him or her about medication and what it is treating. Asks what patient knows or understands about the disease. Uses any available patient profile information (including possible allergies).
6) Asks patient if he or she has any concerns prior to information provision.
7) Responds with appropriate empathy, listening, and attention to concerns. Uses these skills throughout counseling session.
8) Tells patient the name, indication, and route of administration of the medication.
9) Tells patient the dosage regimen.
10) Asks patient if he or she will have a problem taking the medication as prescribed.
11) Tailors medication regimen to patient's daily routine.
12) Tells patient how long it will take for the medication to show an effect.
13) Tells patient how long he or she might be on the medication.
14) Tells patient when he or she is due back for a refill (and number of refills).
15) Emphasizes benefits of the medication and supports its use before talking about side effects and barriers.
16) Discusses major side effects of the drug and whether they will go away in time. Discusses how to manage side effect and what to do if side effect does not go away and becomes intolerable.
17) Points out that additional rare (emphasizes this to patient) side effects are listed in the information sheet (to be given to patient at the end of counseling session). Encourages patient to call if he or she has any concerns about these.
18) Uses written information to support counseling where appropriate.
19) Discusses precautions (e.g., activities to avoid).
20) Discusses beneficial activities (e.g., exercise, decreased salt intake, diet, self-monitoring).
21) Discusses drug-drug, drug-food, and drug-disease interactions.
22) Discusses storage recommendations and ancillary instructions (e.g., shake well, refrigerate).
23) Explains to patient in precise terms what to do if he or she misses a dose.
24) Checks for understanding by asking patient to repeat back key information (e.g., drug name, side effects, what to do about missed doses).
25) Rechecks for any additional concerns or questions.
26) Advises patients to always check their medicine before they leave the pharmacy.
27) Uses appropriate language throughout counseling session.
28) Maintains control of counseling session.
29) Organizes information in an appropriate manner.
30) Follows up to determine how patient is doing.

Although the checklist serves as a package in counseling, only a few items on the list relevant to the topic at hand will be considered. For example, items 8 & 9 are about telling the consumer the name, dosage regimen, indication and route of administration of the medication. Ethically, the pharmacist is under a duty to counsel the consumer on dosage regimen and route of administration before the medication is handled over to him. At this point, counseling helps to protect the consumer from injuries that may arise from taking wrong quantities of the drugs and/or at wrong frequencies, which may result in treatment failures or undesirable side effects. Taking a drug through the wrong route can result in the irritation of the gastro-intestinal tract (GIT), for example, oral administration of pessaries[lvi].

The need for counseling may still arise where, for instance, the consumer misses a dose of the drug or is experiencing mild side effects. This post-exposure counseling is aimed at helping the consumer to comply with treatment regimens. It is submitted that the breach of the duty to properly counsel the consumer whether at the pre or post-exposure stage; that results to any injuries attracts professional discipline based on negligence. Such negligence also grounds an action in tort for the recovery of damages by the consumer.

However, a pharmacist counseling a consumer must strike a balance on the issue of disclosing the name of certain drugs to the consumer. Modern practice with the emerging concept of pharmaceutical care based on pharmacovigilance suggests that the name of

all drugs dispensed to a patient be made known to him for easy monitoring and reporting of ADRs by the consumer either to the dispenser or any hospital. It is submitted that this requirement of the modern practice is an encroachment into the vested discretion of the dispenser whether or not to disclose the names of certain category of drugs to the consumer to avoid misuse or abuse. Non-disclosure in this respect makes it mandatory for the consumer to consult either the dispenser or any other qualified health practitioner before further use of drugs with addiction-forming and addiction-sustaining liability. It is equally submitted that this practice of non-disclosure in pharmacy is of substantial antiquity, eminent solidity and obvious pharmaceutical respectability. It is particularly desirable in our society with a very high prevalence of drug abuse and illiteracy. Moreover, a consumer is always told during counseling that he or she should report any abnormal feelings or signs precipitated by the drugs to any qualified health practitioner for evaluation. With this advance warning as a component of counseling, the balance obviously tilts in favor of non-disclosure.

