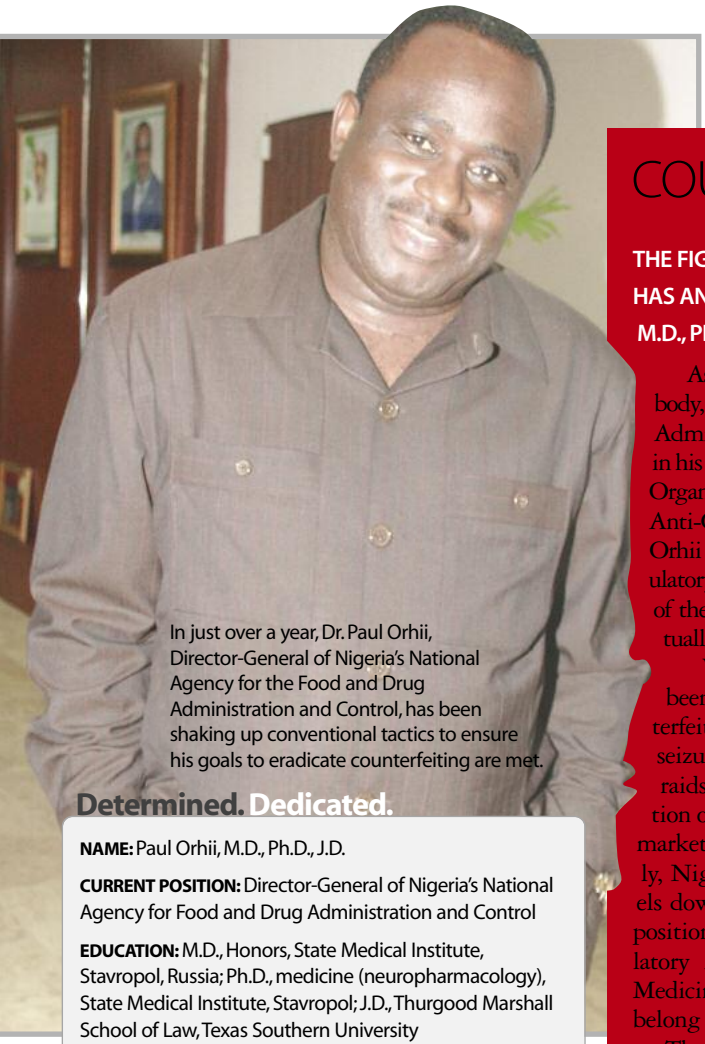
Ensuring Quality Through **OVERSIGHT**

These individuals have the goal of ensuring that the highest quality is brought to bear under stringent regulations to protect the safety of patients and medicines.



In just over a year, Dr. Paul Orhii, Director-General of Nigeria's National Agency for the Food and Drug Administration and Control, has been shaking up conventional tactics to ensure his goals to eradicate counterfeiting are met.

DR. PAUL ORHII

DID YOU KNOW?

Dr. Paul Orhii is completely dedicated to eradicating fake drugs from Nigeria.

Determined. Dedicated.

NAME: Paul Orhii, M.D., Ph.D., J.D.

CURRENT POSITION: Director-General of Nigeria's National Agency for Food and Drug Administration and Control

EDUCATION: M.D., Honors, State Medical Institute, Stavropol, Russia; Ph.D., medicine (neuropharmacology), State Medical Institute, Stavropol; J.D., Thurgood Marshall School of Law, Texas Southern University

DATE AND PLACE OF BIRTH: May 9, 1960, Lessel, Benue State, Nigeria

FIRST JOB: Clerk, Ministry of Justice, Benue State

FIRST INDUSTRY JOB: Internship at NBL Kaduna

PROFESSIONAL MENTORS: Hon. Justice A. I. Katsina-Alu CJN

PROFESSIONAL ASSOCIATIONS: The American Bar Association (ABA); The American Society for Bone & Mineral Research (ASBMR); The Medical & Dental Council of Nigeria; The European Pineal Society (EPS); The American Diabetes Association

WORDS TO LIVE BY: Hard work always pays

COUNTERFEIT CRUSADER

THE FIGHT AGAINST COUNTERFEIT DRUGS HAS AN EMINENT CHAMPION IN PAUL ORHII, M.D., PH.D., J.D.

