



A Review of the Advertisement Restraint Provisions in Nigerian Drug Laws *

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ABSTRACT

This paper examines the advertisement restraint provisions in Nigerian pharmaceutical drug laws in order to determine their adequacy in protecting the pharmaceutical drugs consuming public from the harmful effects of stimulation of use of drugs without medical prescription. Advertising drug products with the sole purpose of stimulating the use of such drugs has become the order of the day in Nigeria. Some of the disease that were not considered fatal when extant drug laws were made such as malaria have now developed resistant and killer strains. The consequence is over the counter (OTC) legal status of malarial drugs is no longer triable and unrestrained advertisement of such drugs has become a recipe for fatalities and death. This paper adopts the doctrinal approach by identifying and analyzing the advertisement restraint provisions of extant pharmaceutical drug laws. The study found that Nigerian pharmaceutical drug laws enables and encourages aggressive but unethical direct to consumer drug advertising. The study also found that this situation does not augur well for the health and well being of Nigerian pharmaceutical drug consumers.

Keywords: advertisement, advertising, drug laws, drug consumers

INTRODUCTION

Spurious and unproven claims by drug advertisers in Nigeria have become the order of the day. First, there is currently a prevalence of so called "alternative medicine" providers touting various but untested potency for their drugs in the cure of virtually all known ailments. Some of them have even laid claim to having the drugs for the treatment of ailments such as "H.I.V" and AIDS which cure the entire orthodox medical world accepts it has not yet found. Another troubling aspect is the "over the counter" (OTC) list which has enabled manufacturers of such drugs to engage in unbridled and unrestrained direct to consumer advertising of their products. This is despite the fact that the malarial ailment has assumed a killer disease status.

MEANING OF ADVERTISEMENT

The word "advertisement" was defined as a public announcement for example in a newspaper or on television that tells people about a product, event, or job vacancy.¹ Advertising on the other hand has been defined as the activity of telling people about products or events in order to make them want to buy the products or go to the events.² The major difference between advertisement and advertising from the above definitions is that while the former simply informs people about the existence of a product or the coming of an event, advertising aims at not just informing people about a product or event but to stimulate them to want to desire partaking in the product or event.

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¹ John Sinclair ed.; *BBC English Dictionary*, (London: Harper Collins Ltd, 1992) p.18

² *ibid*

The Blacks' Law Dictionary³ did not define the word "advertisement" but defined the word "advertising" in the following words: "The action of drawing the public's attention to something to promote its sale; the business of producing and circulating advertisements"⁴ Furthermore, the word "advertisement" has been defined by the British Fair Trading Act as follows: "...any form or representation, which is made in connection with a trade, business, craft or profession in order to promote the supply or transfer of goods or services, immovable property, rights or obligation"⁵

The Control of Advertisement Law (Lagos) defined "advertisement" as follows:

"Advertisement" means any word, letter, model, sign, placard, board, notice, device or representation, whether illuminated or not, which is employed wholly or partly for purposes of advertisement, announcement or direction, including any hoarding or similar structure used, or adapted for use, for display of advertisement.⁶

The Act went on to define the term "display" in relation to advertisement as follows:-

..the display thereof in any public place, or in any other place such that the advertisement is visible from a public place, and , in relation to an advertisement consisting of a hoarding or similar structure, includes a construction or maintenance thereof in any such place as aforesaid.⁷

From the foregoing, it would appear that the terms "advertisement" and "advertising" may be used conterminously. However the Lagos Act conforms with the meaning of "advertisement" given by BBC English dictionary while the meaning of "advertisement" advanced by section 2 of the English Fair Trading Act 1973 is on all fours with the meaning of "advertising" proffered by both the BBC English Dictionary and the Blacks' Law Dictionary. The failure of the Blacks' Law Dictionary to advance a meaning for the word "advertisement" may imply that the word advertising is the proper form to be used in a legal context.

This position was not however adopted by the English Fair Trading Act which used the word "advertisement" to mean the same thing as "advertising" as defined by the both the BBC English Dictionary and the Blacks Law Dictionary.

MEANING OF DRUG

Blacks Law Dictionary defines the word "drug" as

a substance intended for use in the diagnosis, cure, treatment, or prevention of disease, a natural or synthetic substance that alters one's perception or consciousness⁸.