Furthermore, absence of pointed instructions on items 19-22 in the checklist is likely to lead to therapeutic failure which is both a pecuniary loss to the consumer and an aggravation of his condition, arising from waste of time in commencing efficacious treatment. Either way, the consumer has a redress against the pharmacist in damages, in addition to disciplinary measures by the PCN.

3.2.2. Post-exposure (use)

Here again, consumer protection is exacted through administrative/ regulatory functions, contract law and tort law. The remedies available to a consumer at this point include the tort of product liability against the manufacturer, deceit and negligence against the pharmacist as a producer as already considered under post-exposure (use) in para. IIIA2. However, with regard to the functions of administrative agencies like NAFDAC in the practice of pharmacy, the liability rule at this point is reversed; as the agency assumes the position of a producer. The pharmaco-legal issue, therefore, is whether NAFDAC through its drug products certification role incurs liability when a consumer is exposed to counterfeit or fake drugs.

Inegbedion, after analyzing the roles of NAFDAC and Standards Organization of Nigeria (SON) in the context of consumer protection opined that where upon certification and registration of a product by the agencies a consumer is injured by such product, the agencies can be held liable[lvii]. Kanyip, who wrote later on the issue of liability of SON in respect of certified products and who relied heavily on the case of Yuen Kun Yeu & Ors V Attorney General of Hong Kong[lviii] described such assumption of liability as a "fallacy" and that the argument in support by Inegbedion be dismissed[lix].

Inegbedion, still on the issue and in obvious reference to Kanyip's position but in what appears to be a revenge mission stated, "Citing a number of authorities to buttress his position, and writing like an *infallible oracle*, he concluded that the argument of this writer (Inegbedion) in favor of any such liability of SON should be dismissed (Emphasis supplied)"[lx]. Without assuming the role of a legal adjutant, this work deprecates the choice of words by the learned author, as the motive for the use of the metaphor is doubtful. Be that as it may, this work is in full support of Inegbedion's position that an agency who certified and registered a defective product incurs liability.

In the case of NAFDAC, by assigning and forcing manufacturers to affix its number on drug products it has even gone beyond registration and certification to quality assurance to the consumer at the point of obtaining drug products from pharmacists. Now let us examine the basis for liability in this regard. First, the CFDA defines a fake drug to mean, "Any drug or drug product, which is not registered by the Agency (NAFDAC) in accordance with the provisions of the Food, Drugs and Related Products (Registration, Etc.) Decree, 1993, as amended"[lxi].

The logical outcome of this statutory definition of a fake drug is that any drug registered by NAFDAC is genuine. Second, NAFDAC further guarantees the consumer by compelling manufacturers to affix its seal of safety on drug products in the manner of NAFDAC number. Third, in collaboration with manufacturers and GSM network providers NAFDAC has even taken its guarantee of consumers to a higher level. At this level of guarantee, all the consumer needs to do to detect a fake drug is to scratch the silver panel on the packet of the drug to reveal certain numbers with which to call NAFDAC for information on the drug. The reply is usually "fake, don't use" or "genuine, use".

The question then is whether in the face of the above, *caveat emptor* (buyer beware) as a shield for the producer is still valid. In other words, can the consumer still be regarded as his best protector? It is submitted that a consumer who relies on the guarantee furnished by NAFDAC and he is injured has a remedy against it, as the requirement of *caveat emptor* is displaced in the circumstance. It is equally submitted that in the circumstance, NAFDAC can at least be held liable for the tort of negligent misstatement[lxii] or even deceit.

3.3. Consumer Protection as a Matter of Pharmaceutical Care

This layer of drug consumer protection is predicated on an emerging field of practice in pharmacy known as pharmaceutical care (PC). Although this layer of protection stems from the practice of the pharmacy profession it is unique, hence it is accorded special attention in this work. This kind of consumer protection seeks to extend the duties of the practitioner beyond what is presently recognized by the law and the profession. Before now, it was thought that a pharmacist who dispenses a conventional drug in the right doses and has observed all the requirements pertaining to the dispensing of such drug is relieved of any liability. In other words, that a pharmacist's responsibility for the outcomes of drug therapy is limited to the extent of his fault.