As director-general of Nigeria's regulatory body, the National Agency for Food and Drug Administration and Control (NAFDAC), and in his role as vice chairman of the World Health Organization's International Medical Products Anti-Counterfeiting Task Force (IMPACT), Dr. Orhii has been leading the charge to bring regulatory standards in Nigeria up to the standards of the developed world, and he plans to eventually broaden his reach to all of Africa.

With Dr. Orhii in charge, Nigeria has been successful in the fight against counterfeit drugs by ramping up its detection and seizure activities, and NAFDAC frequently raids drug hawkers. As a result, the proportion of counterfeit medicines on sale in street markets has declined considerably. Specifically, Nigeria has brought counterfeit drug levels down from 42% to 16%, maintaining its position as one of the top 18 Medicine Regulatory Agencies in the world — the only Medicine Regulatory authority from Africa to belong to that group.

These are accomplishments that Dr. Orhii rates as his most important. To beat the counterfeiters, Dr. Orhii procured several cutting-edge technologies that were previously unavailable in Africa and deployed them at the ports of entry and in the field. NAFDAC was the first Medicine Regulatory Agency in the world to purchase Ahura Scientific's TruScan, a hand-held device that is being used at borders and medical stores to detect counterfeit medicines on the spot.

He has also deployed mini labs for the speedy evaluation of medicines on the spot. Dr. Orhii has also deployed a text messaging technology to put the power of detecting counterfeits into the hands of Nigerian consumers, thereby enlisting the entire Nigerian public in the war against counterfeiting.

On the back of these achievements, Dr. Orhii held the first workshop that involved all 774 local government council chairmen, notable musicians, and Nollywood stars to engage them in the fight against the menace of drug hawking — an offshoot of counterfeit medicines, other regulated products, and illegal advertisements of herbal medicines in rural areas.

In addition, he led NAFDAC to enter into an international collaboration in the war against counterfeit medicines by establishing strong ties with the U.S. FDA and governments in China, India, Argentina, Israel, and other countries. In response, China has begun making arrests of Chinese citizens for manufacturing fake drugs that are imported to Nigeria, and the Indian Parliament has enacted a law making it a criminal offense punishable by a lifetime jail term for the manufacture and distribution of spurious pharmaceutical products.

With the alliances he is forging in these countries, Dr. Orhii has become a global inspiration for governments seeking their own anti-counterfeiting efforts.

Dr. Orhii has a strong attachment to learning — holding M.D., Ph.D., and J.D. degrees — so it's not surprising that he seeks to offer educational opportunities to those less fortunate in his country.

He is involved in helping to provide educational scholarships to indigent Nigerians for undergraduate and postgraduate courses at home and abroad.

In addition, Dr. Orhii contributes to the rehabilitation of the primary and secondary schools he attended as a youngster to provide students with a conducive learning environment. ✦

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DR. MICHAEL MARCARELLI

DID YOU KNOW?

Before joining the FDA, Dr. Michael Marcarelli worked as a U.S. Drug Enforcement Administration Narcotics Investigator.

Dr. Michael Marcarelli, Director of Division of Bioresearch Monitoring, FDA CDRH, is inspired by the unsung heroes who make subtle differences in how people live their lives each day.

QUALITY OVERSIGHT

OVER THE PAST 20 YEARS, MICHAEL MARCARELLI, PHARM.D., HAS MADE SIGNIFICANT CONTRIBUTIONS TO THE INNOVATION OF REGULATIONS AND MEDICINE.

As director in the division of bioresearch monitoring at the FDA, Dr. Marcarelli, who is also a United States Public Health Service Commissioned Corps Officer, oversees a department of 35 medical officers, scientists, and allied health professionals.