³ B.A Garner; editor-in-chief; Black's *Law Dictionary* 8th. ed.(St. Paul Minnesota: Thompson- West Publishing Co. , 2004)

⁴ *ibid* at p.59

⁵ Article 2 British Fair Trading Act 1973

⁶ Section 45 of the Control of Advertisement (Lagos) Act 1965

⁷ *op cit*

⁸ **B.A Garner**; *Black's Law Dictionary*(8 ed, Minnesota: Thompson- West , 2004) p535

In most countries, the term drug is defined by way of legislation. The United States, Federal Food, Drug, and Cosmetic Act defines “drug” to include “articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals and articles other than food intended to affect the structure or any function of the body of man or other animals.”⁹

In Nigeria, the Food and Drugs Act defines “drug” to include any substance or mixture of substances manufactured, sold or advertised for use in:

- (a) the diagnosis, treatment, mitigation or prevention of any disease or disorder, abnormal physical state, or the symptoms thereof, in man or in animals;
- (b) restoring, correcting or modifying organic functions in man or in animals;
- (c) disinfection or the control of vermin, insects or pests; or
- (d) contraception.¹⁰

This same definition was repeated in the National Agency for Food and Drug Administration Control (NAFDAC) Act¹¹. This works dwell on drug as conceptualized by the Food and Drug Act. In view of the foregoing, “drug” includes any substance or mixture of substances manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state, or the symptoms thereof in man or animal restoring, correcting or modifying organic functions in man or in animals; disinfection, or the control of vermin, insects or pests’ or contraception. For purposes of this work the word should be construed in the above sense and should exclude narcotics and psychotropic substances.

ADVERTISEMENT AND DRUG

Drugs occupy a unique position in health care delivery. They make health care credible because they can cure diseases, relieve symptoms and alleviate suffering. The role of advertisement is not only informing, teaching or reminding the consumer of the existence of goods, it creates benefits in consumer minds and secures product loyalty over substitutes and competitors. In **Director General of Fair Trading v Tobywards**,¹² Hoffman J stated:-

It must be assumed that there may be people who will believe what the advertisers tell them and in these circumstance the making of a false claim is likely to deceive ...
The other element namely that the advertisement is likely to affect the economic behavior of the persons to whom it is addressed, means in this context no more than it must make it likely that they will buy the product.

There are two aspects to advertisement of drugs: the first aspect informs the user of a drug product and about its chemical contents and usages. The second aspect is the promotion of sale. In relation to the first aspect, advertisement to the drug consumer serves as a channel of information in respect of a drug product. It is however the second aspect that raises some ethical questions as it dwells exclusively on the promotion of sales and stimulation of drug consumer to make an economic decision which may in some cases be detrimental to his health interest. Accordingly, the relationship between advertisement and drug could be positive or negative for the consumer of a drug product depending on the motive of such an advertisement. Where the purpose of a drug advertisement is to inform and educate the consumer about the chemical component and uses of a drug product, such an advertisement could be useful to the drug

⁹ The United States Food and Drugs Act 1938

¹⁰ Section 20 Food and Drug Act Cap F32, LFN 2004 as amended.

¹¹ Section 30 NAFDAC Act, Cap N19 LFN 2004 as amended

¹² (1989) 2ALL ER 266

consumer. But in a situation where the purpose of an advertisement is merely to promote the sale of a drug product and stimulate the consumers to opt for them, serious ethical questions are raised.

SHOULD DRUGS BE ADVERTISED?

Advertising appears to be an important driver for the purchase and consumption of pharmaceuticals. Advertising of drugs relates to products that affects consumers' health in a complex domain. The growth of direct to consumer advertising of drug has been driven by structural changes in the health care market, especially the adoption of managed care. Direct to consumer advertising although intended for profit, appears to play a role in helping to fulfill the consumers need for information. Despite the benefits which direct advertisement of drugs to consumers' claim, it is however doubtful whether such advertising will have positive effects on the appropriateness of drug use, compliance with drug instructions, adherence to preventive health measures, use of health care services, and changes in pharmaceutical cost. It is very unfortunate that the information contained in such advertisements are most times incomplete, inaccurate and sometimes misleading.

Direct to consumer drug advertising can cause damage by instigating rapid, widespread stimulation of use of new drugs before harmful effects are fully known. Advertisements exaggerate treatment benefits and use emotive messages to target people with milder health problems, many of whom are unlikely to benefit from the drugs advertised. It also leads to higher drug costs and overall health care costs through substitution of new, expensive drugs without treatment advantages.

