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RESEARCH ARTICLE

SAFEGUARDING THE HEALTH OF NIGERIA: CHALLENGES AND SUGGESTIONS FOR NAFDAC, 1992 – 2008

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ABSTRACT

Between 1974, when the first food and drug decree was enacted, and 1994 when NAFDAC was established, no fake drug manufacturer or importer was prosecuted. Consequently, there was public outrage when no culprits were indicted over the death of 150 children in 1989 as a result of formulation error in a drug. It is interesting to note that this fight cannot be over unless various stakeholders come to collective agreement and working partnership that endures. The source of data for the study is primary and secondary and engages the historical method. The findings show that from April 2001, NAFDAC under a new management, led by Dora Nkem Akunyili engineered great transformation. Nigeria and the world could see the difference a well structured institution with good leadership can make within a very short period. This paper identifier the central position that the issue of food and drug is attracting globally and as well, highlights the numerous factors that account for the success of NAFDAC which can also be injected into the other sectors of the Nigerian Economy.

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INTRODUCTION

Like many other developing countries, Nigeria faces the challenge of providing adequate food and drug supply for its teeming population. Towards this end, policies and programme aimed at boosting agricultural and food production are being actively promoted. However, the issue of food and drug safety poses a daunting challenge. Like several other countries, Nigeria has to contend with the problem of food-borne diseases with their attendant social, economic and health costs. Nigeria needs to take appropriate and pragmatic steps to ensure food and drug safety for domestic consumption and export. This is because food and drug has been identified globally as not only a biological but also an economic and a political weapon. It is constantly a potential source of socio-political problems in communities and nations. An effective national food and drug safety policy should therefore provide the assurance that food and drug supplied to the consumers is adequate, nutritious, of good quality and wholesome.

In recognition of the importance of food and drug safety as an important factor for achieving high level of health for all Nigerians, the government launched the National Policy on Food Hygiene and Safety as an integral part of the Nigerian National Health Policy (Omotayo et al., 2002). The overall goal of this policy is the attainment of high level of food and drug hygiene and safety practices which will promote health, control food-borne disease, minimize and finally eliminate the risk of diseases related to poor food and drug hygiene and safety. Implementation of the policy is aimed at addressing the unsatisfactory level of food and drug hygiene and safety practices, which to a large extent is responsible for the prevalence of food borne disease in Nigeria. National Agency for Food and Drugs Administration Control (NAFDAC) replaced an earlier body, the Directorate of Food and Drug Administration and Control of the Federal Ministry of Health whose performance was limited by factors including legislation that were inadequate to discourage the production and distribution of fake drugs.

NAFDAC is a parastatal of the Federal Ministry of Health, and came into being on January 1, 1994. NAFDAC was established in response to the resolution of the World Health Assembly in 1988 that in order to combat the threat that fake drug poses to global health, countries should initiate a programme for the prevention and detection of counterfeit pharmaceutical products. In December 1992, the maiden governing council of NAFDAC was inaugurated under the chairmanship of Ambassador Tanimu Saulawu. The supporting legislation (Decree No. 15, 1993) was signed into law in January 1993 (Nigeriafirst.org, 2006). By working in a way that has earned NAFDAC much admiration at home and abroad, the regulatory agency has set the standards by which other public establishments could be judged. For example, Nigerians now compare and contrast activities of the Standards Organisation of Nigeria (SON) with those of NAFDAC, especially against the background of the influx of substandard industrial goods like tyres, motor parts, electrical gadgets and cables into the Nigerian market. The study of NAFDAC is important particularly as the agency has set the standard for assessing performance of public institution in Nigeria (Adetuyi, 2006). It is interesting that the world's foremost anti-corruption body has now found in a Nigerian an exemplary person in public service worthy of global emulation (Adetuyi, 2006). Dora Akunyili earned Transparency International's rare recognition for her courageous war against expired, substandard and counterfeit drugs and for boldly challenging other forms of corruption despite the threats to her life (Adetuyi, 2006).

OBJECTIVES AND METHODOLOGY

This paper discusses governmental responsibilities on ensuring food and drug safety in Nigeria. Fake and counterfeit drug was identified as a global problem, it becomes the responsibility of the Federal Ministry of Health, and this led to the birth of NAFDAC as a parastatal.

