BIOGRAPHICAL SKETCH

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NAME: Anthony R. Ball

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

POSITION TITLE: VP Clinical Research & Co-Founder, BioCellR8 LLC

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 *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Northeastern University, USA	B.Sc.	05/2004	Biology
Northeastern University, USA	Ph.D.	00/0000	Bacteriology
American College of Microbiology, USA	NRCM	12/2010	Pharmaceuticals & Medical Devices
George Washington University, USA	MSHS	05/2024	Regulatory Affairs & Leadership

A. Personal Statement

I am a microbiologist (20 years), serial entrepreneur (10 years), inventor of medical technology, and have led several research programs (N=4) and managed dozens of R&D/technical projects during my career (N > 70). I have specialized in alternative antimicrobial drug discovery with a focus on multidrug translocase inhibitors (i.e. multi-drug resistance, MDR) and anti-infective therapies then later expanding to photosensitization and medical devices. My research has involved high-throughput screening methodologies applied to diverse chemical compound libraries, innovative dual-agent drug design strategies, and the development of whole-animal models HTS using *Caenorhabditis elegans*. I have directed the operations of multiple microbiology and in vitro laboratories and overseen pivotal studies adhering to ISO and FDA regulatory standards (e.g. 21 CFR Part 58, 21 CFR Part 11, ISO/IEC 17025, and ISO 13485) including over 70 GLP/GMP validation studies for microbial preclinical safety and efficacy that supported FDA pre-IND/IDE & 510(k) enabling submissions of several Class II and Class III devices. I have also been a Subject Matter Expert (SME) to FDA study sections on behalf of medical device manufacturers. My research has been supported by competitive grants including NIHR21AI059483, NIH R44DK055891-06, NIH 1R43AI077174-01A2, NIH 2R01AI050875-09A1, and DOD W81XWH-16-C-0207. Additional awards have included the Massachusetts Technology Transfer Center Assessment Award 2006, the US Army 2019 xTechSearch Challenge (Proposal # 843116, 2019), and the Marie Skłodowska-Curie European Union Horizon Post-Doctoral Fellowship (H2020-MSCA-IF-2018). I have co-authored 12 peer-reviewed publications in small molecule antimicrobial discovery, natural product medicinal chemistry, photoinactivation, and microbial biofilms (citations: 1,637, i10-index 11 as of December 2024). I have participated in 10 invited presentations at international conferences and hold one utility patent (US20180369560A1) plus two additional patent applications (US20180093107A1, US20200398077A). I have helped to raise over $18 million USD in public and private capital over my career for research and small business innovation. I have a strong background in basic and applied microbiology, photobiology, medical devices, and system integration and possess expertise in quality management, regulatory affairs, small business management/operations, and leadership.

B. Positions, Scientific Appointments, and Honors

Positions and Employment

2004-2009 Research Volunteer, Massachusetts General Hospital, Wellman Center for Photobiology, Boston, MA
2005-2007 Graduate Student, Molecular Biology, Northeastern University, Boston, MA
2007-2007 Research Technician II, Harvard Medical School, Department of Medicine, Boston, MA
2007-2009 Senior Microbiologist, Innovative Chemical and Environmental Technologies Inc., Norwood, MA
2009-2010 Senior Microbiologist, Toxikon Corp. Bedford, MA
2010-2014 Study Director, Toxikon Corp. Bedford, MA
2014-2023 Founder & CEO Gliese 623B LLC, Worcester, MA
2015-2017 Principal Investigator, UV Light Care Inc. Boston, MA
2017-2018 Technical Program Manager, Remphos Technologies LLC, Middleton, MA
2018-2020 CSO & Contract Direct Contact, GAMA Therapeutics LLC, Pepperell, MA
2020-2022 CSO, GROW-RI LLC, Newport, RI
2024-Present VP Clinical Research, BioCellR8 LLC, Charlton, MA

