

**POLYMERIC NANOPARTICLES ENABLE  
SYSTEMIC DELIVERY OF A HIGHLY POTENT STING  
AGONIST FOR TUMOR REMEDIATION**

# BIOMATERIALS FORUM!

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

SECOND QUARTER 2023 • VOLUME 45, ISSUE 2

**ALSO INSIDE**

LETTER FROM NEW PRESIDENT WILLIAM WAGNER



# BIOMATERIALS FORUM



The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 44, Issue 2

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<b>Surface Characterization &amp; Modifications</b>	TBD
<b>Tissue Engineering</b>	Jessica M. Gluck • <a href="mailto:jmgluck@ncsu.edu">jmgluck@ncsu.edu</a>

If interested in filling a vacancy above, please reach out to your SIG Chair. Contact information can be found on individual SIG pages as found [here](#).

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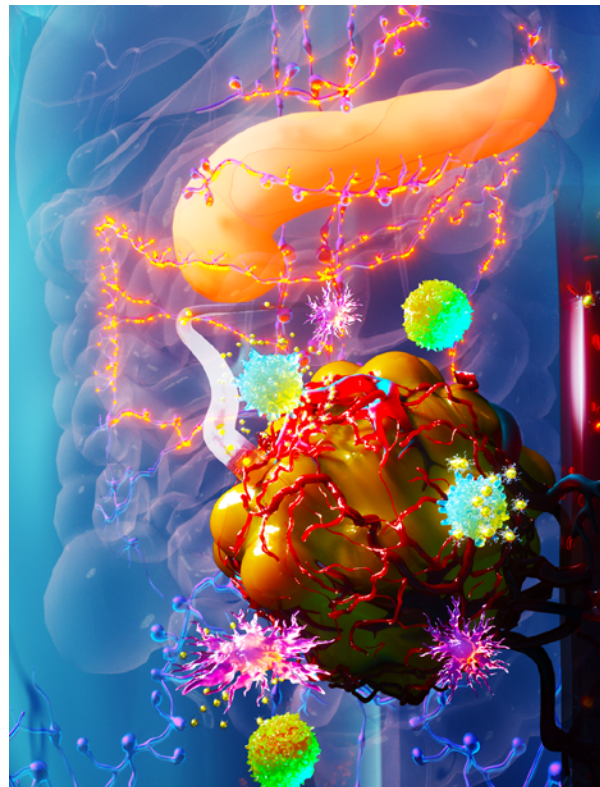
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### ON THE COVER

Covalent conjugation of cyclic dinucleotide (CDN) to nanoparticles (NPs) results in a potent innate immune agonist therapy. The combination of CDN-NP with ICB generated a complete and durable antitumor response in multiple cancer models. NPs were taken up by immune cells in the TME and secondary lymphoid organs. We found that the spleen contributed to immune memory formation and NPs internalized by cancer cells in the TME were transferred to proximal immune cells.

# From the Editor

By Roger Narayan, MD, PhD, Biomaterials Forum Executive Editor



Welcome to the second quarter issue of *Biomaterials Forum*! The issue begins with a letter from our president, Bill Wagner. His note highlights the upcoming 12th World Biomaterials Congress and Fall Symposia as excellent opportunities to share recent advances in

biomaterials research. Natalie Artzi shares a compilation of news from several members of the Society For Biomaterials community. Recent work by Artzi on the use of polymeric nanoparticles for systemic delivery of a stimulator of interferons genes (STING) agonist for cancer therapy serves as the feature of this issue. In the Industry News section, Subramanian Gunasekaran shares his insight into how medical devices are evaluated by the Center for Medicare and Medicaid Services and the influence of the American Medical Association. This discussion is an important consideration for biomaterials researchers as they evaluate pathways to distribute their technologies. Carl Simon describes the publication of the United States Government National Standards Strategy for Critical and Emerging Technology as well

as regenerative medicine workforce reports from the US Government Accountability Office and the US National Academies of Sciences Engineering and Medicine. The issue concludes with news from Karen Burg about the appointment of Dawn Beraud as the incoming Executive Director of the American Institute for Medical and Biological Engineering.

I want to thank the members, Society leaders and staff who provided the articles and helped to prepare this issue. As always, please do not hesitate to contact me at [roger\\_narayan@ncsu.edu](mailto:roger_narayan@ncsu.edu) if you are interested in sharing updates related to your career for inclusion in the member news or an article for an upcoming issue of *Biomaterials Forum*.

