

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
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NAME: Salako-Akande, Ajibike Omosalewa

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: CEO/INVENTOR

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

| INSTITUTION AND LOCATION | DEGREE <i>(if applicable)</i> | Completion Date MM/YYYY | FIELD OF STUDY |
|---|----------------------------------|----------------------------|---|
| University of Lagos, Medical School Nigeria | MBBS | 1980 | Medicine |
| Coppin State College, Baltimore USA | M.Ed. | 1993 | Rehabilitation Counseling/Addiction |
| Morgan State University, Baltimore USA | Postdoctoral Fellow | 2007 (Feb-Sept) | Complementary & Alternative Medicine |

A. Personal Statement

I am a medical doctor and rehabilitation counselor. I have a broad knowledge of medicine and psychology with specific training and expertise in substance use disorder. I have 8 years of experience in general medicine and more than 30 years of experience in clinical counselling including screening, interviewing, recovery support, mentoring and advocacy in co-occurring disorders of mental health and substance abuse. My areas of expertise include General Medical Practice, Substance Abuse, Mental Health, Psychosocial Support, Developmental Disabilities, and Counselling. I also have experience providing “wrap-around” social services for at-risk youth and their families. For example, in 1997 I developed an intensive psychosocial support program that met the need of Baltimore inner city children and their families. This was adopted by the State of Maryland, Department of Health & Mental Hygiene and was disseminated throughout the state. I have experience working in multiple settings, including clinical practice, academic institutions, schools, homes, and community centers, and with multiple populations, including children, adolescents, adults, and ex-offenders.

My research interest has been to find out why drug abusers can't stop using drugs despite genuine promises to loved ones and knowledge of psychological, social, and health consequences. My goal has been to find reasons for this loss of control, and to determine if alternative “natural product” therapies, like nutritional supplements, can be useful for managing substance use disorder. During my 30 years of studying this problem, which includes running an outpatient mental health clinic with consultant psychiatrists for 12 years and regularly attending conferences on the neurobiology of substance use disorder at the National Institute of Drug Abuse (NIDA), I came to the conclusion that persistent craving drives relapse and underlies the loss of control over drug use, and is the primary issue that needed to be addressed in substance use disorder. Craving can result from a number of factors including recall of previous experiences, depletion in brain chemistry/nutritional deficiencies, accumulation of metabolites and new drug formation with similar characteristics. Considering the neurobiology of substance use disorder, and that the nutrients and precursors necessary for neurotransmitter production are commercially available as nutritional supplements, I hypothesized that if they were combined, they may be able to replace and replenish what chronic drug use had depleted, leading to improvement in brain function, less drug craving, and a regain of control over drug use. Based on this framework, I developed 3 product lines to address stimulant (cocaine, amphetamine nicotine and

marijuana), opioid (heroin, prescription opiates) and alcohol use disorders. All are novel nutrient supplement powder that are intended to be over-the-counter and taken orally when dissolved in water for the reduction of cocaine, heroin, alcohol, and marijuana-seeking. Getwele, LLC has filed a provisional patent application which has since converted to a utility application in order to protect our proprietary formulation. Currently, we have met the Federal Drug Administration (FDA) regulation for online sale as functional foods/nutritional supplements. In addition, we will seek FDA MEDICAL FOOD designation for all products. We are currently working with our consulting regulatory agency to achieve this goal.

The manufacturer of all SMAASH-Products has many years of experience in compounding, analysis, and stability testing of products. He provides product development, manufacturing services, and GMP advice for each of my formulations. The standardization of the formulation will be verified by an independent laboratory support).

The development of SMAASH-C as a potential intervention for cocaine use disorder has been a long and exciting journey beginning with the conception and manufacturing, and then initial screening in humans and in safety trials in rats (see references below), and now in preclinical models of cocaine relapse to establish causative effects. As a clinician and the inventor of SMAASH-Products, I have seen firsthand the powerful anti-relapse effect that they exerts, and am eager to see this work come to fruition since I truly believe that they will dramatically decrease cocaine, heroin, alcohol and marijuana craving and enable individuals to return to being healthy productive citizens.

- a. Gardner N, Luke K, Wheatley A, De La Haye W, Bahado-Singh P, Dilworth L, McGrowder D, Barton E, Young L, **Salako-Akande A**, Lowe H, Morison E, Eldermire-Shearer D, Asemota H (2015) Measurements of plasma cocaine metabolite levels and liver CYP450 3A4 isoenzyme activity as indicators of cocaine dependence in rats treated with Salako Nutritional Supplements. International Journal of Measurement Technologies and Instrumentation Engineering, USA 5(2), 28-43.
- b. Webber-Waugh A, Thaxter NK, Anderson-Johnson P, **Salako- Akande A**, Asemota H, Young L (2017) Drug seeking behaviour of amphetamine addicted Sprague-Dawley rats is eliminated after nutritional supplementation. Journal of Behavioral and Brain Science, USA 7(12): 585-597.