Other Experience and Professional Memberships

2006- Member, American Society for Microbiology
2016- Member, Optica (formerly Optical Society of America)
2022- Member, Regulatory Affairs Professionals Society

Ad hoc Reviewer

2011-2014 Photochemistry and Photobiology
2022- Antimicrobials, Israel Science Foundation
2024- Academia Biology

Honors & Awards

2005 Teaching Assistant Award, Department of Biology, College of Arts and Sciences, Northeastern University; Microbiology for Health Sciences
2006 Research Assistant Award, NIH R21AI059483
2006 Most Cited Paper, Bioorganic & Medicinal Chemistry, 2006–2009 Award
2006 Massachusetts Technology Transfer Center Assessment Award
2006 Northeastern University, Travel Grant
2013-2014 Voting Member, Infusion Device Standards Committee, Association for the Advancement of Medical Instrumentation
2013-2016, ASM Speakers' Bureau, American Society for Microbiology
2016 Massachusetts Life Sciences Center, Student Internship Challenge Award
2017 US11071853B2, "System and method for sterilization using ultraviolet radiation", Inventor
2017 U.S. Army Medical Research Acquisition Activity (USAMRAA), Miniature, point-of-care device for establishing sterile connections in combat environments (Contract # W81XWH-18-C-0003)
2018 Marie Skłodowska-Curie European Union Horizon, Post-Doctoral Fellowship; Individual Fellowships (H2020-MSCA-IF-2018)
2019 Army XSearch, (Proposal # 843116)
2019 Semi-finalist to START MassVentures
2020 Finalist to WPI Venture Forum
2021 Women in Leadership, Entrepreneurship Award, GROW-RI
2022 Semi-finalist George Washington University Innovation Forum

C. Contributions to Science

1. My early research was in the area drug discovery under mentorship of Kim Lewis (Northeastern University), George Tegos & Michael Hamblin (Harvard-MGH/Wellman Center), Fred Ausubel (MGH), Norm Letvin (Harvard-Beth Israel Deaconess Medical Center) & others. Work involved antimicrobial potentiation by plant

metabolites [a], structure-activity relationships of MDR pump inhibitors [b], synthesis of functionalized MDR pump inhibitors [c], antimicrobial conjugates [d], and identification of novel antimicrobials using a live-animal infection model [e]. The aim of this work was to increase the density of chemical space for discovery and application of intelligent design for antimicrobial drugs. Taken together, these works provided insight into a possible means of rescuing old, failing, or weakly active antimicrobials (1,000-fold activity increase of the Berberine conjugate), and also that traditional *in vitro* HTS misses approximately 2/3rds of potential hits compared to the live HTS animal model.

a. Belofsky G, Carreno R, Lewis K, Ball A, Casadei G, Tegos GP. Metabolites of the “Smoke Tree”, Dalea spinosa , Potentiate Antibiotic Activity against Multidrug-Resistant Staphylococcus aureus. J Nat Prod. 2006 Feb 1;69(2):261–264. PMID: 16499327
b. Ambrus JI, Kelso MJ, Bremner JB, Ball AR, Casadei G, Lewis K. Structure–activity relationships of 2-aryl-1H-indole inhibitors of the NorA efflux pump in Staphylococcus aureus. Bioorganic & Medicinal Chemistry Letters. 2008 Aug;18(15):4294–4297. PMID: 18632270
c. Samosorn S, Bremner JB, Ball A, Lewis K. Synthesis of functionalized 2-aryl-5-nitro-1H-indoles and their activity as bacterial NorA efflux pump inhibitors. Bioorg Med Chem. 2006 Feb 1;14(3):857–865. PMID: 16203150d.
d. Ball AR, Casadei G, Samosorn S, Bremner JB, Ausubel FM, Moy TI, Lewis K. Conjugating berberine to a multidrug efflux pump inhibitor creates an effective antimicrobial. ACS Chem Biol. 2006 Oct 24;1(9):594–600. PMID: 17168555
e. Moy TI, Ball AR, Anklesaria Z, Casadei G, Lewis K, Ausubel FM. Identification of novel antimicrobials using a live-animal infection model. Proc Natl Acad Sci USA. 2006 Jul 5;103(27):10414–10419. PMID: 16801562