However, PC as a new field of practice seeks to hold the pharmacist responsible for the consumer's idiosyncrasies resulting in adverse-drug-reactions (ADRs)[lxiii]. It does this through the concept of PV which requires the pharmacist to give notification relating to a patient with ADRs or laboratory test abnormality suspected to be induced by a drug to the National Pharmacovigilance Centre (NPC) under NAFDAC. Clearly, the liability rule is administrative and the remedy is, therefore, administrative in the manner of disciplinary measures. But whether or not NAFDAC has the power to impose fines on an erring pharmacist is not clear from the Act establishing it. What is however clear under the law is that only the PCN has the power to discipline erring pharmacist.

4. Consumer Remedies

In this work, the remedies available to the consumer in the context of the topic under consideration and the liability rules already identified correlate with the range of consumer protection. Some of the remedies are direct and beneficial to the consumer while others are indirect but necessary for his protection. The remedies include: punitive measures by way of imprisonment or fine of producers, compensation order under CPCA[lxiv], administrative remedy by way of disciplinary measures on producers, repudiation of contract, right to damages in contract and tort, replacement of hazardous products with safer and more appropriate alternatives under the CPCA[lxv].

For a better understanding of the liability rules, of how the remedies arise and against whom the remedies are enforceable, this work has adopted the case study approach. The above outlined remedies are fairly illustrated by the sensational pfizer's trovan case with the following facts:

On April 3, 1996, Pfizer's team of physicians arrived in Nigeria to conduct clinical trials on children infected with bacterial meningitis. Nigerian officials authorised Pfizer to conduct the testing in two wards of the infectious Disease Hospital. Pfizer selected two hundred sick children from the many children who were awaiting treatment, divided the children into two groups, and treated one group with Trovan. The other group of children was "purposefully 'low-dosed' with cerftriaxone, an FDA-approved drug. According to Pfizer protocol, the children were supposed to have their blood tested at the point when they were diagnosed and entered into the trial and again after five days of treatment. If a child was not responding well to Tronvan, protocol required switching the child's medication to certriaxone. According to an internal Pfizer document, however, this plan for follow-up blood testing was generally abandoned "due to the shortage of medical staff. As a result, Pfizer did not analyse the children's blood samples and therefore could not determine those cases in which the medication was not an effective treatment until the child manifested visible and often permanent impairment.

Pfizer protocol required injecting ceftriaxone onto the subject's vein or muscle. Again, due to the shortage of skilled workers, the drug was usually injected into the child's buttocks or thighs (i.e., muscle injections) to save staff time and trouble. The shots were severely painful leading to report of "great fear and sometimes dangerous struggles with children. To lessen the pain after initial injections, the report indicated, researchers reduced the amount of antibiotic given to children who were improving to one-third of the recommended amount. Pfizer maintained that the reduced dose was more than sufficient. The drug's manufacturer, Hoffmann-La Roche, however, reported that the reductions could have lowered the drug's efficacy and skewed any comparison to Trovan. There is also evidence that Pfizer failed to switch to standard therapy the children who were receiving Trovan but not showing any sign of improvement. This breach in standard protocol allegedly led to severe brain damage or death for several children. The requirement of informed consent from either children or their guardian is part of Pfizer's protocol but it could not produce any evidence that its staff had informed the children's parents that the proposed treatment was experimental, that they could refuse it, that serious risks were involved or that other organizations at the same site offered more conventional treatment for free. In addition, Pfizer failed to follow its own protocol that required staff to offer or read documents to participates in either English or Hausa to facilitate their informed consent. When interviewed later, many of the patients and their parents claimed that they did not know they were participating in an experimental drug trial. Pfizer described the lapse as a procedural error, but stressed in a written statement that "verbal consent was obtained".

After spending two weeks in the Kano camp conducting tests, Pfizer withdrew its personnel without administering any post-trial care. Five children who received Trovan and six children to whom Pfizer had administered a low dose of Ceftriaxone died. Others suffered blindness, deafness, and paralysis. While US medical guidelines recommend that meningitis experiments include long-term follow up, Pfizer's clinical protocol made no mention of the need for long-term monitoring.