Yours truly,  
Roger Narayan

## CALL FOR COVER ART

WE WANT TO FEATURE YOUR EXCITING BIOMATERIALS ARTWORK ON THE COVER OF *BIOMATERIALS FORUM*!

**Deadline:** Accepted on a rolling basis.

**Instructions:** Please email artwork (digital images, artistic creations, etc.) to [info@biomaterials.org](mailto:info@biomaterials.org), to the attention of the Executive Editor of the *Biomaterials Forum*. All artwork with biomaterials relevance that have not appeared as a *Forum* cover are welcome. Multiple submissions are permissible.

**Description:** Selected artwork will appear as the cover of a future issue of *Biomaterials Forum* along with a brief "On the Cover" description of the subject and name/affiliation of the creator.

**Format:** High-resolution electronic version in .gif, .tiff or .jpeg file format.



# From the President

By William R. Wagner, PhD, SFB President



In collecting my thoughts for this note, I was thinking back 30 years to my first Society For Biomaterials (SFB) meeting in Birmingham, Alabama. By that time, I had been to a number of scientific meetings across different fields, but this particular society felt much more welcoming, stimulating and, well, fun. In the coming years as a junior faculty member, I continued to find opportunities and make new friends in SFB and the meetings were “must-attend” for their content and collegiality. That spirit has been maintained in the SFB as the field has changed, and from my current perspective the reason is clear — engaged members willing to provide service to the Society with an attitude of continuing improvement. Our members take ownership. It is also critical that we work with an excellent and passionate management team at Association Headquarters.

So, what is the status of SFB today? As with many scientific societies, our financial model is heavily dependent on successful annual meetings. It’s more than financial, however. These meetings are where we engage new members, provide value for membership, and transmit our values, mission and vision. The pandemic and our pathway back to normalcy has been challenging. I want to recognize the superlative efforts put in by Elizabeth Cosgriff-Hernandez, past SFB president, and the leadership team in navigating through these troubled waters. As we know on so many fronts, recovery has not been a matter of simply flipping back on a switch, and for SFB this meant making prudent decisions that would stabilize our finances while simultaneously putting on an excellent annual meeting in San Diego. Thanks to our dedicated members and volunteer leadership (particularly meeting program chairs Karen Christman and Jennifer Woodell-May) the meeting was a success and has corrected our course. We certainly have challenges ahead, and more in the way of fiscal recovery, but my perspective is that we have a vibrant membership and leadership team that will continue efforts to strengthen our position.

The year ahead is a special one. [We have the 12th World Biomaterials Congress \(WBC\), which will be held in Daegu, South Korea, May 26-31, 2024.](#) The abstract submission deadline is September 30, 2023. WBCs provide unique opportunities to meet and get acquainted with your international colleagues, experience a different culture, and learn the latest from the best labs in the world. Our field is international, and this is a unique opportunity to engage a broad cross-section of researchers that would normally not attend our meeting. If you can possibly make it, I strongly encourage you to attend.

Travel funding can be a challenge and SFB recognizes that many, particularly trainees and junior researchers, may not be able to travel to South Korea for the WBC. We thus wanted to provide an opportunity for scientific exchange in the US in the fall of 2024 with several smaller, regional meetings. The vision for these meetings was inspired in part by the many successful Biomaterials Days held regionally in prior years. The 2024 Fall Symposia featured gatherings throughout the country on September 19-20 at the following universities: Northeastern University, Case Western Reserve University, Georgia Institute of Technology, University of Texas at Austin, University of Colorado – Anschutz Medical Campus, and University of Washington. Symposia programs will include shared plenary speakers from the above locations with content accessible remotely. Each meeting will feature regional presentations, speakers, and posters. Our emphasis is keeping costs low, participation opportunities high, and content strong. It’s a new approach for SFB and I hope that you will find it valuable — and fun. Thanks to the many involved in organizing these symposia and to Anita Shukla, the program committee chair for the Fall Symposia.

I welcome feedback or questions regarding the Society and appreciate all of your ongoing efforts to grow and strengthen SFB so that it can continue to have an impact on tomorrow’s researchers and to fulfill its vision of “serving as the world’s preeminent interactive global community committed to advancing excellence in all aspects of biomaterial science, engineering and technology for promoting human health and well-being.”