2. Following exploration of concepts in rational antimicrobial design, focus was then directed to applied research exploring novel strategies for circumventing antimicrobial resistance. Much of this work, which was privately funded, remains unpublished – to be reported later, but the concepts in general have been discussed in book chapter [a], and elsewhere [b,c,d]. Some of the work such as continuous biofilm disruption and total infection control systems was supported by the NIH [e f]. Primarily the work focused on several types of drug delivery systems and chelators; we coined the term “stealth antimicrobials” and “trojan horse antimicrobials” such as a pseudomonad-derived pyridine-2,6-dithiocarboxylic acid (PDTC) complexed with antimicrobial silver directed against ESKAPE pathogens and hydrolytic lysins (provided by Vincent Fischetti, Rockefeller University) incorporated into Levan and directed against Streptococci. Other areas of research included decontaminating surfaces, chembio protection, antimicrobial (and antimicrobial peptide) impregnated medical devices such as foley catheters, and an siRNA delivery system using a Levan nanoparticle vehicle. Additionally, I began actively exploring light-based drugs (photosensitizers) and inhibition of their efflux from the bacterial cell. Photosensitizers producing intracellular reactive oxygen species for microbial death were explored. A collaboration led to a review article motivated by the elegant complexity of biofilms’ role in infectious diseases and the limitations in their efficacious study through assays and devices application [d].

a. Ball AR, Tegos GP. Emerging antimicrobial drug-discovery strategies: an evolving necessity. In: Tegos A, Mylonakis E, editors. Antimicrobial drug discovery: emerging strategies [Internet]. Wallingford: CABI; 2012 [cited 2024 Dec 9]. p. 7–25. Available from: http://www.cabi.org/cabebooks/ebook/20123306541
b. Vera DMA, Haynes MH, Ball AR, Dai T, Astrakas C, Kelso MJ, Hamblin MR, Tegos GP. Strategies to Potentiate Antimicrobial Photoinactivation by Overcoming Resistant Phenotypes†. Photochemistry and Photobiology. 2012 May;88(3):499–511. PMID: 22242675
c. Kourtesi C, Ball AR, Huang YY, Jachak SM, Vera DMA, Khondkar P, Gibbons S, Hamblin MR, Tegos GP. Microbial Efflux Systems and Inhibitors: Approaches to Drug Discovery and the Challenge of Clinical Implementation. TOMICROJ. 2013 Mar 22;7(1):34–52. PMID: 23569468
d. Magana M, Sereti C, Ioannidis A, Mitchell CA, Ball AR, Magiorkinis E, Chatzipanagiotou S, Hamblin MR, Hadjifrangiskou M, Tegos GP. Options and Limitations in Clinical Investigation of Bacterial Biofilms. Clin Microbiol Rev. 2018 Jul;31(3):e00084-16. PMID: 29618576
e. Sarangapani S. Continuous Biofilm Disrupting Materials | SBIR.gov [Internet]. SBIR-STTR Fund. 2009 [cited 2024 Dec 9]. Available from: https://legacy.www.sbir.gov/sbirsearch/detail/194674
f. Sarangapani S. A Total Infection Control Foley Catheter System | SBIR.gov [Internet]. SBIR-STTR Fund. 2006 [cited 2024 Dec 19]. Available from: https://legacy.www.sbir.gov/sbirsearch/detail/1070169