Drugs are not ordinary consumer products. In most instances, consumers are not in a position to make decisions about when to use drugs, which drugs to use, how to use them and to weigh potential benefits against its risks as no medicine is completely safe. Professional advice from either prescribers or dispensers are needed in making these decisions. However, even healthcare professional (medical doctors and pharmacists) are nowadays not in a capacity to take informed decisions about all aspects of medicines without special training and access to necessary information. The use of ineffective, poor quality, harmful medicines can result in therapeutic failure, exacerbation of disease, resistance to medicines and sometimes death. It also undermines confidence in health systems, health professionals, pharmaceutical manufacturers and distributors. Money spent on ineffective, unsafe and poor quality medicines is wasted. Thus government needs to establish strong national regulatory authorities to ensure effective regulation of the advertisement of medicines. One of the forms or mode of such regulation is by controlling promotion and advertising of medicines.

In answering the above question it would appear that the advertisement of drugs directly to the consumer is unethical and should be discouraged. It does not matter whether the drugs are over the counter (OTC) drugs or ethical/prescription drugs. We are living in an age where many so called "alternative" medicine providers make bogus and untested claims about the potency of their drug products and sell them at very exorbitant prices to the consumers after stimulating them by means of advertisement to purchase their drugs. It is therefore safer to leave the decision about whether or not to use a particular drug product for a particular ailment in the hands of qualified physicians and pharmaceutical practitioners. The information contained in leaflets accompanying drug packets are sufficient to satisfy the right of the pharmaceutical drug user to know the contents and use patterns of drugs made available in the market. For the purposes of safety and security of the health of pharmaceutical drug users, the law should aim at discouraging the advertisement of drugs *via* the electronic and other news media so as not to wrongfully stimulate drug users into making economic decisions to purchase drugs that are of doubtful utility to them

ADVERTISEMENT RESTRAINT PROVISIONS IN NIGERIAN DRUG LAWS

The control of drugs (pharmaceuticals) in Nigeria is currently based on at least six existing laws; the Pharmacists Council of Nigeria Act, ¹³the National Drug Formulary and Essential Drug List Act¹⁴, the

¹³ Cap P17, LFN 2004

¹⁴ Cap N29 LFN 2004

National Agency for Food and Drugs Administration and Control Act,¹⁵ the Food and Drugs Act,¹⁶ the Food, Drug and Related Products (Registration etc) Act,¹⁷ and the Counterfeit and Fake Drugs and Unwholesome Processed Food (Miscellaneous Provisions) Acts¹⁸. It is pertinent at this juncture to analyze the advertisement restraint provisions of these laws.

(a) Pharmacists Council of Nigeria Act

The Pharmacist Council of Nigeria Act deals with the control of the pharmacy profession. This Act repealed and replaced the Pharmacist Act, 1964¹⁹ and is supplemented by the Poisons and Pharmacy Laws of various states.²⁰ The members of the pharmacy profession play a significant role in the manufacture, sale and distribution of drugs.²¹ This Act has no advertisement restraint provision whether with respect to drug or the pharmacy profession.

(b) The National Drug Formulating and Essential Drug List (EDL) Act

The first requirement for any drug to be imported into, displayed for sale, sold or manufactured in Nigeria is that the drug should be contained in the National Drug Formulary and Essential Drug List²². National Drug Formulary has been defined as a manual containing a list of medicine that is approved for prescription throughout the country, indicating which products are interchangeable. It includes key information on the composition, description, selection, prescription, dispensing and administration of medicines. Those drugs considered less suitable for prescription are clearly identified.²³ The phrase "Essential drugs" have been defined by the World Health Organization (WHO) as those drugs that satisfy the health needs of the majority of the Population.²⁴ They should therefore be available at all times in adequate amounts and in the appropriate dosage forms at all levels of the health care delivery.

Section 2 of the Act established a National Drug Formulary and Essential Drugs List, and prohibits the advertisement, sale, display for sale, manufacture or importation of any drug which is not contained in the list.²⁵ However, the Minister may allow the importation, manufacture of any drug not in the list subject to some conditions.²⁶ Furthermore, the minister must be satisfied that it is necessary to import or manufacture such a drug and may on the recommendation of the appropriate body, permit the importation or manufacture of such drug and the inclusion of such drug in the list.

The appropriate body for this purpose is the National Drug Formulary and Essential Drug List Review Committee established by Section 4 of this Act. The Committee from time to time reviews the list and advises the Minister on any addition to or deletion from the list, as may be necessary.²⁷ The members of the Review Committee are appointable by the Federal Ministry of Health for three years subject to a reappointment for a further period of three years. By Section 9, a secretariat in the Department of Food and Drugs Administration and Control in the Ministry was established with responsibility for monitoring and implementation of the list.