This paper aims at the following

- to discuss the emergence of NAFDAC
- to investigate NAFDAC battle against fake drugs
- to highlight some remarkable achievements of NAFDAC
- to proffers applicable suggestion for NAFDAC

This paper is basically a review and syntheses of literature. It adopted a research survey method, of which, mostly personal interviews, conducted face-to-face with cautiously selected respondents. Internet resources were also wisely selected for review. Lastly, attention was placed on issues of how life were saved as published in the dailies and other media (both local and international) during the period of study.

Centrality of Food and Drugs in Global politics

Sonaiya (1993) notes that in West Africa, research towards a close integration of crops and livestocks was urgently needed in all zones. He also exposes that food production systems are unable to feed the people adequately because of the many physical, biological, technological and legal constraints. He suggests that multidisciplinary studies are needed to understand and resolve the problems arising from cultural and legislative constrains (Sonaiya, 1993). Henry (2000) presents a case for the privatization of significant portions of the drug process. The first part of the book discusses the need for basic changes in the way the FDA conducts business and the second part of the book proposes a model for regulatory reform. The model for the proposal is based on 1996 work by the Progress and Freedom Foundation (Washington, DC), and Miller's model expands and details the original rationale. The book provides a provocative view of the current drug development process that is governed by a singular organisation in the United States, the FDA. In the FDA's cohort of industrialized nations, experts from the private sector are used extensively in drug evaluation. Challenges exist in the discovery, development, and approval of new molecules. Researchers and authorities in the United States have not reached consensus about a risk benefit ratio for new pharmaceuticals that is acceptable to the community. Henry proposes that the pharmaceutical companies contract with independent firms who would be responsible for the drug development process and make a final recommendation to the FDA about the approvability of the drug.

Folawiyo (1988) notes that the control of drugs is necessary, especially for the juvenile. He also noted that passing laws could have a beneficiary or a harmful effect depending upon the wisdom of the legislation (Folawiyo, 1988). Due to the current upsurge of drug misuse especially in those of school age, Folawiyo holds that it would seem reasonable to apprehend the supplier of these minors rather than to focus on catching the users or possessors. According to him, the maker, the smuggler, the pusher and the transporter must be punished. Folawiyo asserts that the most convincing statement that can be made in the way of living is striving for security, so important in times of hardship and poverty, is an inadequate goal during period of relative affluence. Those of middle-class who do not need to struggle to obtain food and shelter find such an out-moded aspiration unacceptable. It is a feeling of existential meaninglessness, which attracts some people to the drug. The acquisition of a sense of meaningfulness in the anti-dote. Dean (2000) notes that there are difficulties faced by food manufacturers in meeting the growing clamour for a greater variety of prepared foods at a lower cost whilst trying to safeguard the interest of allergy sufferers. Dean noted that it would be impractical to eliminate from the diet food ingredients, which are perfectly harmless to the vast majority of population in the United Kingdom. The way forward therefore lies in the provision of good information about exactly what it is in good food. Finally, Dean concluded that the practical protection, which individuals with food allergy and intolerance can expect from the law, is information rather than elimination. This is why outside legal control; UK food retailers have done much to champion the cause of food intolerance. Most major supermarkets require their suppliers to provide detail

information about what it is in their own-label products. Such information is available to callers and published in leaflets, and there are proposals to make it available on the Internet, the book reveals.

The Emergence of NAFDAC

Fake and counterfeit drug problem has been identified as a global problem by World Health Assembly, and this led to the adoption of a resolution in 1988 for prevention and detection of counterfeit pharmaceutical products, regarding exports, imports, smuggling, manufacture etc (NAFDAC, 2006). The importance of food and drugs to man and animal is very obvious. They need food in order to grow and sustain life while life goes on, and because of the inherent disposition to illness, the organs of the body may not always function properly (Ogbeche, 2006). It is the duty of all government to protect the health of the citizens, and in Nigeria this is the responsibility of the Federal Ministry of Health. Within the Ministry, and until 31st December 1992, these responsibilities as regards foods and drugs devolved on the Department of Food, Drugs Administration Control (FDAC) (NAFDAC, 2006). They are also traceable to a lack of awareness by the public in practical terms of the sensitivity of relevance of matters concerning control measures on food, drugs, cosmetics, water and chemicals to both preventive and curative health care. Such control measures, when executed successfully, provide guaranteed savings of high percentage of the expenditure of the government and individuals to cure and relieve illness. These problems led to the birth of NAFDAC as a parastatal of the Federal Ministry of Health. NAFDAC was established by Decree No. 15 of 1993 to carry out among other things, all the control functions of the former FDAC while the service functions remain within the ministry.