Warm regards,  
William Wagner, SFB President

*If you have any questions,*

require any information or have suggestions for improved services, please feel free to contact the Society’s Headquarters office:

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# Member News

By Natalie Artzi, PhD, SFB Member-at-Large

## Abby Whittington, Associate Professor, Chemical Engineering, Materials Science & Engineering, Virginia Tech.

Dr. Whittington received a Commercialization Champion Award from Virginia Tech for her work on biodegradable polymers to replace single use plastics in medical and dental applications.



Abby Whittington, PhD, with award

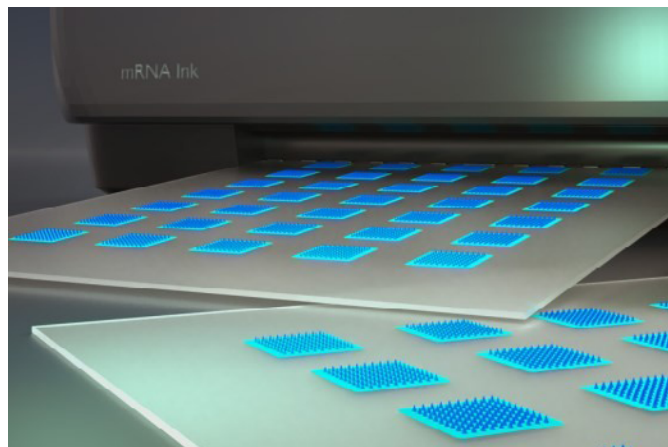
coatings for medical devices has been licensed by a medical device company Circa Bioscience and is on path to get commercialized after promising pre-clinical and scientific results. Dr. Khanna has had a remarkable influence on the biomaterials field by peer-reviewed scientific publications in high impact journals cited internationally. Dr. Khanna has been honored as a member of the Worldwide Women's Association (WWA) recently for her extraordinary accomplishments, excellence and leadership pursuits to influence and enrich the biomaterials and bioengineering field.



## Ana Jakelenc, Research Scientist and Co-Principal Investigator in the Langer Lab, at the Koch Institute for Integrative Cancer

### Research at MIT.

The research article, "A Microneedle Vaccine Printer for Thermostable COVID-19 mRNA Vaccines," was published in *Nature Biotechnology*.



MIT researchers have designed a mobile vaccine printer that could be scaled up to produce hundreds of vaccine doses in a day. This kind of printer, which can fit on a tabletop, could be deployed anywhere vaccines are needed. Pictured is an artist's interpretation of the printer.



## Astha Khanna, Head- Product Development, Graver Technologies, LLC

Dr. Khanna has exemplified the role of a successful researcher and mentor in the field of medical and biological engineering. Her work has been widely accepted and has influenced the bioengineering and biomaterials field in a remarkable way. Her doctoral research technology on designing biocompatible



Membership award from Worldwide Women's Association

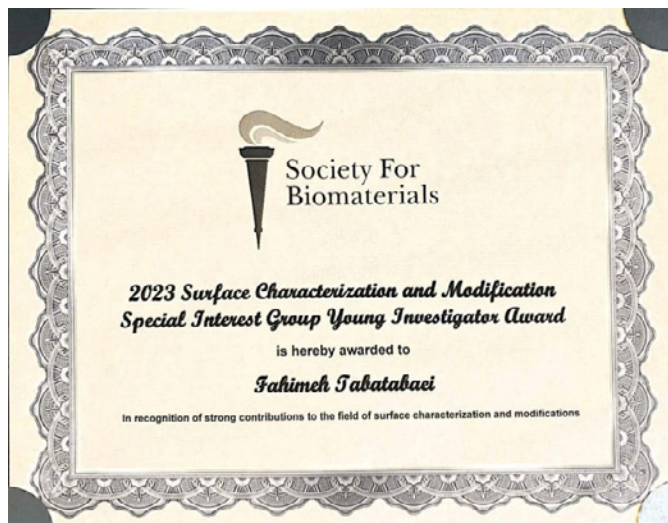
Dr. Khanna has also been widely recognized for outstanding contribution to the biomaterials field by virtue of her work that has been published in the most prestigious journals. Her recent publication in the *Journal of Biomaterials Research Part A* titled "Cardiovascular Human Organ-On-A-Chip Platform for Disease Modeling, Drug Development And Personalized Therapy" has been recognized to unravel advances in the revolutionizing field of organ-on-chips that are engineered or native functional tissues cultured under controlled microenvironments inside microchips. These systems employ microfabrication and tissue engineering techniques to recapitulate human physiology and can model cardiovascular diseases, to perform drug screening, and to advance personalized medicine. [Read the article here!](#)