3. Concurrently to the work reported above, I focused on mastering techniques for regulatory approval of medical devices in the area of microbiology. This work supported over 70 device clearance market approvals at the FDA (examples [a,b,c,d,& e]) and the development and validation of new methodologies for the safety evaluation of medical devices [f,g]. Meanwhile research continued with conjugated photosensitizers and the photochemical/photophysical and *in vitro* microbiological evaluation of various conjugated antimicrobial dyes to EPIs and was reported. The major facilitator translocase NorA that confers modest drug resistance to cationic amphipathic antimicrobials and fluoroquinolones was targeted with INF55-(Ac)en–Methylene Blue conjugates [h] and also evaluated against *Escherichia coli* and *Acinetobacter baumannii* [i]. From 2015 to 2021 I functioned as principal investigator directing the research efforts at a BSL-2 laboratory, rapid prototyping and electrical engineering workshop, occupying research space at UMass Lowell-Massachusetts Medical Device Development Center (M2D2), Mansfield Bio-Incubator, and Massachusetts Biomedical Initiative. The efficacy of light to directly overcome multidrug resistance was also studied resulting in the proof-of-concept demonstration that ultraviolet light dose regiments irreversibly collapse antibiotic resistance in MRSA and disrupt synthesis of Staphyloxanthin, a virulence factor required for host survival [j]. The first 3 years of operations were funded by private capital followed by an SBIR contract for the Army Futures Command, where we ultimately produced an ultraviolet germicidal inactivating, self-sterilizing, anti-shadowing, re-usable, handheld, and battery-powered medical device to be used by first responders on the battlefield[k,l]. Related, another light-emitting device was developed with the dual purpose of mediating wound healing and inactivation of wound bed microbes[m]. This concept was showcased at MassMedic Medtech (2016) and Army XTechSearch Challenge (2019); however, the patent applications were abandoned due to disruptions caused by the COVID-19 pandemic. These works lead to the formation of several medtech companies (Gliese 623B LLC, UV Light Care Incorporated, and GAMA Therapeutics).

a. ARROW INTERNATIONAL, INC. 510(k) Premarket Notification, 510(k) Number: K071538, Device Name: ARROW, ARROWG+ARD AND ARROWG+ARD BLUE PLUS PRESSURE INJECTABLE CENTRAL VENOUS CATHETER [Internet]. FDA, 510(k) Premarket Notification Database. 2007 [cited 2024 Dec 19]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K071538
b. CARTICEPT MEDICAL INC. 510(k) Premarket Notification, 510(k) Number: K101194, Device Name: NAVIGATOR DELIVERY SYSTEM (OR NAVIGATOR DS) MODEL: NAV-010 [Internet]. FDA, 510(k) Premarket Notification Database. 2011 [cited 2024 Dec 19]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K101194
c. ARROW INTERNATIONAL(SUBSIDIARY OF TELEFLEX INC.). 510(k) Premarket Notification, 510(k) Number: K112896, Device Name: ARRW EVOLUTION [Internet]. FDA, 510(k) Premarket Notification Database. 2012 [cited 2024 Dec 19]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=k112896
d. OSPREY MEDICAL, INC. 510(k) Premarket Notification, 510(k) Number: K131478, Device Name: CONTRAST CONSERVATION SYSTEM [Internet]. FDA, 510(k) Premarket Notification Database. 2013 [cited 2024 Dec 19]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K131478
e. NP MEDICAL, INC. 510(k) Premarket Notification, 510(k) Number: K130023, Device Name: K100 NEUTRAL DISPLACEMENT NEEDLE FREE CONNECTOR [Internet]. FDA, 510(k) Premarket Notification Database. 2013 [cited 2024 Dec 19]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K130023
f. Ball A, Brady M, Desai L. A Simple Solution for Medical Device Viral Ingress Testing of Human Immuno Virus and Hepatitis B Virus. Parenteral Drug Association. Bethesda, MD; 2014.
g. Association for the Advancement of Medical Instrumentation. Medical Device Safety Assurance Case Report Guidance TIR38. Arlington, VA; 2015
h. Rineh A, Dolla NK, Ball AR, Magana M, Bremner JB, Hamblin MR, Tegos GP, Kelso MJ. Attaching the NorA Efflux Pump Inhibitor INF55 to Methylene Blue Enhances Antimicrobial Photodynamic Inactivation of Methicillin-Resistant Staphylococcus aureus in Vitro and in Vivo. ACS Infect Dis. 2017 Oct 13;3(10):756–766. PMID: 28799332
i. Rineh A, Bremner JB, Hamblin MR, Ball AR, Tegos GP, Kelso MJ. Attaching NorA efflux pump inhibitors to methylene blue enhances antimicrobial photodynamic inactivation of Escherichia coli and Acinetobacter baumannii in vitro and in vivo. Bioorganic & Medicinal Chemistry Letters. 2018 Sep;28(16):2736–2740. PMID: 29519734