NAFDAC Battle against Fake Drugs

A total of 250 fake drugs and wholesome processed food cases were handled by National Agency for Food, Drug Administration and Control (NAFDAC) between January 1994 and December 1999 (NAFDAC NEWS 2001). About 201 of the cases, which were directly handled by the Federal Task Force on counterfeit and fake drugs, were related to illegal manufacture and importation of fake, substandard and expired drugs. Mrs. Ariz Madukwe also hinted that the street value of impounded drugs destroyed in the last eight years by the Federal Task Force (an arm of NAFDAC) was N204.2 Million (NAFDAC NEWS 2001). She therefore called for increase public enlightenment campaign and collaboration of all professional and sectoral groups in the fight against fake drugs phenomenon.

Speaking with the Nigerian Tribune on the challenges faced by the Agency in its fight to combat drug counterfeiting, Dora Akunyili explained that because of the nation's weak laws, "criminals are now shifting from cocaine, hard drugs pushing, and gun running to drugs counterfeiting" (Akinmade, 2006). The Director General said the drugs counterfeiting business remained lucrative in the country even, as the law was weakening the business. She lamented that "the penalty for a fake drug producer or importer ranges from N5, 000 to N10, 000 or between three months and five years imprisonment," (Akinmade, 2006) which, she added, allowed convicted drug dealers to work the street free. The 'industry' she came up against, fetches billions of Naira for the evil men, so the backlash against her was vicious. In December 2003, an assassination attempt was made on her life. Gunmen fired at the vehicle she was traveling in, but by God's grace the bullet pierced through her headgear without any significant wound. Police arrested - then allegedly executed - five of the attackers. "God indeed saved my life," Akunyili testified at a preliminary hearing in the case. Threats of physical harm, abusive telephones calls, hate mails, mysterious items and live animals like tortoise placed in her office, were some of the insidious methods that the cabal adopted to threaten her. Her family and staff have not been spared either. They too received threat letters and calls. In the midst of all these, she persevered. Her strength derives from her strong belief in God. As a strong Catholic, she believes firmly that God is in

full control and nothing can happen to anyone if God has not approved of it. This belief makes her fearless.

Naturally, member of her family usually worried about her safety. Her children were particularly terrified to the extent that her fourteen-year-old son asked her to reconsider her service as DG (NAFDAC) because of the threat to her life (Creative 2006). His remark was,

...do you realize that you are burning people's money and risking your life? If it is because of these new cars that you are remaining in this scary job, drop them; we were better off and more relaxed when you were at the PTF (Creative 2006).

NAFDAC Directors during the period of study have commanded public attention and earned public respect and applause. For Dora, she has received numerous honours more than any other person since 2001 to 2003. Any time an honour has been bestowed on her in Nigeria and overseas, it has been greeted with tremendous public excitement and applause (Okpalafulaku, 2003). Perhaps, the greatest honour that Dora has received is the gratitude of millions of Nigerians for saving life. The period of study was simply characterized with 'Zero Corruption, No Sacred Cows' and NAFDAC Directors led by personal example. This has made the entire NAFDAC management to have a zero-tolerance attitude towards corruption (Creative 2006). And the staffs do not care whose ox is gored in the task to rid Nigeria of dangerous drugs. All NAFDAC executives work for long hours daily, and they do so with courtesy. Dora is one of the very few executives of government bodies who insist on personally seeing all her visitors' daily, and tries as much as possible to solve their problems without in any way compromising the integrity of her office.