B. Positions and Honors

Positions

| | |
|--------------|---|
| 1980-1981 | Medical Intern, Military Hospital, Kaduna Nigeria |
| 1980-1982 | Youth Corp Service, Military Academy, Kaduna Nigeria |
| 1982-1986 | Senior Medical Officer, Military Hospitals Kaduna & Ibadan Nigeria |
| 1986-1988 | Internal Medicine Residency, University College Hospital, University of Ibadan, Nigeria |
| 1989-1991 | Residential/Drug Abuse Counselor, Dulaney Station, MD USA |
| 1993-1997 | Associate Professor, Coppin State University USA |
| 1995-1997 | Addictions Consultant, DART Treatment Program, Baltimore MD USA |
| 1995-2009 | Founder/CEO, Awele Treatment & Rehab Clinic, Inc., Baltimore MD USA |
| 1997-Present | Founder/ Executive Secretary, Awele Foundation International/Nigeria |
| 1997-2009 | Founder/CEO, Awele Social Health Clinic, Hyattsville MD USA |
| 1999-2002 | Quarterly Guest Speaker on Substance Abuse Education, Morgan State University Radio Talk Show, MD USA |
| 2006-2007 | National Steering Committee on Complementary and Alternative Medicine, School of Public Health, Morgan State University USA |
| 2009-2010 | Monthly Guest Speaker on Substance Abuse Education, Eko FM and Radio, Nigeria |
| 2009 | Guest Speaker on the functions of vitamins and minerals at the NTA Television Network, Lagos, Nigeria |
| 2012-2014 | Substance/Sexual Abuse Counseling Intern, Huber & Associates, Baltimore USA |
| 2012-Present | Innovator/Owner, Getwele Natureceuticals, Baltimore MD, USA |
| 2017-Present | CEO Getwele Recovery & Wellness Center, Baltimore MD USA |

Certifications

1994 Registered Addiction Counselor (RAD), District of Columbia
2012 Certified Addiction Trainee (CADT), Board of Professional Counselors, Maryland Department of Health and Mental Hygiene, Maryland
2013 Board Certified Professional Counselor, (BCPC), American Psychotherapy Association
2016 Recovery Advocate (RCA), Connecticut Community for Addiction Recovery

Honors

1994-1998 Awarded copyrights on Screening for Drug Abuse in the disabled clients of Division of Vocational Rehab, Maryland; Medical education and behavior change; and Intensive Psychosocial Support/Psychiatric Rehab Program (PRP)
1997 Inducted into WHO's WHO of America
2003/2014 Awarded Provisional PATENT for the use of nutritional supplements for treating drug abuse by the US Patent office.
2003 Awarded Mayoral Fellow by the Mayor of Baltimore in recognition of community work
2005 Awarded Permanent PATENT for the use of nutritional supplements for treating drug abuse by the Nigerian Patent office

Professional Membership

- American Psychotherapy Association, USA
- British Association of Psychotherapists, England
- Nigerian Medical Association

C. Contributions to Science

1. My contributions have focused on the development of dietary supplementation to provide precursors and nutrients that the brain can convert to neurotransmitters as a means of combating persistent craving. This is a line of inquiry that I began 21 years ago, and is based on the premise that chronic drug use leads to the depletion of amino acids/neurotransmitters and nutrients and the proliferation and accumulation of metabolites. The hypothesis is that if the supplements are used as replacement and replenishment precursors, the brain will convert them to neurotransmitters, brain function will improve, and drug seeking will decrease. To test this hypothesis, I performed a small pilot open trial study in humans on cocaine, heroin, alcohol and marijuana between 1995-2000 with consultant psychiatrists monitoring the study, and found that each of the formulations decreased drug craving without inducing side-effects. So far, approximately 75 patients (men and women) have used SMAASH-Products (~0.4 g/kg/day; 6-12 months) with reports consistently indicating reduced cocaine, heroin, alcohol and marijuana craving, less severe withdrawal symptoms, including reduced stress and anxiety, and less frequent relapses. They also appear to increase treatment retention and interest in recovery with most patients maintaining abstinence through a 1-year follow-up period.