In 2001, the families of the dead and injured children filed suit against Pfizer under the Alien Tort Statute (ATS) for violating a norm of "customary international law prohibiting medical experimentation on non-consenting human subjects. Specifically, Pfizer was sued for violating the principle of informed consent, refusing to provide the best treatment available when it supplied low doses of the drug approved by the FDA and when it failed to monitor the progress of the children in the study, and for its decision to conduct a trial using a medication that is known to cause liver damage in children. What the families soon learned however- and arguably what Pfizer had known all along – is that neither international nor US law provided redress against American companies for human rights violations committed abroad. What follows is a discussion of how this fact is changing[lxvi].

Before examining the remedies, it is expedient to comment on the status of the major actors in the clinical trial. The pharmaceutical company, Hoffmann-La Roche, is the manufacturer of the drug known as trovan (trovafloxacin) used in the study and by virtue of which he is a producer. Pfizer, represented by its team of physicians is a consumer in relation to Haffmann-La Roche by virtue of disposal but a producer in relation to the children, the ultimate consumers.

Now, let us examine the possible remedies thrown up by the facts of the case under the following heads:

4.1. Punitive Measures by Way of Imprisonment or Fine of Producers

The facts of the case reveal that trovan is known to cause liver damage in children and that the medication was not an effective treatment for meningitis, hence the death of several children going by the combined effect of the provisions of the CPCA[lxvii] and the CFDA[lxviii], Hoffmann-La Roche, as the manufacturer of trovan, is liable to punitive measures. Also, it is liable for the Common-Law crime of fraud.

4.2. Compensation Order

This is an ancillary remedy for a consumer against any person convicted for the contravention of an enactment for the protection of the consumer. In this regard, the CPCA[lxix] provides:

A court by or before a person is convicted of an offence may, in addition to dealing with such person in any other way, make an order (in this Act referred to as "compensation order") requiring the person to pay compensation for any personal injury, loss or damage- resulting from that offence of such amount as it may deem fit or as assessed by a competent professional authority.

With this provision, Hoffmann-La Roche, is to pay compensation for the death of the children and to those who suffered blindness, deafness and paralysis in addition to whatever criminal liability it has incurred.

4.3. Disciplinary Measures by Administrative Agencies

Based on the unprofessional manner the team of Pfizer's physicians carried out the study and in contravention of its protocol[lxx], the physicians are liable to professional discipline. The physicians in this case, as producers, stand in place of pharmacists in the context of the topic under consideration and under Nigerian law, they may either be reprimanded, suspended from practice or their names struck off the Register of pharmacists on the direction of the tribunal for negligence or breach of fiduciary duty which in this case has occasioned the death of several children and injuries to others. Surely, the same fate awaited the physicians in the US.

4.4. Rights to Repudiate Contract and to Damages for Breach of Contract

This remedy avails Pfizer as a consumer to Hoffmann-La-Roche, the manufacturer of trovan. Pfizer, in the circumstances of this case is entitled to repudiate whatever arrangement (contract) under which it got the drug from Hoffmann-La Roche. Also, it is entitled to compensation from Haffmann-La Roche by way of third party procedure if sued by the consumers (children) for damages. As earlier mentioned, the restriction imposed by the topic does not allow for an elaborate discussion on this head of remedy as well as the liability rule giving rise thereto.

4.5. Right to Damages in Tort

For the death of the children and injuries to others, a wide range of remedies in tort avail the consumers to be enforced through a representative action and against Hoffmann-La Roche (as the manufacturer of trovan), Pfizer (as a producer) or even the Nigerian Officials (as the regulatory sponsor)[lxxi]. In the case under review, the consumers have the remedy of strict product liability against Hoffmann-La Roche, as the manufacturer of trovan. This liability is redressed in tort with damages. Pfizer, as the immediate producer, under tort is liable for negligence, deceit, battery, lack of informed consent[lxxii], breach of the children's right to be treated with dignity. Again, these heads of tort are redressed with damages.