One of his many responsibilities is to oversee federally regulated nonclinical and clinical research to assure the protection of animal and human research subjects, to determine compliance with federal regulations and statutes governing such research, and assure the quality and integrity of clinical or non-clinical data submitted to the FDA in support of medical product development applications.

He and his staff plan, organize, develop, and direct operations that support the agency's statutory authority over nonclinical and clinical research, including the development, issuance, and assessment of approximately 350 on-site inspections, concentrating on human subject protection, compliance with federal regulations and policy, and research integrity issues.

One of his most significant achievements has been developing the concept of a quality system approach to the oversight of FDA-regulated clinical trials.

Dr. Marcarelli has developed new and cutting-edge programs to address such issues as electronic health records, in vitro diagnostics, bioethics, human subject protection, and good laboratory practices.

Dr. Marcarelli's pharmacy training and background demonstrates that the role of the traditional pharmacist can be expanded to permeate all areas of medicine, medical technology, and regulatory science.

Before joining the FDA, Dr. Marcarelli was a pharmacist with the DEA working as a clandestine laboratory expert.

Dr. Marcarelli also has worked on many high-priority projects together with other centers within the FDA to address important regulatory issues, such as combination products, human subject protections, good clinical practices, sponsor-investigators, sponsor-monitoring, and adverse event reporting.

He also helped create a sustainable internship program within CDRH and students from Johns Hopkins University's master of science program in bioscience regulatory affairs.

With greater globalization, Dr. Marcarelli says one of the biggest challenges for industry and regulators is adequately understanding and addressing the regulatory requirements from a multitude of countries.

A believer in the benefits of industry/agency collaboration, Dr. Marcarelli says one of the biggest joint achievements was the Critical Path Initiative and its attempt to translate new discoveries into marketable products that address unmet public health needs.

Though he regularly interacts with officials at many levels, he says the funniest occurrence in his career was meeting a high school friend whom he hadn't seen in 25 years across the table at an FDA regulatory meeting.

And if there's one thing life in government has taught him, it's discretion: when asked about his greatest professional challenge, he quips that he can't discuss it publicly. ✦

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Creative. Intuitive.

NAME: Michael Marcarelli, Pharm.D., M.S.

CURRENT POSITION: Director of Division of Bioresearch Monitoring, FDA CDRH

EDUCATION: Master of Science, Johns Hopkins University, Bioscience Regulatory Affairs, Baltimore; Doctor of Pharmacy, University of Arkansas for Medical Sciences, College of Pharmacy; B.S. Pharmacy, Northeastern University

DATE AND PLACE OF BIRTH: June 1955, Medford, Mass.