In collaboration with Drs. Gardner, Young, Asemota, Ms. Webber-Waugh, and colleagues at the University of the West Indies (7/01/07 - 4/01/14), I have also tested the effects of SMAASH-C on multiple behavioral, toxicological, and neurochemical measures in animal models. Our behavioral results showed that oral SMAASH-C treatment at the equivalent dose used in humans (~0.4 g/kg/day; 8-12 weeks) markedly reduced cocaine and amphetamine-seeking in rats as measured by the time spent in an environment previously associated with the drug using the conditioned place preference (CPP) test (De La Haye et al. 2010; Gardner et al. 2015; Webber-Waugh et al. 2017). Twelve-weeks of SMAASH-C treatment was also safe, and on its own, did not affect the relative weights of any of the major organs (the liver, spleen, intestine, brain, heart and stomach) or markers of oxidative stress/antioxidant enzyme specific activities in these organs (Gardner et al. 2009). In fact, our findings in animals chronically treated with cocaine indicate that SMAASH-C offset markers of cocaine-induced toxicity (e.g., lipid peroxide levels in stomach and liver, Kupffer cells in liver and GST in brain), and normalized cocaine-induced decreases in amino acids/neurotransmitters (e.g., glutamate; Gardner et al. 2009; 2012; 2015), and antioxidant levels (cysteine-glutathione). It also enhanced CYP450 3A4 metabolism of cocaine resulting in faster plasma clearance (Gardner et al. 2010; 2015).

Now, in these studies with Dr. Lynch (2016-present), we will follow-up on our exciting pilot data showing that 2 weeks of oral SMAASH-C treatment (0.4 g/kg/day; 15 days) markedly decreased cocaine-seeking during extinction and in response to cocaine-associated cues without affecting food intake, body weight, or non-specific responding. These data are consistent with reports in my patients, and strongly support the efficacy of SMAASH-Products as safe and efficacious anti-relapse intervention. We plan to move on to study the product for Heroin next and subsequently for Alcohol.

- a. Gardner N, Wheatley A, Bahado-Singh P, Dilworth L, De la Haye W, Lowe H, **Salako A**, Asemota H (2009) The effects of nutritional supplements in the reduction of hepatocellular oxidative damage associated with cocaine dependence. Proceedings from the Faculty of Medical Sciences 18th Annual Research Conference and Workshop on Child Health: From the Womb to Adolescence. University Hospital of the West Indies, Mona, Jamaica.
 - b. Gardner N, Wheatley A, De La Haye W, Lowe H, **Salako A**, Asemota H (2010) Cocaine hydrochloride metabolite clearance in plasma of rats fed nutritional supplement following cocaine dependence. Journal of Arts, Science and Technology, University of Technology Jamaica 4: Supplement 1.
 - c. De La Haye W, Gardner N, Luke K, Wheatley A, Bahado-Singh P, Lowe H, Ahmad M, **Salako A** Asemota H (2010) The use of nutritional supplements in reducing craving associated with cocaine dependence. 2nd International Conference on Drug Discovery abstracts, Dubai, UAE.
 - d. Gardner N, Wheatley A, De-la Haye W, Lowe H, **Salako A**, Asemota H (2012) The effect of nutritional supplements in fecal lipid contents following cocaine dependency. Proceedings from the Faculty of Pure and Applied Sciences Conference, University of West Indies, Mona Jamaica.
2. As a related contribution, I also introduced and documented an effective Complementary & Alternative Treatment for addictive drugs. This work emphasized the detrimental role that nutritional deficiency can play during treatment for substance use disorder if not addressed. It is a well acknowledged fact that the current psychosocial treatment only for cocaine and Medication Assisted Treatment for Heroin and other opiates are not very effective as we see high rate of relapse.
- a. **Salako-Akande** AO, Brunner YL, Kinyua AM (2007) Alternative treatment for drug abuse: the role of nutritional supplement. Focus on Alternative and Complementary Therapies UK 12(S1): 44.

D. Completed Research Support

Proof of Concept of Salako Nutritional Supplement

Science Foundation Jamaica, Ministry of Health Jamaica, Henry Lowe Foundation Jamaica, & Awele Foundation International USA, 7/01/07 - 4/01/14

Use of Nutritional Supplements in the Treatment of Cocaine Addiction: Mechanism of Action in an Animal Model. This project supported a Ph.D. dissertation work in Biotechnology completed by NS Gardner at The University of the West Indies (2014). I provided the concept and nutritional supplements and trained all personnel on the concept. I was also one of her Ph.D. mentors.