

2nd International Conference on

CELL AND GENE THERAPY

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2nd World Congress on

PUBLIC HEALTH, EPIDEMIOLOGY AND NUTRITION

April 15-16, 2019 | Milan, Italy

CELL AND GENE THERAPY 2019 & PUBLIC HEALTH CONGRESS 2019







KEYNOTE FORUM DAY 1

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Bahr BA, Arch Gen Intern Med 2019, Volume 3 DOI: 10.4066/2591-7951-C2-025



Bahr BA University of North Carolina, USA

BIOGRAPHY

Bahr BA completed his PhD in 1989 from the University of California–Santa Barbara, USA, helping to identify a target for the early diagnosis of Alzheimer's disease. He was appointed as the William C Friday Chair and distinguished Professor at University of North Carolina-Pembroke, USA in 2009. He has over 140 publications with a publication H-index of 44. He received the North Carolina Governor O Max Gardner Award in 2017.

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PLANT EXTRACTS AMPLIFY A PROTEIN CLEARANCE PATHWAY AND PRESERVE SYNAPTIC INTEGRITY IN A BRAIN SLICE MODEL OF PROTEIN ACCUMULATION STRESS

Brain aging can slowly lead to synaptic and cellular vulnerabilities, in-fluencing cognitive function and dementia risks. Removal of old and altered proteins becomes less efficient with age, causing neuronal stress as protein clearance systems depreciate. A growing number of studies point to natural products and a healthy diet to avoid poor cognitive aging. Here, we examined a group of plant extracts for their effects on a protein clearance pathway that has been linked to protection against Alzheimer-type cognitive decline. When applied to hippocampal slice cultures for 3 days, two of the extracts were found to markedly enhance cathepsin B (CatB), a key protein clearing enzyme of the autophagy-lysosomal pathway. American ginseng (P. guinguefolius) produced a 4-fold increase in the 30-kDa active form of CatB (CatB-30). Interestingly, a close correspondence between CatB-30 levels and improved levels of the postsynaptic protein GluR1 was found in brain slices treated with American ginseng. Extracts of bacopa (B. monnieri) caused similar CatB-30 modulation in the tissue slices, but in the absence of correlated GluR1 levels. Small increases in CatB-30 were produced by extracts from Panax ginseng and wild blueberry (V. myrtillus). When extracts were tested for protection in a brain slice model of protein accumulation stress, American ginseng was found to be the most effective. The extract significantly protected synap-





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tic integrity in chloroquine-treated slice cultures, chloroquine being a well-known lysosomal disruptor used to model age-related compromise of the autophagy- lysosomal pathway and producing the typical synaptic decline associated with such stress. These results indicate that natural products can positively influence a protein clearance pathway in the brain to promote synaptic maintenance. The findings suggest that CatB positive modulation leads to enhanced synaptic health, indicating a natural preventative strategy to attenuate early proteinopathy and reduce the risk of age-related cognitive impairment.







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Theresa A Deisher, Arch Gen Intern Med 2019, Volume 3 DOI: 10.4066/2591-7951-C2-025

Theresa A Deisher

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BIOGRAPHY

Theresa A Deisher obtained her PhD in Molecular and Cellular Physiology from Stanford University School of Medicine, USA. She is an expert in adult stem cell research and she is the first person to discover adult pluripotent stem cells. She is an inventor of over 35 issued US/Japan patents, whose discoveries have led to clinical trials of fibroblast growth factor 18 for osteoarthritis and cartilage repair and for Factor XIII for surgical bleeding. Prior to founding AVM Biotechnology, she worked at leading biotechnology companies including Genentech, Repligen, ZymoGenetics, Immunex and Amgen as their principal scientist and R&D Vice President. She had an extensive scientific and management experience in the commercial biotechnology field. She is a frequent lecturer on stem cell issues and an active member of ASH (The American Society of Hematology) and ASCO (American Society of Clinical Oncology).

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A NOVEL LYMPHOABLATION PRECONDITIONING AGENT (AVM0703) VIA RECEPTOR MEDIATED INDUCTION OF APOPTOSIS TO REDUCE PATIENT TOXICITIES PRIOR TO CART THERAPY OR STEM CELL TRANSPLANTS TO REDUCE TOXICITIES AND IMPROVE PATIENT SAFETY

hemotherapy preconditioning prior to CART cells has been strong-Iv associated with CRS, neurotoxicity, patient death and in some instances, has led to clinical trials being put on hold. There is an urgent need to develop a non-toxic and safe agent that lympho-ablates similar to chemotherapy. AVM0703 lympho-ablates both T and B lymphocytes for 'immune reset' via receptor mediated induction of caspase dependent apoptosis, sparing neutrophils, platelets, RBCs and stem cells. AVM0703 preconditioning will expand the number of patients eligible for CART therapy to include those too frail to tolerate chemotherapy preconditioning and will reduce the toxicities both medical and financial of chemotherapy or biologics based lymphoablation. HSC based gene therapy holds promise as a cure for many inherited primary immune deficiencies such as sickle cell disease, cerebral adrenoleukodystrophy, cystinosis, epidermolysis bullosa, hemophilia, enzyme replacements disorders, cystic fibrosis and muscular dystrophies. The toxicities of required chemotherapy preconditioning limit the number of people who choose HSCGT. A rela-