NAFDAC Directors have demonstrated that there are enough laws in our statue books to deal with social monsters like corruption and incompetence. After all, they did not ask for or obtain a special legislation before they got cracking, and in the process earned themselves national and international acclaims. What is required to transform Nigeria into a country of our desire is the will power to do the right thing, the will power to punish offenders of the law appropriately and reward the law-abiding adequately. Where there is the will power, there will be no sacred cow. Nigeria does need a critical mass of public officers with the will to enforce the laws of the land. In this connection, one-person worthy of public acknowledgement is Dioka Ejionueme, an incorruptible lawyer and pharmacist who heads NAFDAC's Enforcement Division (Okpalafulaku 2003). NAFDAC has set the standards to assess public institutions in Nigeria. One important lesson from the awards bestowed on NAFDAC Directors in past years, especially that of May 25 by Transparency International, is that meritorious and selfless services will always be recognized and rewarded, irrespective of race or gender. Chief Obafemi Awolowo, one of Nigerian foremost politicians, once noted that the greatest legacy any leader or public officer can leave behind is to etch his or her name in the heart of people (Okpalafulaku, 2003). This, Dora Akunyili has done.

NAFDAC Directors, unveiled the plans of the Agency to tackle the menace of fake drugs in Onitsha (The Onitsha Market Saga) during an interactive session to raise awareness of the activities of the University of Bristol, United Kingdom (UK) seeking collaboration with some Nigerian Universities to improve humanity. The program was organized by NAFDAC in conjunction with the British Council in Lagos. Lamenting the menace of fake drugs in Onitsha, the Director General described the situation as 'a disaster', calling it a shame. According to her, in all other markets in Nigeria, the Agency did not discover up to 10 percent of fake drugs in any. On the contrary, Dora Akunyili said the amount of fake drugs found in Onitsha is up to 30 per cent (Adeyemi, 2006). This high quantity contributed significantly to increase the average percentage of counterfeit drugs in Nigeria to 16 per cent. NAFDAC initiated some measures to tackle the menace of fake drugs in the Onitsha Market. Part of it is compelling all importers of pharmaceutical products to become

members of the Association of Pharmaceutical Importers of Nigeria (APIN) (Awotale 2007). This aim of this exercise is to use the instruments of the pharmaceutical body to check the unscrupulous activities of the importers of fake and counterfeit drugs into the country. NAFDAC war on the notorious drug markets in the country did not start with Onitsha. The drug market in Ariaria, Aba was alleged after NAFDAC investigation, to have over 75 per cent of drugs in stock as fake batches in 2002. Attempts to whip the merchants of death into line by regulatory officers from NAFDAC were resisted leading to the closure of the market for some months. In Sabongeri market Kano, a NAFDAC survey, revealed that 90 per cent of drugs sold in 2004 were unregistered by NAFDAC and therefore fake. This led to a closure, which was subsequently reviewed three months after. Priori to the promulgation of decree 21 of 1988 (the first law on fake drugs) there were only four major drug markets in the country. They include the Bridge Head Market, Onitsha, Idumota Market in Lagos, Sabongari and Ariaria market (Ukwuoma, 2007).

On the World Health Organisation (WHO)/British Department for International Development (DFID) study of level of incidence of fake drugs in Nigeria which revealed that all parts of Nigeria, minus Onitsha, have less than 10 per cent of drugs as counterfeit. She said

Onitsha has over 30 per cent and this has brought NAFDAC overall figure to 16.7 per cent. Even though this is a great improvement to the figures recorded by many researches before 2001 which range from 41 per cent to 68 per cent, it is still an uncomfortable figure because life is involved". The NAFDAC boss revealed: "we have carted away 40 lorry loads of fake drugs. We have not done more than 50 percent of the work in the market. We also dismantled illegal clinics where abortions are procured, and infusions are administered. In Onitsha they have something called washing of blood. They lie down and put drip and lasxis, you known lasxis makes people urinate, but they call it washing of their blood. Even the doctors are taking advantage of the situation and are carrying out the Jankara practice (Ukwuoma, 2007).