FIRST JOB: Cashier in neighborhood drug store

FIRST INDUSTRY-RELATED JOB: Retail pharmacist, Peoples Drug Stores

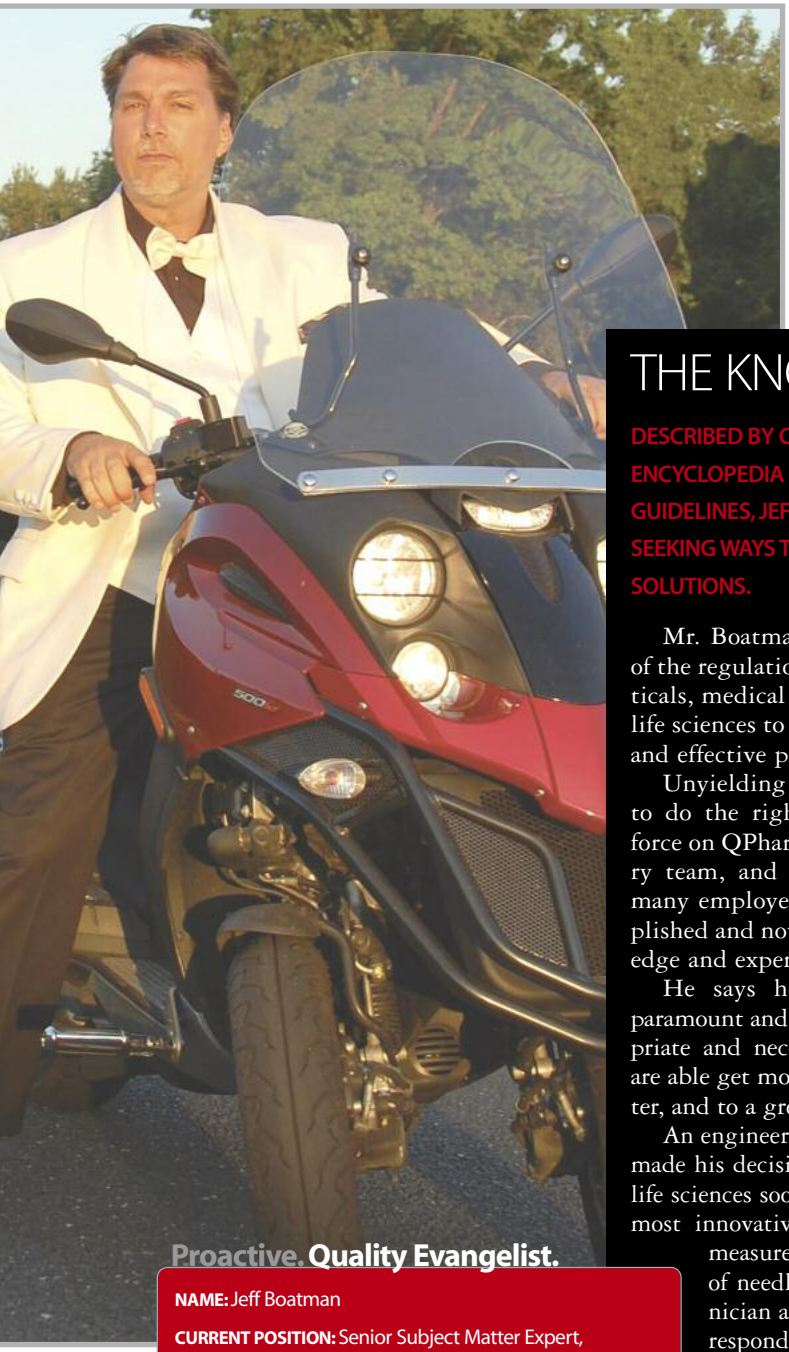
DREAM JOB: Professional golfer

PROFESSIONAL MENTORS: Tom Colonna and Hank Dausch

PROFESSIONAL ASSOCIATIONS: Regulatory Affairs Professional Society; Food, Drug, and Law Institute; Drug Information Association; Association of Clinical Research Professionals; Society of Clinical Research Professionals

CONNECTED VIA: Facebook, Twitter, and LinkedIn

WORDS TO LIVE BY: Life is too short



Jeff Boatman, Senior Subject Matter Expert at QPharma, doesn't merely follow quality practices; he preaches them at every opportunity because he wants others to benefit from his positive experiences.

DID YOU KNOW?

Jeff Boatman was the copilot of a plane that crashed.

JEFF **BOATMAN**

Proactive. Quality Evangelist.

NAME: Jeff Boatman

CURRENT POSITION: Senior Subject Matter Expert, QPharma Inc.

EDUCATION: Nuclear Physics, USAF Air University, 1981

DATE AND PLACE OF BIRTH: September 1959, Columbus, Ga.

FIRST JOB: Nuclear weapons specialist (a crash course in regulated industry, where the tolerance for lack of quality is essentially zero)

FIRST INDUSTRY-RELATED JOB: Manufacturing technician

DREAM JOB: Inventor

PROFESSIONAL MENTORS: Ellen Golds, Boston Scientific

PROFESSIONAL ASSOCIATIONS: American Society for Quality; International Society of Pharmaceutical Engineers

CONNECTED VIA: LinkedIn

THE KNOWLEDGE TREE

DESCRIBED BY COLLEAGUES AS A WALKING ENCYCLOPEDIA OF REGULATORY LAWS AND GUIDELINES, JEFF BOATMAN IS CONSTANTLY SEEKING WAYS TO DRIVE QUALITY SOLUTIONS.