In the circumstances of this case, the Nigerian Official (Regulatory Sponsor) is obviously a joint *tort-feasor* with Pfizer having authorised the clinical trial that caused the injuries. The basis for its liability has been examined under para. IIIB2. Further, assuring that the Nigerian officials as mentioned in the case represented NAFDAC, the authority given Pfizer to conduct the trial was in breach of the law. In this regard the FDRA provides that:

No person shall, in the course of his business –

a. import or supply a drug, drug product; cosmetic or medical device; or
b. procure the importation or supply of a drug, drug product, cosmetic or medical device; or
c. procure the manufacture or assembly of a drug, drug product, cosmetic or medical device, for the purpose of a clinical trial test, unless he is a holder of a valid clinical trial certificate and the trial is to be carried out in accordance with the terms of the certificate and the *provisions of any regulation in force*[lxxiii].

It is submitted that as at April 3, 1996, when the Nigerian Officials authorised Pfizer to conduct the trial there was no valid regulation in force hence no valid clinical trial could have been conducted. It is equally submitted that the breach of the law alone was sufficient to treat the Nigerian Officials as joint *tort feasors* with Pfizer.

5. Possible Qualifications, Exemptions, Exceptions, Excuse and Defences to Consumer Rights and Remedies (Producer Protection)

This segment of the work examines the possible qualifications, exemptions, exceptions, excuses and defences to the consumer's rights and remedies which tend to ameliorate the burden on the producer under the concept of consumer protection. Kanyip, in analysing the meaning of protection has made a case for some measure of protection for the producer[lxxiv]. He cited the case of Bluett V Osborne[lxxv] in support of his argument. He maintained that the implied term of the sale of goods law that a defect was outside the scope of warranty if it was possible to inspect the goods and if the seller was merely a dealer serve as immunity for industries (producer) from potential liability. He also alluded to the immunity of legal practitioners in legal proceedings as a form of protection for producers. It is in this light that this work examines some of the qualifications, exemption, exceptions, excuses and possible defences to the rights of the consumer as protection for the producer. This is particularly necessary to avoid a one-sided treatment of the pharmaco-legal issues raised in this work. The relative protection the law accords the producer (pharmacist) is in recognition of the fact that his over exposure to liability will operate as a boomerang on the society. Also, the law recognises the need not to unduly fetter the discretion of a professional, especially those handling life's utensils.

5.1. Statutory Defences

From what has been discussed thus far, one way by which the law protects the consumer is by prohibiting certain activities of the producer, who has been identified in this work as the manufacturer, importer, wholesaler or the retailer (pharmacist). According to the law no producer must sell or dispense any unsafe or hazardous goods[lxxvi], counterfeit, banned, fake, substandard or expired drug[lxxvii], and adulterated drug[lxxviii]. Also, no producer must proffer any information or advertisement leading to injury or loss to the consumer[lxxix] or advertise any drug in Nigeria unless it has been registered in accordance with the provisions of the Act or regulation made under it[lxxx]. Under the FDA[lxxxi], legal proceedings for the sale of adulterated drug shall not be commenced except within six months of the commission of the offence. It is submitted that the protection which the provision affords a producer is limited to proceedings under the FDA as there is no similar provision in the other enactments dealing with similar offences.

However, the following provision appears to be a definite qualification, exemption, excuse or exception and hence a defence in any proceeding for an offence consisting of the sale or dispensing of drugs in contravention of any enactment. The provision states:

1) Subject to subsection (2) of this section, it shall be a defence in any proceedings for an offence consisting of the sale of any article in contravention of this Act or the regulations to prove:

a. that the accused sold the article in the same package and in the same condition as it was in when he bought it; and
b. that the accused could not with reasonable diligence have ascertained that the sale of the article would be in contravention of this Act or the regulations.

2) A person charged with an offence under this Act shall not be entitled to avail himself of the provisions of subsection (1) of this section unless he has given notice of his intention to do so at least ten days before the date of the trial and has at the same time disclosed to the prosecution the name of the person from whom he bought the article in question and the date of the purchase thereof[lxxxii].