Dora Akunyili stated, "Once we clean up Onitsha, the incidence of fake drugs will reduce substantially. It will be less than 10 per cent and we will be at par with other developing countries." An official statement from the agency's Head of Public Relations, Abubakar Jimoh, read "the closure of the market became inevitable to check the increasing danger the market posed to public health in the country". He ranked the Onitsha market as being head and shoulders above all other markets in fake/counterfeit medicines in the country. The NAFDAC boss appreciates that there are genuine drug dealers in Onitsha drug market, but they have been totally compromised by drug counterfeiters. According to her

...as long as the genuine drug traders are not ready to help us face the criminals, they will continue to suffer with them, because it is not practicable to isolate the genuine drug dealers in the process of closing the market." Akunyili insists: "we are not in a hurry to open the market. The market will remain closed until the agency concludes the screening of every shop in the market, remove all the fake drugs and streamline the activities of the traders (Ukwuoma, 2007).

The war against fake and substandard food, drugs and other regulated products in Nigeria cannot be fought and won solely by NAFDAC and her chief executive officer (Emmanuel, 2007). It is interesting to note that this fight cannot be over unless various stakeholders come to collective agreement and working partnership that endures. It is worth mentioning that the agency's grassroots sensitization has gone a long way in educating the society on the health and socio-economic effect of fake drugs but a step further towards the realization of its goals by

forming liaisons with village heads, town unions, traditional rulers and religious leaders will be highly commendable. These key players in the community development should be trained to pass on the message to the members of their immediate environment (Nnakwe 2007).

Achievements of NAFDAC

First and foremost, NAFDAC enhanced Nigeria's corporate image. One of the greatest achievements of NAFDAC is the institutionalization of the culture that promotes transparency, accountability, hard work, and abhors corruption. This brought about behavioural change in the staff and indeed has become the oil that lubricates the wheel of the Agency's success. Transparency in the regulatory processes enhanced communication with stakeholders with resultant increase in voluntary compliance. NAFDAC's anticorruption stance brought support for the Agency and helped it to achieve better regulation in Nigeria. Secondly, there was great improvement in the Health and Pharmaceutical Sub-Sector. The Executive Secretary of PMG-MAN attributed improved performance of the sector to 100% import inspection policy and the new impetus NAFDAC, which has seriously curtailed dumping (The Guardian 2001). GlaxoSmithKline recorded a 77% growth in sales during 2003. The General Manager, West Africa attributed this tremendous increase to "NAFDAC living up to its responsibilities of enforcing strict compliance toproduct (The Guardian 2003) MAY & BAKER's profit growth rose by 88% for the first half of 2003. Phar Deko Plc witnessed an increased demand for its products resulting in a 78.5% increased in turnover in 2002 (The Punch 2003). It is noteworthy that the company had not paid dividends since 1999 due to loses but the company declared dividends in 2003 (The Punch 2003). NEIMETH International Pharmaceuticals Plc recorded 105% increase in the profit before tax at the end of its financial year in March 31, 2003 (The Punch 2003). NAFDAC activities have reinforced the confidence of investors in the pharmaceutical industry, as evidenced in the continuous upward movement in the share prices of the pharmaceutical companies quoted in the Nigerian stock exchange.

Thirdly, NAFDAC increased public awareness. The consciousness of all stakeholders, particularly on the dangers to health of fake drugs and other substandard products, has increased tremendously. In a public opinion poll conducted by The Guardian Newspaper on the activities of NAFDAC, 83% of 1,200 respondents rated NAFDAC's performance as good to excellent (Nigeria Tribune 2003). Fourthly, there was an increased output. From April 2001 to 2003, the Agency has carried out seventy-six-destruction exercise of counterfeit and substandard products valued at over N7.2 Billion (The Guardian, 2002). A visible upsurge in the number of registered products has been recorded. The total number of regulated products registered between year 2001 to 2003 accounts for more than 60% of product registered by the Agency since inception. The upgrading of the Agency's laboratories to international standards yielded fruits in form of international accreditation. The seafood laboratories have EU accreditation while WHO recognizes the vaccine laboratory in West Africa Sub region.

Fifth was a favourable Government Policies. The following new government policies were spearheaded by NAFDAC

- The return of NAFDAC to the port in October 2001. This has yielded immense results in the level of seizures, sanctions and sanity that have prevailed since the period.
- Release of Shipping and Cargo Manifests by the Nigerian Port Authority (NPA), Shipping Lines and Airlines to NAFDAC inspectors.
- 3. Outright ban on importation of drugs and other regulated products (food, cosmetics, chemicals/detergents, medical devices, and all drinks) through all land borders.