Mr. Boatman uses his deep knowledge of the regulations surrounding pharmaceuticals, medical devices, and all of the other life sciences to ensure companies make safe and effective products.

Unyielding in his desire for companies to do the right thing, he is an integral force on QPharma's cutting-edge regulatory team, and he is an inspiration to its many employees and clients, both accomplished and novice, who rely on his knowledge and expertise.

He says he learned that quality is paramount and that by following the appropriate and necessary guidelines companies are able get more products out quicker, better, and to a greater financial benefit.

An engineer par excellence, Mr. Boatman made his decision to make his career in the life sciences soon after developing one of his most innovative inventions: a machine to measure peak insertion torque values of needle hubs. An entry-level technician at the time, Mr. Boatman was responding to a mysterious breakage problem that stalled an entire manufacturing line and was costing the organization millions of dollars in lost revenue. Top management had predicted it would take months to isolate and fix the problem. Then, over a weekend, and without direction or permission, Mr. Boatman came into the lab and made his device out of an old Chatillon instrument and some clamps that were sitting around the lab. By the time management returned to the office on the following Monday, Mr. Boatman had solved the problem.

Over his career, he has impressed many with his resourcefulness and adaptability. But his real breakthrough and success in the industry he traces to one professional mentor. He was brought to Boston Scientific under the radar former R&D Manager Ellen Golds. The company's budget didn't allow for another engineer, so he came on board as a technician. But Ms. Golds gave Mr. Boatman far broader responsibility than his title suggested and he wound up doing the job of an R&D engineer, a quality engineer, a production engineer, a draftsman, and a documentation specialist. Under any other boss, he says he would have hated the assignment because he was being asked to do more than his job; under Ms. Golds, he loved it because he was being allowed to do more than his job. Most importantly, when faced with his engineering recommendations on one hand and company politics on the other, she always backed Mr. Boatman. Since then, the two have collaborated on many other projects.

As a leader who cares about the staff he leads, Mr. Boatman says his toughest assignment to date was helping to validate — decommission — a facility that was slated for closure and relocation to another state. He was challenged with laying off the staff while having to maintain employees' cooperation during the transition, not an easy task, but one he did with compassion and empathy.

Mr. Boatman demonstrates daily that it's not just about getting the job done; it's about getting the job done effectively and efficiently and, most importantly, with the support and respect of colleagues.

Exhibiting characteristics such as determination, confidence, and resourcefulness, he is a leader who makes things happen and who understands the value of quality.

He preaches these virtues at every opportunity so others can benefit from his positive experiences. ✦