## Fahimeh Tabatabaei, PhD, Study Director, iFyber

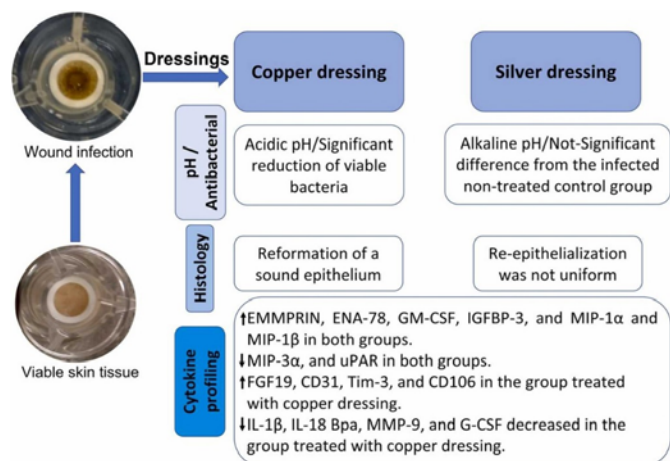
Fahimeh has recently been selected for the Society For Biomaterials (SFB) Surface Characterization and Modifications (SC&M) SIG Young Investigator Award! As a recipient of this award, the SC&M SIG recognizes her strong contributions to the field of surface characterization and modifications. She was invited to the SIG meeting, which was held virtually in May.

Member News (Continued)



SFB 2023 SC&M SIG Young Investigator Award

Dr. Tabatabaei also shares a new publication titled “Copper-Based Dressing: Efficacy in a Wound Infection Of Ex Vivo Human Skin.” [Read the final version here!](#)



The study has brought together the cutting-edge ex vivo human skin tissue model and an innovative in-house copper dressing.



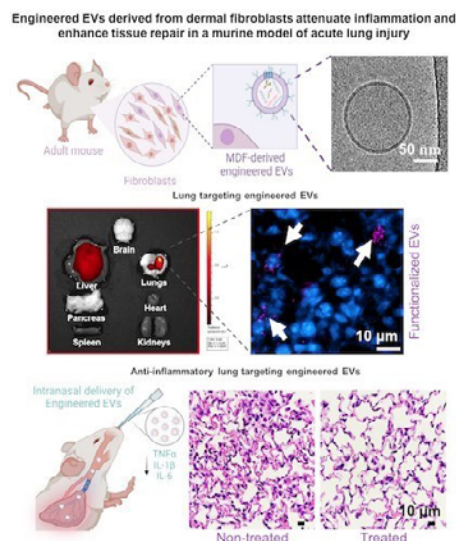
**Lawrence Gettleman, DMD, MSD, Professor of Prosthodontics & Biomaterials, Emeritus; University of Louisville; School of Dentistry**

Dr. Gettleman was elected Fellow of Sigma Xi, The Scientific Research Honor Society. He has been a member of Sigma Xi since 1986 and an officer of the Louisville Section since 1996, establishing awards at regional science fairs.



**Natalia Higueta-Castro, Associate Professor, Department of Biomedical Engineering & Neurosurgery, The Ohio State University**

New publication in *Advanced Materials* reporting the use of skin cells to derive engineered EVs for lung therapeutics



Engineered extracellular vesicles (EVs) derived from adult dermal fibroblasts show enhanced intrapulmonary targeting and retention, and can effectively deliver therapeutic cargo to the inflamed lung to reduce inflammation, mediate tissue repair and drive metabolic changes that favor further activation of anti-inflammatory pathways. These EVs could potentially represent a powerful tool for the treatment of acute lung injury.



## Member News (Continued)



### Nicholas A. Peppas, Sc.D., The University of Texas at Austin

[Dr. Peppas received AIMBE's 2023 Professional Impact Award](#) for his stellar impact on the field through outstanding mentoring of students and early career faculty.