It must be stated at once that the provision does not afford the producer as a manufacturer any protection, being the last in the chain of producers. In effect, the sale of drugs in contravention of any enactment is a strict liable offence with respect to the manufacturer, whereas, the defence as provided ameliorates the strict liable stings of the offence in the case of other producers in the chain.

On the applicability of the defence to similar offences in other enactments, this work is of the view that it applies by virtue of the Evidence (Amendment) Act[lxxxiii]. In other words, in proceedings under enactments other than the FDA, the defence avails the producer. However, a pharmacist (producer) who has injured a consumer by dispensing a counterfeit drug can only take refuge under the provision by proving that:

a. he sold the drug in the same package and in the same condition as he bought it;
b. that he was not in position to ascertain that the drug in question was a counterfeit;
c. that he has given at least ten days notice of his intention to rely on the provision to the prosecution before the trial;
d. that he has disclosed the name and address of the person from whom he bought the drug to the prosecution at the same time as in paragraph (c) above.

This work holds the view that the proof of the above facts is a complete defence to the offence; hence the producer is not liable to any penalty.

Still on the applicability of the defence to similar offences contained in other enactments, this work recommends a more modern and elegant drafting device to protect the producer in similar circumstances. Instead of the windy provision just analysed, the word "knowingly" should be used in penal provisions on counterfeit drugs to remove their strict liability stings. Although, the introduction of the *mens rea*, "knowingly", has the effect of shifting the onus of proof on the prosecution, it is consistent with our adversatorial system of criminal justice. All what the prosecution requires in order to prove such knowledge is to set out objective factual circumstances from which the court will infer knowledge on the part of the producer. Such circumstances may include the logical obverse of paragraphs (a) and (b) above.

It is in line with the above reasoning that the committee of legal experts constituted by the Director-General, NAFDAC, to propose amendment to the CFDA, of which the author of this work is a member, proposed the amendment of the relevant section to read:

> Any person who-
> ……
> ……

(c) Knowingly distributes, sells or displays for sale; any counterfeit, adulterated. . . or expired medical products … commits an offence[lxxxiv].

It is hoped that the proposed Bill, if passed by the National Assembly will provide the necessary protection for the producer to allow him perform his professional duties without the fear of imagined liabilities.

5.2. Assorted Defences

Besides the statutory defence, there are a host of others against consumer rights and remedies. Notable amongst them are contributory negligence, *caveat emptor*, *volenti non-fit injuria* and the omnibus defence of professional discretion. The producer-consumer relationship between the manufacturer, the import, the wholesaler and the retailer of drugs admits of the defences of contributory negligence and *caveat emptor*. In this wise, they operate much the same way as in any relationship capable of giving rise to tortuous liability.

It is indeed difficulty and perhaps strange to attempt to set up the defence of *volenti non-fit injuria* in the relationship between the pharmacist and the consumer. The pharmaco-legal issue here is whether the consumer can actually be said to have volensed to the

administration of counterfeit or fake drugs on him. It is difficulty but possible. Only a few years ago, some HIV infected patients (consumers) demonstrated publicly against the insistence of the Government that clinical trials on medical products for the treatment of HIV/AIDS must complete its circle before their use on Nigerians. The consumers had their way and many of them opted for the treatment with medical products that have not been approved for use. Reports had it that many of them died from reactions to and toxicity from the medical products. The next question is, whether they were entitled to damages from the producer (sponsor[lxxxv]). It is submitted that in such situation, there is valid "informed consent" and the absence of other abuses such as the breach of the study protocol, the defence of *volenti non-fit injuria* will avail the sponsor, provided the injury suffered is within the category of risks explained to the participant (consumer) in the process of obtaining his or her consent, otherwise, the conclusion will be that no valid consent was obtained. The consideration for the application of the defence in such a situation is the risk/benefit ratio. With the high level of virulence of the virus and mortality rate of infected persons at that time, it was only sensible that any medical product that offered hope, however dim, was considered beneficial no matter the level of risk associated with it. The defence was therefore a protection for the sponsor who acted in the interest of the consumer.