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tively non-toxic lymphoablating small molecule such as AVM0703 will expand the opportunity for HSCGT. Spontaneous lymphocyte recovery is observed within 14 days. AVM0703 enhances the efficacy of autologous concentrated intra-articular bone marrow injections to treat knee arthritis, accelerates G-CSF-mediated mobilization of HSC into peripheral blood and dramatically enhances CART efficacy against melanoma. AVM0703 is being developed as a replacement for chemotherapy preconditioning (PC) required before allogeneic stem cell transplant (allo Tx), Autologous Hematopoietic Stem Cell Based Gene Therapy (AHSCGT) or Adoptive Cell Therapy (ACT). AVM0703 is being developed as a stand-alone treatment for direct apoptotic killing of relapsed/refractory lymphocytic leukemia, lymphoma and multiple myeloma and for residual HIV and steroid-resistant GvHD.







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Bryan Poltilove, Arch Gen Intern Med 2019, Volume 3 DOI: 10.4066/2591-7951-C2-025



Bryan Poltilove

Thermo Fisher Scientific, USA

BIOGRAPHY

Bryan Poltilove is general manager of cell and gene therapy, he has overall P&L responsibility for the Thermo Fisher business segment, including long-range product line strategy, investment and day-to-day business operations. Previously, he led a \$350M business segment of cell biology reagents and instrumentation. Prior to joining Thermo Fisher, he served as the Director of Revenue Strategy and Operations for the Corporate Executive Board and held several roles with Johnson & Johnson. He holds Bachelor degrees in Chemical Engineering and Economics from MIT and an MBA from Northwestern University, USA.

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TECHNOLOGY TRENDS IN THE DEVELOPMENT AND COMMERCIAL-SCALE MANUFACTURING OF CELL AND GENE THERAPIES

The cell and gene therapy industry has now exceeded 1000 clinical trials and annual global financing increased 40% YOY to over \$10B (ARM 2018 Q3 Report). As the industry continues its monumental expansion, developers much find new methods to scale their supply chains to control costs, speed and reproducibility. Meanwhile new regulations and standards are increasing pressure for more controlled processes, validation and risk mitigation. Raw material documentation, supply chain redundancy and closed manufacturing systems are key aspects to enabling the next wave of therapies. This talk will showcase some of the latest trends in the industry, emerging technologies and best practices that start early in development to enable robust, sustainable operations and commercial success.







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Claudio Giuliano, Arch Gen Intern Med 2019, Volume 3 DOI: 10.4066/2591-7951-C2-025



Claudio Giuliano

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BIOGRAPHY

Claudio Giuliano is a player in the venture capital industry since the year 2000. He is the co-founder of Innogest Capital, a venture capital firm with about €200 mln under management and is a partner in the Healthcare and Cardiovascular practice at Innogest in 2007. He served as Chairman of the VC committee at the Italian VC and PE Association (AIFI) and is part of several private and public bodies involved in start-up and entrepreneurship development. Prior to Innogest, he was an Associate Director at The Carlyle Group, London; Strategy consultant at Bain & Co, Italy and Supply chain manager at Hewlett-Packard California and France. He holds a Summa cum Laude Master of Science in Electronic Engineering from Politecnico di Torino, Italy, a Summa cum Laude Diplôme d'études approfondies in Microelectronics from l'Institute Nationale Polytecnique in Grenoble, France and an MBA from INSEAD (Dean's List), in Fontainebleau, France.

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CELL AND GENE THERAPY: NOW IS THE BEST TIME TO INVEST

n the recent years author have seen the re-born of cell and gene therapy approaches; the field has made very important steps toward a concrete clinical application and this has translated in a gained interest from investors and big corporate. 2017 FDA approval of YESCARTA, the CART technology form Kite Pharma, is only one of the successful stories, accounting 72% of positive responders after one single administration. This also translated in \$11.9B acquisition from Gilead. Unfortunately, the successful clinical translation of cell and gene therapy is linked to a number of challenges they just now started to see (i.e. clinical validation, scalability and pricing); to face these challenges they need great science to meet the mind-full entrepreneurs. This is exactly what they do as venture capitalists: they help to create value from ideas. They support the team towards the important milestones of their product's validation and they guide them to the market. They do not provide financial support only but also they provide a team of experts and KOLs that can support the company in the identification of the best and shortest strategy to reach the patients.