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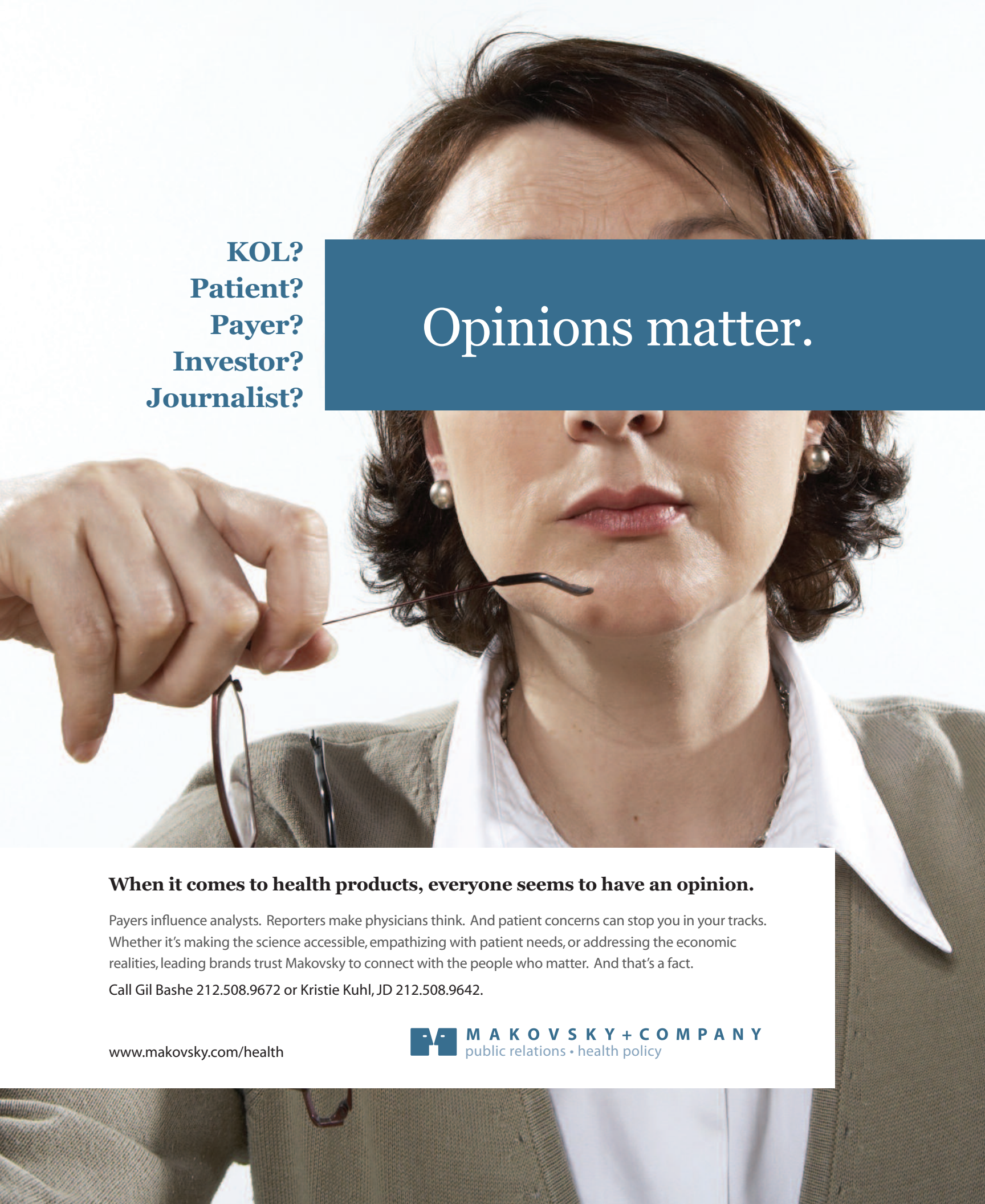

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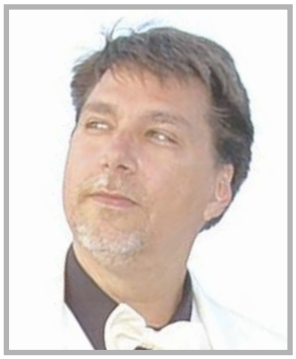


With an encyclopedic knowledge of all things related to regulations, whether it be FDA, ISO, etc., Jeff Boatman, senior subject matter expert at QPharma, is the go-to guy for his colleagues at his company as well as others. He doesn't need any resources; he is able to quote the exact regulation, including references.

Mr. Boatman uses his deep knowledge of the regulations to drive companies to make safe and effective products and is unyielding in his desire for companies to do the right thing.