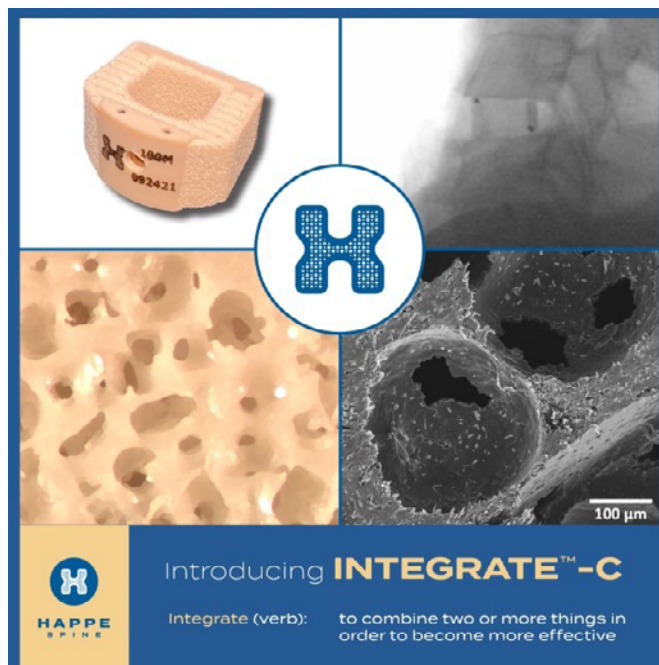


[Professor Peppas was also honored with an honorary doctorate degree from Tel Aviv University.](#)



### Ryan K. Roeder, Professor, University of Notre Dame; Founder and CTO, HAPPE Spine

HAPPE Spine received 510k clearance from the FDA for the INTEGRATE-C™, which is the first interbody fusion cage that is fully integrated with porosity and hydroxyapatite.



**Abstract**  
**Intelligent Biomaterials and Hydrogels in Nanotechnology and Precision Medicine**

Engineering the molecular design of intelligent biomaterials by controlling structure, recognition, and specificity is the first step in coordinating and duplicating complex biological and physiological processes. Recent developments in siRNA and protein delivery have been directed towards the preparation of targeted formulations for protein delivery to specific sites, use of environmentally-responsive polymers to achieve pH- or temperature-triggered delivery, usually in modulated mode, and improvement of the behavior of their mucoadhesive behavior and cell recognition. We address design and synthesis characteristics of novel crosslinked networks capable of protein release as well as artificial molecular structures capable of specific molecular recognition of biological molecules. Molecular imprinting and micro-imprinting techniques, which create stereospecific three-dimensional binding cavities based on a biological compound of interest, can lead to preparation of biomimetic materials for intelligent drug delivery, drug targeting, and tissue engineering. All these studies will not be helpful to our patients if they were not done in an environment promoting diversity and inclusivity among our members. To this extent, we stress the need for stronger and converging interactions of the researchers in our group, as well as identification of Health Disparities that drive our recent work.

**Prof. Nicholas A. Peppas**  
**2023 Tel Aviv University**  
**Honorary Doctorate**

**May 18<sup>th</sup>, 2023**  
The Raya and Josef Jaglom Auditorium, Senate Building  
Tel Aviv University

**AGENDA**  
08:00 - 10:00  
Roundtables Meeting with PhD students and postdoctoral fellows  
10:00 - 10:30  
Coffee break & light snacks  
10:30 - 11:30  
Opening and greetings  
Prof. Ronit Satchi-Fainaro  
Director, Cancer Biology Research Center (CBRC)  
Short intro talks by colleagues  
11:30 - 12:30  
Prof. Nicholas Peppas  
(The University of Texas at Austin)  
"Intelligent Biomaterials and Hydrogels in Nanotechnology and Precision Medicine"

**Roundtables Meeting**  
A chance for PhD students and postdoctoral fellows to listen, discuss, receive new insights and enjoy the personal exchange with Prof. Nicholas A. Peppas.