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Pierre A Morgon, Arch Gen Intern Med 2019, Volume 3 DOI: 10.4066/2591-7951-C2-025

Pierre A Morgon

MRGN Advisors, Switzerland



BIOGRAPHY

Pierre A Morgon is Chief Executive Officer of MRGN Advisors, a consultancy advising CEOs and investors in the healthcare sector and regional partner for Switzerland at Merieux development and an evergreen investment fund. He is a lecturer in several MBA programs in world-class business schools and in life science conferences and at the mass challenge incubator in Switzerland where he mentors start-up life sciences companies. He is also holding the following board positions: Chairman of the board of Virometix; Non-Executive; Director to the Board of Theradiag; Non-Executive Director to the Board of Eurocine Vaccines; Non-Executive Director to the Board of Vaccitech; Non-Executive Director to the Board of Univercells. He holds a Doctorate of Pharmacy, Master's in Business Law and an MBA Degree.

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SUCCESSFULLY ACTIVATING POSITIVE BEHAVIORS OF THE STAKEHOLDERS INVOLVED IN VACCINE PURCHASING AND USAGE THROUGH TECHNOLOGICAL ADVANCES

he vaccine segment is anticipated to be one of the fastest growing, one of the healthcare industry and several leading firms have stepped up vaccine investments in recent years. Unlike therapeutic agents, vaccines are administered to healthy individuals only once or very infrequently during a life time. Vaccines generate well-documented positive externalities, yet their poor awareness and acceptability among vaccine end-users may contribute to resurgence of transmissible diseases and consequently trigger governmental interventions such as mandating vaccination. In addition to technical and clinical development per the highest guality standards, bringing new vaccines to market requires carefully orchestrated programs targeting the multiple types of stakeholders along the entire value chain and addressing their respective purchasing behavioral drivers. Against a backdrop of anti-vaccination buzz and vaccine fatigue, successful global launch and sustainable usage of a vaccine requires the development of a multi-pronged strategy addressing all aspects in relation to acceptability (e.g. the motivation to immunize despite the guasi-disappearance of the disease), accessibility (e.g. supply chain services), availability (e.g. mechanisms ensuring reliability of supply) and affordability (e.g. tiered pricing policy taking country differences in per capita income into account). Leveraging novel technological advances can positively influence the ability to activate these levers successfully.

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Alfiia I Aminova, Arch Gen Intern Med 2019, Volume 3 DOI: 10.4066/2591-7951-C2-025

Alfiia I Aminova

Sechenov First Moscow State Medical University, Russia



BIOGRAPHY

Alfiia I Aminova is a Paediatric faculty from Sechenov First Moscow State Medical University, Russia.

She is the Head of the clinic Federal Research Center for Medico-Prophylactic Technologies for Health Risk Management during 2009-2013. She is working as a Lecturer at two different Universities. Her highest qualification is in Paediatrics and Gastroenterology. Her area of scientific interests is children's gastroenterology, ecology, sports medicine and rehabilitation. She has more than 300 publications, including 127 in peer-reviewed journals and she is the author of seven inventions, two monographs and more than 30 manuals for doctors.

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MONOHYDRIC PHENOL IMPACT ON THE STATE OF CEREBRAL BLOOD FLOW AND COGNITIVE FUNCTIONS OF CHILDREN

Introduction: It is known that among the factors which induce the development of cerebrovascular disorders are hypoxia and the impact of toxic substances on the central nervous system, phenol and its derivatives (cresols) belong to the group of highly hazardous substances (category 2). The main sources of anthropogenic phenols are chemicals such as coke and petro-chemicals, textiles, pulp and paper industry. Phenols and cresols are able to accumulate in the brain parenchyma. This may lead to the development of cerebrovascular disorders. The objective of this study is to evaluate the patterns of cerebral haemodynamics and cognitive function impairments for children with vegetovascular dystonia associated with exposure of monohydric phenols.

Conclusions: Thus, dysfunction associated with aerogenic phenol and cresol influence is characterized the linear velocity of the blood flow in the cerebral arteries, a low level of audio-verbal memory, the overall mental development and a high degree of anxiety are the effect markers of conditions of phenol and cresol influence. Identified patterns of cognitive, behavioural status and cerebral haemodynamics are recorded on the background of marker deviations of homeostatic parameters concerning phenol in children in the form of increased level of regulatory hormones and cholinergic neurotransmitters (adrenocorticotropic hormone, cortisol, serotonin and cGMP), increased lipid peroxidation products, activation and consequent depletion of antioxidant blood activity and an increase of MDA concentration. Submitted patterns of cerebral blood flow and cognitive and behavioural functions can be used as an additional criterion of dysfunctions of the central humoral- metabolic mechanisms in children with influence of monohydric phenols.