Mr. Boatman takes regulatory issues and quality so seriously that he says the defining moment in the industry for him was when the Quality System Regulation became effective, concurrent with EN46001, the CE marking directives, and ISO 9001:1994. This occurred while at Becton Dickinson (BD), which was under the direction of then-CEO Ray Gilmartin, who decided that not only would the company comply with the new requirements, it would embrace them. Mr. Gilmartin's tough stance ran contrary to the prevailing attitude in the industry, which was that compliance was too costly, would slow things down and inhibit creativity, and was anathema to how things were traditionally done. Mr. Boatman says he learned two important lessons from his time at BD: first, this "quality nonsense" really does work, if it is embraced rather than treating the process as a distasteful obligation; and second, a focus on quality and embracing compliance standards provides a win for companies.

He does, nevertheless, have strong concerns for issues confronting the industry, particularly the strength of the FDA. Earlier in his career, he says the FDA padlocked doors when there was a violation. Gradually, the FDA —and numerous other federal agencies — fell into a pattern of political machinations instead of being first and foremost a bastion of scientific reasoning, and rapid, decisive actions to protect the public health took a back seat. He says while the FDA and Department of Justice (DOJ) are two agencies that have managed to obtain some of the biggest judgments in history, these are few and far between and frankly are the result of corporate smugness rather than effective regulatory actions.

He says even though FDA Commissioner Margaret Hamburg, M.D., and HHS Secretary Kathleen Sebelius have made some bold moves to strengthen the agency, the industry no longer believes that the FDA has any real teeth. He fears this may be true so long as warning letters for producing adulterated products continue to address violations with alerts such as: "please provide within two weeks your plan to stop poisoning people." As a result the industry is in a state of tremendous uncertainty as to just how far the FDA will really go.

When not pondering the best solutions for the industry, colleagues, and clients of QPharma, Mr. Boatman thinks about the larger problem facing the United States — the budget deficit. He says while most Americans either give it no thought or don't believe the United States could ever default on its debt, the situation does terrify him. While he is cautiously optimistic that it is unlikely, he has started investing a bit in gold. When he looks at the great looming crises — global environmental meltdowns, global energy meltdowns, and global financial meltdowns — he believes that the latter is the far more likely, if only because so few take it seriously. ✦

Getting Personal with JEFF BOATMAN

READING LIST: Personal — The Rise and Fall of the Third Reich; Business — Managing the Professional Service Firm

BUCKET LIST: Become a certified quality engineer

INSPIRATION: Music by Vivaldi, The Four Seasons

TOP IPOD DOWNLOADS: NPR broadcast — All Things Considered

LIFE LESSONS: Steer clear of the boss' daughter

UNDER THE COVER OF INVISIBILITY: Visit a board-certified anti-invisibility dermatologist

DR. MICHAEL MARCARELLI •

INTELLIGENT OVERSIGHT

Getting Personal with

DR. MICHAEL MARCARELLI

FAMILY: Wife and two college-age children

HOBBIES: Tennis, golf, and hiking

READING LIST: The Tipping Point and Blink by Malcolm Gladwell; Skipping Christmas by John Grisham

BUCKET LIST: Attend the four major tennis championships: Australian Open, Wimbledon, French Open, and U.S. Open

INSPIRATION: Unsung heroes

TOP IPOD DOWNLOADS: Nickelback songs

SCREENSAVER: A photo of the family pets

MOST UNUSUAL PLACE VISITED: A jail that was transformed into a restaurant/bar, with the former jail cells becoming treasured coves for couples who wanted a romantic dinner

A LITTLE KNOW FACT: Before joining the FDA, he worked as a U.S. Drug Enforcement Administration Narcotics Investigator

As director in the division of bioresearch monitoring at the FDA, and a commissioned officer in United States Public Health Service, Captain Michael Marcarelli, Pharm.D., has been enhancing the agency's intelligence, operations, and oversight.

Dr. Marcarelli, who oversees a department of 35 medical officers, scientists, and allied health professionals, has been instrumental in establishing and developing initiatives, policy, guidance, and regulatory interpretations to enhance the effectiveness of divisional operations and ensure consistency with agency policies and guidelines.

As a direct conduit to the FDA Commissioner and other high-level FDA managers, Dr. Marcarelli analyzes and provides recommendations on research compliance and oversight issues and consults on major areas of national or international uncertainty.