The monitoring is aimed at effective implementation of the list. Accordingly, the minister may remove any drug from the list where it has been established to his satisfaction that the drug in question is no longer safe for use. If carefully selected, an Essential Drugs List should satisfy the needs of the vast majority of the population. It is however clear that it may not provide the needs of every person. It should

¹⁵ Cap N19, LFN 2004

¹⁶ Cap F32, LFN 2004

¹⁷ Cap F33, LFN 2004

¹⁸ Cap C34, LFN 2004

¹⁹ See Poison and Pharmacy Laws, Caps 118, 101 and 145 of Delta, Lagos and Anambra States

²⁰ Second Schedule, paragraph 21

²¹ Such a Person can only sell Patent and Proprietary Medicine

²² Section 2 of the National Drug Formulary and Essential Drug List Act

²³ Section 12, Cap. N29, LFN 2004 P.1.

²⁴ Balasubramaniam; "Quality Drugs at Affordable Prices", *Health Action International Asia Pacific*, (2002).

²⁵ Section 2 of the Act.

²⁶ *Op. cit*

²⁷ Section 10 *ibid*

be noted that it is only section one of this Act that restrains the advertisement of a drug. However this prohibition is restricted to drugs not contained in the list. In other words the Act neither restrains the advertisement of over the counter (OTC) drugs nor prescription drugs. Once such drugs are contained in the drug formulary /essential drug list. The Act may therefore be said to be in line with the position of those who see nothing wrong in the advertisement of drugs.

(c) National Agency for Food and Drugs Administration and Control Act.

This Act empowers the agency to regulate and control the advertisement of drugs amongst other regulated products.²⁸ Again no specific provision was made prohibiting advertisement of drugs. There was also no specific provision restraining the advertisement of some drugs and not others. The implication is that the agency may prohibit the advertisement of some drugs and not others if it so wishes

(d) The Food and Drugs Act

This Act prohibits the advertisement of drugs represented for the treatment or prevention of the diseases specified in the first schedule to the Act. The schedule list sixty five disease and disorders²⁹ Section 5 prohibits advertisement of drug in any manner that is false or misleading or is likely to create a wrong impression as to its quality, character, value, quality or safety. The Act provides the nearest legal framework to a structural restraint on the advertisement of drugs by prohibiting the advertisement of ethical drugs. Malaria drugs are however not included in the prohibition list. This is a serious omission considering the killer role of malaria in our nation today.

(e) Food Drugs and Related Products (Registration, etc.) Act 1993

This Act prohibits the advertisement of drug products unless such a drug product has been duly registered in compliance with the provisions of the Act by the National Agency for Food and Drug Administration and Control (NAFDAC).³⁰ This Act expressly permits the advertisement of drugs subject however only to such a drug having been duly registered with NAFDAC.

(f) Counterfeit and Fake Drugs and Unwholesome Processed Food (Miscellaneous Provisions) Acts.

Section 1 of this Act provides that 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 unwholesome processed food, in any form whatsoever, commits an offence and shall, accordingly, be punished as specified in the Act.³¹

The words “advertisement” or “advertising” were not used in this Act. However it may be argued that these words were contemplated by the phrase “displays for the purpose of sale”. It is highly regrettable that such an act that set out to protect drug consumers did not contemplate the fact that controlling and monitoring advertisement of drugs is one of the principal regulatory strategies in drug consumer protection. This is especially so because aggressive advertisement is one of the weapons employed by traffickers in counterfeit and substandard drugs to deceive the unsuspecting consumers into purchasing their hazardous and life threatening products. It is thought that stiffer penalties should be meted out to manufacturers of fake and counterfeit drugs who take a step further to advertise such deadly substances to the hapless consumers

²⁸ Section 5

²⁹ Section 2 Food and drugs Act.

³⁰ Section of the Food, Drug Product Registration Etc. At Cap F33, LFN 2004

³¹ Section 1 of the Counterfeit and Unwholesome Processed Foods Act Cap C34, LFN 2004

THE POSITION IN OTHER JURISDICTION

It is pertinent to compare the position in Nigeria with some selected jurisdiction.