A cursory look at the omnibus defence of professional discretion as a protection for the producer is sufficient for this work. Sometimes, the law even vests on the producer the discretion to act in a particular circumstance. For example, the PPA[lxxxvi] provides thus:

- The seller of a poison shall not deliver it until-

He has made or caused to be made an entry duly signed by him, in the disposal of Poisons Book stating the date of the sale, the name and address of the person to whom it is delivered, the name and quantity of the article sold, the purpose for which it is stated by the *purchaser* to be required *and he has satisfied himself that the poison is required for the purpose stated.*

It is submitted that it is the discretion under this section that was assaulted in the case of Cynthia considered under para. IIIB1, when a pharmacist was charged for selling rohypnol tablet without prescription even as the section says he can act upon satisfying himself. This is even when the apex Court, in interpreting a similar provision of the Criminal Procedure Act[lxxxvii] has held that, "in satisfying itself the Court does not go out to meet the accused and, *whether the Judge is satisfied or not remains his subjective judgment*"[lxxxviii].

In the same vein, a pharmacist who has satisfied himself that the poison (rohypnol) is required for the purpose stated is free from any liability and cannot be questioned on the basis of the exercise of his discretion. Moreover, the law says the pharmacist is to be satisfied with the purpose stated by the purchaser and not in prescriptions. This work is of the view that whenever any pharmaco-legal issue borders on practice, professional discretion properly exercised comes in to protect the pharmacist otherwise drug administration will be at the receiving end.

6. Conclusions

This work has endeavored to look at the two sides of some of the pharmaco-legal issues for consumer protection. Its approach is informed by the possible boomerang effects on the society, of overly exposing the producer (pharmacist) to liabilities, as same is capable of hampering his professional judgments.

To properly situate the range of consumer protection in contemplation, this work has designed a model to aid the understanding of the issues involved. At the end of the examination of the pharmaco-legal issues using the Drug Consumer Protection Model (DCPM) as a compass, this work is of the view that consumer protection in pharmacy hangs on a delicate balance. While this work recognizes the need to protect the consumer (patient), it also advocates the absence of undue fetters on professional discretion. In fact, the earlier the law begins to see pharmacists as trained professionals whose motive in rendering services to the society is not profit-driven, the better.

7. References

i. Kanyip, B. B. (2005) Consumer protection in Nigeria: law, theory and policy, Abuja, Rekon Books Limited, p. 37
ii. ibid, p. 38
iii. Resolution 39/248 of April, 1985
iv. See note 1 above, at p. 36
v. It can be described as guaranteeing that the consumer (patient) uses his medication as correctly, efficiently and safely as possible. It requires that all practitioners should assume responsibility for the outcomes of drug therapy in their patients.
vi. PV is the structured process for monitoring and detection of adverse drug reactions, (ADRS) in a given context.
vii. Something peculiar to an individual or thing, in medicine; an abnormal, unusual reaction to a drug, chemical, food or other substance.
viii. See note 1 above, at p. 332
ix. Ibid, at p. 27
x. CAP C-25, Laws of the Federation of Nigeria (LFN), 2004
xi. Ibid, loc. cit.
xii. S. 32
xiii. Ajai, O. (1992/93) Caveat venditor! consumer protection decree No. 66 of 1992 (now Cap C-25, LFN, 2004) arrives in the Nigerian market place" Nigerian current law review 23 at p. 26
xiv. See note 1 above at pp. 19/20
xv. Constitution of the Federal Republic of Nigeria, CAP C-23, LFN, 2004, s.17
xvi. 39/248 of 9 April, 1985
xvii. CAP 152, L & F, 1958