His broad expertise enables him to serve as a technical expert and develop strategies designed to facilitate collaborative relationships and partnerships to further agency intelligence, operations, and developmental efforts in federal research oversight.

As a respected thought leader, Dr. Marcarelli also interacts with officials within the agency and other agencies, as well as from foreign embassies, the private sector, and congressional staffs to resolve problems, gain consensus, and to analyze and review a broad range of issues.

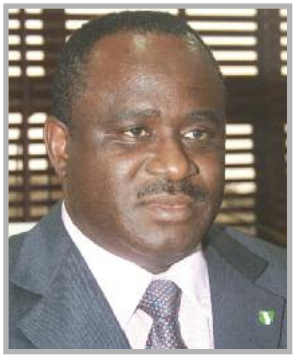
He also is a spokesperson for the FDA at professional, scientific, and industry meetings on research compliance or other public health issues, and he teaches FDA national training courses.

Dr. Marcarelli has been published in many peer-reviewed journals, such as RAPS Focus, and MDDI.

He has been with the FDA since 1987, joining the agency from the Department of Justice's Drug Enforcement Administration.

Next on Dr. Marcarelli's list is to go back to school; he wants to obtain a Ph.D. in regulatory affairs. ✦

DR. PAUL ORHII • MARK OF EXCELLENCE



From his research work to find a cure for prostate cancer and fetal alcohol syndrome to his campaign to eradicate counterfeit drugs from Nigeria and all of Africa, the success Paul Orhii, M.D., Ph.D., J.D., has achieved in helping the pharmaceutical and medical industries is undeniable.

A biomedical scientist for more than 11 years in Russia and the United States, a lawyer, as well as doctor of neuropharmacology, Dr. Orhii has a wealth of insight and experience.

He also has had vast exposure to divergent cultural, political, and economic systems of the world and a great capacity for languages, including Russian and Tiv, the language spoken by 6 million Nigerians. It is therefore not surprising that the Nigerian government looked to Dr. Orhii as director-general of the National Agency for Food and Drug Administration and Control (NAFDAC).

A stellar young student while attending the University of Jos in Nigeria, Dr. Orhii won a scholarship to study medicine in Russia. Immediately after finishing his medical degree, he was offered an opportunity to pursue a Ph.D. in medicine (neuropharmacology), making him the first foreigner to be sponsored by the school and to be awarded a teaching assistantship.

The work stemming from his Ph.D. program attracted international attention and he was soon invited to make presentations at prestigious international scientific meetings. His abstract won a travel award to the 3rd International Congress of Comparative Physiology and Biochemistry in Tokyo in 1991. He was also invited to continue his research work in many countries, including the United States, Israel, England, Japan, and Australia, but he opted to return to Nigeria, where he served in the National Youth Service Corps, teaching pharmacology to medical students at the department of pharmacology at the University of Jos. When Nigeria's universities were closed indefinitely during the 1992-1993 academic year, Dr. Orhii came to the United States, where he worked as a biomedical scientist with the University of Texas Health Science Center at San Antonio.

Dr. Orhii's research within the Department of Medicine, Division of Gastroenterology & Nutrition included studies into the neuroprotective role of brain astrocytes in fetal alcohol syndrome, oxidative stress, and neurodegenerative conditions. He also conducted clinical studies to determine the mechanisms underlying the toxic effects of ribavirin in chronic viral hepatitis C patients.

Dr. Orhii has been invited to speak in more than 20 countries, and his work has been widely recognized with 23 awards and notations in Nigeria and internationally. ✦

Getting Personal with

DR. PAUL ORHII

FAMILY: Wife, Eugenia; three sons and one daughter

READING LIST: Shakespeare

GIVING BACK: Educational Scholarships for Nigerian students; rehabilitation of primary and secondary schools (alma maters)

INSPIRATION: Kobe Bryant

MOST UNUSUAL PLACE VISITED: Johannesburg, South Africa

LIFE LESSONS: Go to school; education is key