**Postdocs and Ph.D. students click here for Roundtables Registration**

[click here to register for Prof. Peppas Lecture](#)



The INTEGRATE-C, by HAPPE Spine, is the first interbody fusion cage that is fully integrated with interconnected, cancellous porosity and exposed hydroxyapatite to promote cell signaling, bone ongrowth and bone ingrowth endplate-to-endplate. The implant is also both radiolucent and radiovisible for superior intra-operative and post-operative imaging.



### Syam P. Nukavarapu, University of Connecticut

Dr. Syam Nukavarapu has been promoted to the rank of Professor in the Department of Biomedical Engineering, University of Connecticut. He established and directs the Tissue Engineering Science and Technology Laboratory (TEST Lab) that works at the interface of biomaterials design, tissue engineering and technology development. For his outstanding research and teaching accomplishments, he has been awarded with Castleman Professorship by the School of Engineering, University of Connecticut.



## Member News (Continued)


**Sarah Stabenfeldt, Professor, Arizona State University, BME**

Dr. Stabenfeldt has been promoted to the rank of Full Professor at Arizona State University's School of Biological and Health Systems Engineering.

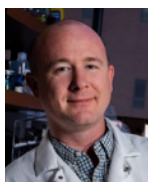
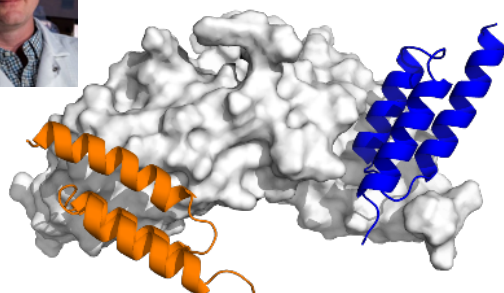

**Eric Shelton, Vice President, Global Commercial DSM Biomedical**

DSM Biomedical is a part of dsm-firmenich, innovators in nutrition, health and beauty, and the world's unrivaled biomaterials expert and committed partner in driving sustainable innovation in healthcare. For more than 30 years, the company has been at the forefront of biomaterial science and process innovation, and the leading resource for global medical device and pharmaceutical companies. As a strategic partner with an approach driven not only by market dynamics but by the unique needs of every customer, DSM Biomedical brings an unparalleled breadth of product portfolios, proprietary manufacturing and processing capabilities, world-class IP and extensive regulatory experience and expertise. Furthermore, DSM Biomedical's products and services are recognized for their unmatched quality, consistency and performance in multiple markets across the globe, supporting their company-wide vision of solving the world's healthcare needs through sustainable science. To learn more, visit [DSMBiomedical.com](https://www.DSMBiomedical.com).


**Marian Hettiaratchi, Assistant Professor, Knight Campus for Accelerating Scientific Impact, University of Oregon**

[Knight Campus team published a paper in Advanced Healthcare Materials](#) wherein they pursue a strategy for promoting bone healing

by employing small protein binders known as affibodies to aid in regeneration.


**Scott Wood, Assistant Professor, Department of Nanoscience & Biomedical**


Affibodies with different affinities (blue and orange) binding to bone morphogenetic protein-2 (BMP-2) (gray) in different locations

**Engineering, South Dakota Mines**

Dr. Wood was recently awarded an NSF PFI-TT grant to support development and commercialization of a novel biomaterials-based microphysiological joint on a chip platform.


**NAI Senior Members**
**Akhilesh Gaharwar, Professor, Texas A&M University, Biomedical Engineering**

Multiple biomaterials researchers were inducted into the National Academy of Inventors (NAI) in 2023. Michael King was inducted as a NAI Fellow; Ayse Asatekin, Karen L. Christman, Margot Damaser, Lola Eniola-Adefeso, Akhilesh Gaharwar, Harvinder Gill, Hitesh Handa, Mehdi Nikkha, and Tatiana Segura were inducted as NAI Senior Members.



2023 NAI Fellows


**Aliasger Salem, PhD, University of Iowa**

Recent published research from [Aliasger Salem's group](#) has shown that a new ciprofloxacin

## Member News (Continued)

[derivative has synergistic activity with paclitaxel against endometrial cancer](#), as well as [nanoparticle formulations of these drugs enhanced the response even further](#).



**Guillermo Ameer, ScD, Daniel Hale Williams Professor of Biomedical Engineering and Surgery**

Guillermo Ameer was awarded the Excellence in Biomaterials Science Award from the Surfaces in Biomaterials Foundation and the inaugural

Athanasίου Medal for Translational Bioengineering from the Biomedical Engineering Society.