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Gerald C Hsu, Arch Gen Intern Med 2019, Volume 3 DOI: 10.4066/2591-7951-C2-025



Gerald C Hsu EclaireMD Foundation, USA

BIOGRAPHY

Gerald C Hsu received an honorable PhD in Mathematics and majored in Engineering at MIT. He attended different universities over 17 years and studied seven academic disciplines. He has spent 20,000 hours in T2D research. First, he studied six metabolic diseases and food nutrition during 2010-2013, then conducted research during 2014-2018. His approach is "math-physics and quantitative medicine" based on mathematics, physics, engineering modelling, signal processing, computer science, big data analytics, statistics, machine learning and AI. His main focus is on preventive medicine using prediction tools. He believes that the better the prediction, the more control you have.

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FROM PUBLIC HEALTH POINT OF VIEW TO INVESTIGATE THE CONTROL OF OBESITY, DIABETES, AND CARDIOVASCULAR RISK VIA NUTRITION AND EXERCISE

Introduction: Public health data shows that, in 2017, USA had two million deaths which diabetes, heart diseases, stroke and nephrosis occupied 45% (~907,000). Furthermore, >85% of T2D patients are overweight and >50% are obese.

Methods: The author spent 20,000 hours during the past 8.5 years, using math-physical medicine to conduct his research. He has collected and processed ~1.5 million data, including 300,000 medical conditions and 1.2 million lifestyle details. He then utilized advanced mathematics, optical physics, signal processing, energy and wave theories, statistics, big data analytics, machine learning and artificial intelligence to develop five prediction models, including weight, FPG, PPG, adjusted glucose and HbA1C.

Results: His clinical case studies have offered the following results: BMI reduction from 32 (obese), to 24.7 (normal); FPG reduction from ~200 mg/dL to ~105 mg/dL; PPG from 279 mg/dL to 119 mg/dL; Daily averaged glucose from >250 mg/dL to ~116 mg/dL; HbA1C from 10% to <6.5%; Risk reduction of having cardiovascular diseases and stroke from 70-90% prior to 2010 (suffered 5 heart attacks) to 26.4% in 2017; Averaged carbs/ sugar intake amounts (38% contribution on PPG) are 14.5 gram/meal and

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~60 grams/day (low carb diet). Exercise amounts (41% contribution on PPG) are 4,300 steps/meal and 18,000 steps/day.

Conclusion: His methodology and prediction models (>99% accuracy) are proven to be effective tools on controlling T2D. His flow diagram can also provide an effective guidance to patients to control and improve their conditions on obesity, diabetes and heart problems. These technology-based prediction and prevention models could be used as educational tools to diabetes patients through public-health channels and programs.







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Trevor Clark, Arch Gen Intern Med 2019, Volume 3 DOI: 10.4066/2591-7951-C2-025



Trevor Clark

Massey University, New Zealand

BIOGRAPHY

Trevor Clark is a proud Kiwi (New Zealander), currently based in Sydney Olympic Park at the Australian College of Physical Education where he is Head of Department, Sport Performance and Sport Business. He oversees bachelor degree programs in coaching (strength and conditioning) and (management) and one each in applied fitness and business leadership. He also manages a post graduate diploma in sports administration. He maintains strong affiliations with his industry and holds elite level accreditations with the Australian Strength and Conditioning Association and Exercise and Sport Science Australia. However his passion still revolves around rugby league which has a very strong presence in Sydnev and Australia.

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SPORTS RELATED CONCUSSION

ccelerometer devices will quantify the magnitude of head impacts throughout sport to determine potential for brain injury. There aren't any printed head impact knowledge for rugger league. The main objective of this study was to quantify head impacts for amateur senior rugby league players to ascertain potential for brain injury. Data on head impact magnitude, frequency and distribution were collected with instrumented behind-the-ear XPatches (accelerometers) worn by 42 premier senior amateur rugby league players participating in 2014 and 2015 domestic seasons of matches. During the study there have been twenty,837 impacts >10g recorded. The mean number of impacts per player over the season was 672±237 resulting in 52±79 impacts to the head per player, per match. Players recorded a median [IQR] linear (14 [10 to 23] g) and rotational (3,181 [1830 to 5,612] rad/s2) accelerations over the study. Over the study there have been 103 impacts (0.5%) for linear acceleration and four, 505 impacts (22%) for movement acceleration, on top of antecedently printed linear and movement injury tolerance thresholds. The median peak linear acceleration of 14g was lower, while the median rotational acceleration of 3,181 rad/s2 was higher than the medians reported in American high school football, collegiate football and youth ice hockey. The potential for brain injury in rugby league players as indicated by head impact acceleration is likely similar to American football and rugby union. Given world-wide growth of rugby codes, sports clinicians need to be aware of the potential for head injury and likely concussion prevention and management options.