xviii. See note 9 above
xix. CAP F-32, LFN, 2004
xx. CAP F-33, LFN, 2004
xxi. CAP C-34, LFN,2004
xxii. CAP N-29, LFN, 2004
xxiii. CAP N-1, LFN, 2004
xxiv. CAP P-28, LFN, 2004
xxv. s.11
xxvi. s.12
xxvii. ss. 11 & 12
xxviii. s. 1
xxix. s. 3 (1) (a)
xxx. s. 50 (1) & (3)
xxxi. s.1 (2) & (3)
xxxii. s. 8 (3) & (4)
xxxiii. ss. 1 & 6.
xxxiv. s. 8
xxxv. s. 13
xxxvi. No. 15 of 1990
xxxvii. s. 14 (1)
xxxviii. ss. 42 (1) & (2), 43 (1) & (3)
xxxix. ss.16 & 17
xl. s. 15
xli. ss. 16 (2) & 17(2)
xlii. ss. 16 (3)
xliii. s.17
xliv. ss. 65
xlv. ss.62 (1) & 64 (1)
xlvi. s. 4 (1)
xlvii. See note 20 above, s.1
xlviii. s. 17
xlix. s. 18 (1)
l. s. 1(1)
li. 2000
lii. Omotoso G. (ed.) (2012 September 3) The Nation of Monday, p. 20
liii. S. 30 (1)
liv. Beam Pharmacy (Nig) Ltd & 3 Ors V NDLEA & 3 Ors: Motion No: NSD/LF18m/2007
lv. Developed by Bruce-A. Berger, PhD, and Bill G. Felkey, MS, Auburn University: Harrison School of Pharmacy.
lvi. A small piece of solid medicine placed in a woman's vagina and left to dissolve to cure an infection.
lvii. Inegbedion, N.A. (1993) Consumerism, merchantability and the standards organization of Nigeria in EDSU L.J, Vol. 2. No. 1, p. 79
lviii. (1988) A.C 175
lix. See Note 1, p.145
lx. Inegbedion N. A., (2010) The role of regulatory agencies in respect of defective products and the legal implication of certified products" in Justice Journal: vol. 2, p.56
lxi. S. 14
lxii. Hedley Byrne & Co. Ltd. V. Heller & Partners Ltd (1964) A.C 465; (1963) 2 All E.R. 575.
lxiii. Is a response to a medicine (drug) which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.
lxiv. s. 13
lxv. s. 8
lxvi. Informed consent: Enforcing Pharmaceutical Companies' Obligations http//www.hhr journal. org/index. php/ hhr/ article/ view Article/200/297, Downloaded 6/26/2011, 7.26 a.m.
lxvii. See note 26 above
lxviii. See note 28 above
lxix. s. 13
lxx. Is a document prepared by the sponsor (Pfizer) and approved by the regulatory sponsor (Nigerian Officials) containing details of the clinical study.
lxxi. Government Agency that gives authorization for clinical trials. In the UK, it is medicines and Healthcare Regulatory Products Agency (MHRA) and in Nigeria it is NAFDAC by virtue of S. 5 of the FDRA.

lxxii. Informed consent requires researchers to convey to the subjects, in an adequate manner, the risks and potential benefits of the trial, their right as participants and their free choice whether or not to participate in the trial. Informed consent ensures protection of the human subject's "right to bodily integrity" that is, to "exercise sovereignty over her body.
lxxiii. s. 5
lxxiv. See note 1 above at pp. 26-28
lxxv. (1816) 171 Eng. Rep. 504
lxxvi. s.12 of the CPCA
lxxvii. s.1 of the CFDA
lxxviii. s.1 of the CFDA and s.1 (2) of the FDA
lxxix. See note 24 above
lxxx. ss.1 & 6 of the FDRA
lxxxi. s.17 (3).
lxxxii. s.18 (1) (a) & (b) & (2) of the FDA.
lxxxiii. 2011, S.141 provides that any exception, exemption, proviso, excuse, qualification, whether it does or does not accompany in the same section the description of the offence in the legislation creating the offence, may be proved.
lxxxiv. s.1 (1) (c) of the proposed Bill.
lxxxv. A person who takes responsibility for the initiation, management and financing of a clinical trial.
lxxxvi. s.30 (2) (a)
lxxxvii. CAP C-41, LFN, 2004, s.218
lxxxviii. (2008) All FWLR (pt. 405) 1656