Canada

Drug advertising is prohibited in Canada as a health protection measure. Manufacturers cannot advertise drugs directly to the public because of their toxicity and the potential for harm from medically unnecessary or inappropriate use.³²

United States of America

The position in the USA is that pharmaceuticals have long been marketed directly to consumers. This has however continued to generate controversy. Prior to 1962, the Federal Trade Commission (FTC) had jurisdiction over all advertising. That year, the Kefauver-Harris Amendments to the Food, Drug, and Cosmetics Act transferred jurisdiction of prescription drug advertising from the FTC to the FDA, strengthening the premarket review process for such drugs.³³ Since then the FDA has been the primary regulator of prescription drug advertising including that aimed at consumers, while the FTC retains authority to regulate Over The Counter (OTC) drugs advertising. Until 1980s, pharmaceutical advertising was mainly aimed at medical professionals. In 1983, after companies had begun advertising directly to consumers, the FDA requested a voluntary moratorium on direct to consumer advertising. Two years later, the moratorium was lifted without any new regulations or requirements. The FDA only requires that direct to consumer advertisement of drugs must meet the same requirement as direct to physician adverts and include a brief summary of the drug's side effects, contraindications, warnings, and precautions, and provide "fair balance" between the drug's risks and benefits. In 1997, direct to consumer advertising took an important turn when the FDA loosened its requirements for direct to consumer broadcast (DTC) adverts.³³ The new rules, which were finalized in 1999, required that broadcast adverts need only provide warnings. Under the new requirement, a adverts must disclose the drug's major risks and most common adverse effects in the audio or audiovisual parts of the presentation. In addition, the advert may make adequate provision for dissemination of package labeling information by referring consumers to a toll free telephone number, a website, print adverts, or their health care providers. In addition to the FDA, A number of organizations do their own policing of drug advertising. The National Advertising Division (NAD), founded in 1971 by the Council of Better Business Bureaus, is the major regulatory body for advertising, including pharmaceutical advertising. Prescription drug advertising is also regulated by the pharmaceutical industry throughout the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA has developed a 15 point Voluntary Guidelines for advertising which has been adopted by 25 pharmaceutical companies. The key points are to comply with FDA guidelines, emphasize risks and benefits in adverts, delay adverts for new drugs until doctors have sufficient time to learn about them, and submit all television adverts to the FDA for review.

However this position in the US has generated so much controversy among legislators, health care professionals, regulatory organizations, advert experts, and consumer advocates. There is need for more stringent oversight to protect consumers from detrimental and socially undesirable effects of DTC advertising. This is because DTC advertising confuses and misleads consumers, interferes with the physician-patient relationship, stimulates unnecessary demand for drugs (especially for costly brands) leads to inappropriate prescription drug use, and contributes to rising health care costs.

RECOMMENDATIONS AND CONCLUSION

Nigeria drug laws do not contain sufficient provisions on drug advertisement restraint. The question of advertisement of drug raises serious ethical issues that cannot just be glossed over in an enactment. While

³² B. Mintze "Should Canada allow Direct to Consumer Advertising of Prescription Drugs?" Canadian Family Physician February 2009, Vol 55 no.2 131-133

³³ M. Hunt "Direct to Consumer Advertising of Prescription Drug" *National Health Forum*, Washington DC :George Washington University, April, 1998

³³ F .B Palumbo, D. Mullins; "he Development of Direct to Consumer Prescription Drug Advertising"; *Food, Drug Law Journal*, 2002, vol. 57 No. 3, pp423-443

the situation in the United States of America has metamorphosed from direct to physician advertisement of drug to direct to consumer advertisement of drugs, Canada outrightly prohibits direct to consumer advertisement of drugs.

The situation in Nigeria where many so called alternative medicine providers are fleecing the unsuspecting drug consumers by aggressively marketing their drugs with spurious therapeutic claims leaves much to be desired. Much as some of the drugs could pass as food supplements and vitamins, the providers claim omnibus but untested potency for the drugs and by means of aggressive advertisement hoodwink the drug consumers to buy such drugs at very exorbitant prices. It is suggested that a complete ban of direct to consumer drug advertisement will help to rid the nation's drug market of fake, counterfeit and substandard drugs.

The situation in the United States is not comparable with that of Nigeria in view of the gnawing divide in the literacy rate of the two countries. The literacy rate in Nigeria is not suitable for such a liberal approach to drug advertising. Besides, a developed country like Canada with a very high literacy rate still recognizes the ethical inappropriateness of drug advertising by prohibiting the practice.

The decision to use or not to use a particular drug should be exclusively left in hands of physicians and medical professionals and not the manufacturers of drug and the mass media. Every information and persuasion with regards to the quality, potency or otherwise of a particular drug product should be directed to qualified physicians and medical professionals who are in a position to scientifically assess the veracity of drug advertisement claims.