j. Ball A. System to eradicate disease-causing germs and produce avirulent phenotype survivors susceptible to microbiocides using a light dose regiment [Internet]. WO2020257564A1, 2020 [cited 2023 Aug 2]. Available from: https://patents.google.com/patent/WO2020257564A1/en?oq=WO2020257564A1
k. Ball A, Gershaw D. Miniature, point-of-care device for establishing sterile connections in combat environments. Research Gateway Park, Worcester MA: Gama Therapeutics LLC; 2021 Mar p. 340. Report No.: Contract W81XWH-18-C-0003.
l. Jose Salinas. Miniature, point-of-care device for establishing sterile connections in combat environments. | SBIR.gov [Internet]. SBIR-STTR Fund. 2016 [cited 2023 Aug 2]. Available from: https://www.sbir.gov/node/870647
m. Ball A. System and Method For Healing and/or Disinfecting Wounds and Burns [Internet]. US20180093107A1, 2018 [cited 2021 Oct 10]. Available from: https://patents.google.com/patent/US20180093107A1/en?q=623B+LLC&assignee=Gliese+623B%2c+LLC

4. During the COVID-19 pandemic I was unable to continue raising funds to maintain laboratory operations and ceased research efforts to await more favorable times. I pivoted into less regulated industries seeking to commercialize applications utilizing photobiology. This led to the formation of GROW-RI LLC (products sold by OEE Datawatch[a]) and BioCellR8. GROW-RI LLC offered affordable system integration and automation services to small business farmers and food growers[b]. Several projects were undertaken and resulted in the creation of UVGI equipment for sanitization of poultry eggs, autonomous detection and retrieval of chicken carcass, image analysis and identification of leaf blight, computer controlled and mechanical positioning for the delivery of multi-wavelength grow lighting to promote desirable qualities such as coloration, flavor profile, flowering, growth, and shelf-life. We also conducted research in the utilization of control systems for delivery of virucidal ozone into offices and movie studies (unoccupied) for COVID-19 prevention and sanitation. With the pandemic over, BioCellR8 LLC, which enacted its operating agreement in August 2024, has been formed to promote translational sciences, incubating novel technologies and accelerating clinical research for commercialization of new antimicrobials. During this time, I completed a MSHS in Regulatory Affairs and Leadership which has equipped me with the ability to more effectively parlay with regulators, manage regulatory filings (global), and provide recommendations on clinical protocol design under the presumption that once research efforts renew I will be best positioned to translate research into clinical application.

a. Rajotte B. Vertical Farming Automation Kioks [Internet]. OEE DataWatch. 2024 [cited 2024 Dec 19]. Available from: https://oeedatawatch.com/vertical-farming-automation/
b. Rebekka Boekhout. Providing low-cost, high-functionality automation systems [Internet]. Verticalfarmdaily.com. 2021 [cited 2023 Aug 2]. Available from: https://www.verticalfarmdaily.com/article/9351911/providing-low-cost-high-functionality-automation-systems/

Complete List of Published Work:

https://scholar.google.com/citations?hl=en&user=4ksbbpAAAAAJ&view_op=list_works

D. Research Support

none