 Lastly, the designation of specific seaports and airports as exclusive ports of entering for the importation of drugs and pharmaceutical raw materials.

Sixth was Provision and Improvement of Infrastructure. That creation of functional NAFDAC offices in the 36 states of the Federation and Abuja, zonal offices in the six geopolitical zones and the three special zonal offices brought NAFDAC close to the regulated industries and the consumers. The acquisition of new corporate headquarters in Abuja was a monumental achievement. NAFDAC constructed two gigantic warehouses for thermo-stable products. Four of NAFADC laboratories have been upgraded to international standards while three new laboratories are under construction. (Kaduna Lab was then razed by fire). Computerization of the Agency's activities, creation of the NAFDAC websites as well as provision of adequate office equipment, enhanced information flow within and outside the Agency. Provision of functional utility vehicles greatly enhanced transportation of staff for regulatory assignments. Lastly, NAFDAC enjoyed Land and International Aid. Transparency and the culture of accountability of the Agency have attracted support from both National and International organizations towards upgrading NAFDAC laboratories, building capacities of staff and other technical collaborations. Many organizations donated laboratory and office equipment, sponsored various staff training programmes and financed baseline studies on salt iodization, vitamin fortification and counterfeit medicines. NAFDAC monitoring of salt iodization in Nigeria has earned Nigeria UNICEF's rating as the first country in Africa to achieve universal salt iodization. The country has 100% compliance at manufacturer's level, 98% and 88% at distribution and household levels respectively. She has also achieved 85% factory level compliance in Vitamin A fortification of vegetable oil. According to baseline surveys conducted in 2002 and 2003 (twice), there were positive results indicating a drop in the prevalence of unregistered drug products in Nigeria. The prevalence was almost 70% in 2001, and dropped by 58% in 2003 (Creative 2006).

Conclusion

NAFDAC must solicit the support and strength of various allies. In order to stifle and permanently halt the movement of these fake drugs across our borders, a partnership should be established between the Nigerian government and neighbouring countries like Cameroon, Niger, Benin Republic, Togo, Ghana etc. Some of these governments do not take the eradication of fake drugs as a priority; their constant trafficking across porous borders must be checked carefully to curb yet another scourge. NAFDAC laboratories all over the country are world class and conform to international standard, but these laboratories are of no use if the cycle facilitating the circulation of fake drugs is not broken. An intelligent network can also be deployed to discover the manufacturers and their vendors, from the State Security Service (SSS) to the Civil Defence Corps and down to the local vigilante groups in varying communities. Such networks can provide useful information that save thousands of lives. An amicable and functional relationship should be established between the aforementioned groups and NAFDAC. In the same vein, NAFDAC should partner with state governments to create State-NAFDAC so that the gains will permeate all the nooks and crannies of the country. There should also be a meaningful co-operation with NAFDAC consultant in Asia, Europe and America through regular training of staff. If this is done, then there will be a cross fertilization of up-to-date ideas on scientific knowledge about product to avoid adulteration and laxity on the part of manufacturers. The fight cannot be won alone; the government must give special consideration and concession to NAFDAC to help wage a successful war against fake drugs and allied The Federal government can start by increasing its subvention and budgetary allocation to the agency. A review of the salary by the national salary and wages commission will not be asking too much either. An increase in the basic allowance and benefit especially those related to the health of the work force will be most adequate. This is important in order to maintain a healthy and result oriented work force. Dora Akunyili is a person of big ideas, a

conceptual thinker, emotionally powerful, and having clear vision of moulding Nigeria's NAFDAC after the Americans FDA. There is no doubt that NAFDAC under Dora Akunyili has accomplished a great deal. Yet, during her regime, the indefatigable lady still looks down the tunnel and sees most work that has to be done. She advocates a better operating environment, with more comprehensive and updated laws, more responsive and cooperative attitude from sister regulatory agencies like Customs, Immigration, Police, Standard Organisation of Nigeria, etc. By doing her work well, Dr. Akunyili has brought honour to her country and people, and helped in presenting a new image of Africa different from the fraud, violence, corruption, aggrandizement and inefficiency that are routinely shown to the world. She has served her country diligently and honestly in the past years. In the process, she has saved millions of lives and brought sanity to an abused food and drug regulatory environment.

What a fight, what a life!

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