**Congratulations to our SFB members who have been named 2023 BMES Fellows!**

- Danielle S.W. Benoit, PhD, University of Oregon
- Ke Cheng, PhD, Columbia University
- Eun Ji Chung, PhD, University of Southern California
- Jianping Fu, PhD, University of Michigan, Ann Arbor
- Akhilesh K. Gaharwar, PhD, Texas A&M University
- Yi Hong, PhD, The University of Texas at Arlington
- David H. Kohn, PhD, University of Michigan
- Michael J. McShane, PhD, Texas A&M University
- Sarah Stabenfeldt, PhD, Arizona State University

**And, to the 2023 BMES Award Winners for their outstanding achievements and contributions to the field of biomedical engineering!**

- **BMES Athanasίου Medal of Excellence in Translational Bioengineering Award: Guillermo Ameer**, Daniel Hale Williams Professor of Biomedical Engineering & Surgery, Northwestern University
- **Wallace H. Coulter Award for Healthcare Innovation Award: Jian Yang**, Chair Professor, Biomaterials and Regenerative Engineering, Westlake University
- **2023 Diversity Lecture Award**, University of Florida/ J. Crayton Pruitt Family Department – Department Representative: **Christine Schmidt**, Distinguished Professor & J. Crayton Pruitt Family Endowed Chair
- **Rita Schaffer Young Investigator Award: Shreya Raghavan**, Assistant Professor, Biomedical Engineering, Texas A&M University

**CALLING ALL  
BOOKWORMS!**

If you'd like to contribute a review of your recent favorite read to the *Biomaterials Forum*, send it for consideration to the Editor at [Roger\\_narayan@ncsu.edu](mailto:Roger_narayan@ncsu.edu). If it's approved, it will be published in a future Forum Book Review column!





# Polymeric Nanoparticles Enable Systemic Delivery of a Highly Potent STING Agonist for Tumor Remediation

By Natalie Artzi, PhD

The systemic delivery of stimulator of interferons genes (STING) agonists based on cyclic dinucleotides (CDNs) yields limited anticancer activity, owing to poor serum stability and cellular internalization, even when CDNs are complexed with nanoparticles (NPs). We recently designed a CDN-conjugated nanoparticle based on poly( $\beta$ -amino ester), or pBAE, which is stable and safe, resulting in a potent innate immune activation once it is systemically administered. CDNs are covalently conjugated to pBAE NPs through a cathepsin-dependent linkage, which facilitates endosomal processing and CDN release.

As a result, CDN-NPs exhibited superior potency, drug loading and stability when compared with electrostatically formulated nanoparticles and particle-free CDN therapies. Intravenously administered CDN-NPs induced significant tumor regression in melanoma, colon cancer, and breast cancer mouse models in a STING-specific manner, even at sub-microgram doses (0.5  $\mu$ g), suggesting that CDN-NPs may be effective across multiple cancer types without requiring tumor-specific targeting agents (Figure 1).<sup>1</sup>

## COMPLETE AND DURABLE ANTITUMOR RESPONSES

In melanoma and colon cancer mouse models, the CDN-NPs generated complete and durable antitumor responses, as well as immunological memory, when combined with immune checkpoint blockade therapy. Mechanistically, CDN-NPs induced changes in myeloid populations and increased the expression of pro-inflammatory markers by DCs and macrophages in the tumor microenvironment and secondary lymphoid organs (SLOs). We found that tumor control relied on multiple cell types, including NK cells, macrophages and CD8 and CD4 T cells. Combining CDN-NPs with therapies that enhance non-MHC dependent clearance of tumor cells (phagocytosis, granzyme release) could provide a way to augment the efficacy achieved here.

## IMPORTANCE OF HIGHLY STABLE NANOPARTICLE SYSTEMS

The CDN-NPs also provided important insight pertaining to the relationship between NP biodistribution (BD) and therapy pharmacodynamics (PD). CDN-NPs were internalized by DCs, macrophages, granulocytic cells and monocytic cells in the Spleen, TME, and SLOs. Despite the substantial accumulation of nanoparticles in the spleen, the organ did not play a major therapeutic role; rather, it contributed substantially to the efficacy of immune-memory response upon rechallenge. In addition, we discovered that CDN-NPs that have been internalized by cancer cells in the TME, where STING activation was found to be ineffective, are being transferred to proximal immune cells, where STING signaling is critical.

This results in their activation and therapeutic responses that contribute to tumor control *in vivo*. This points toward the importance of engineering highly stable nanoparticle systems, here by chemical conjugation rather than by electrostatic complexation of drugs to nanoparticles, to improve immunotherapy outcomes. These findings underscore the importance of studying the temporal interplay between the make-up of immune-cell populations, that is immune cell composition and activity, and the dynamic distribution of therapeutic NPs across organs and cell types and inform the design of more effective NP-based immunotherapies.

## REFERENCE

1. Dosta P, Cryer AM, Dion MZ, et al. "Investigation of the enhanced antitumor potency of STING agonist after conjugation to polymer nanoparticles." *Nat. Nanotechnol.* <https://doi.org/10.1038/s41565-023-01447-7>

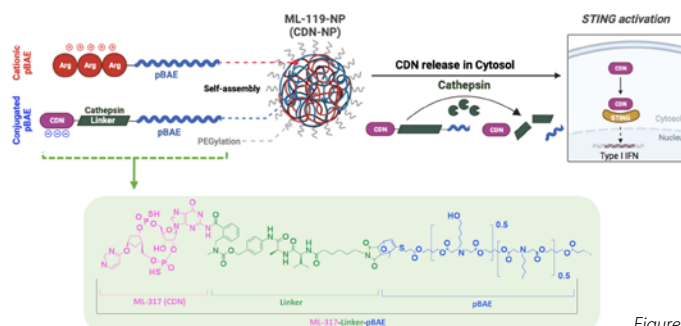


Figure 1. STING Activation



# Industry News

By Subramanian Gunasekaran, PhD

In this article, we delve into the dynamics of the federal agencies and their interactions, shedding light on how medical devices are evaluated, valued and coded within complex healthcare systems.

**Product Clearance through the FDA, Guardian of Safety and Efficacy:** First and foremost in the process of commercialization of a medical device, is its clearance through FDA, the federal agency responsible for approving and overseeing the safety and efficacy of such products.

**Commercial Valuation by CMS:** The journey of commercializing a product begins with the submission of the product description, indications and clinical data to the Center for Medicare and Medicaid Services (CMS). This is followed by CMS assigning the commercial value along with an HCPCS Code to the product.

**Medical Billing & Coding:** It is a highly complicated but essential process for every manufacturer to learn and understand how the method of coding and billing is to be accomplished by a Provider who uses the product as per the instructions of the manufacturer.

Medical coding software companies like Codify, AAPC and Supercoder.com are likely to be influenced by major pharma company products and ignore the small company products even if such products are clinically more effective. Accordingly, the manufacturer should face the reality of highly biased medical coding & billing software for proper recognition to ensure fair reimbursement for their products.

The role of billing agents is extremely important for the proper submission of the CMS-1500 form by the Provider/Doctor and waiting for a few weeks for the payment from the insurance.

## **The Influence of the American Medical Association**

**(AMA):** Currently, the commercial valuation of a medical device is performed thrice annually by the Relative Value Update Committee (RUC) comprised of 31 physicians from the societies affiliated with the AMA. Unfortunately, the most powerful RUC committee that assigns the commercial value of advanced medical devices does not consist of any expertise from the field of biomaterial science.

**Payment to the Providers:** Providers upon the usage of a product get the payment for the product from Payors such as the government insurance agencies like CMS & its MACs (Medicare Administrative Contractors) or private insurance payors either PPOs (Preferred Provider Organizations) or HMOs (Health Maintenance Organizations).

**Hospital Supplies:** Selling the product through the hospitals has to go through another complicated system of supply chain management mostly managed by the Purchasing/Materials Management departments of the hospital. Added to the complication, most hospitals will have their own confidential Group Purchase Organizations (GPOs) through which the manufacturer should strike a purchase deal after convincing their Value Analysis Committee (VAC). Nobody knows how this committee is framed to value advanced medical devices. Most of the time it is governed by inadequately skilled purchase managers and nurse practitioners. Unfortunately, there is no logical scientific approach to get a proper valuation of a product.

**Conclusion:** Lack of proper communication between the FDA and CMS makes the latter agency assign the medical products' commercial valuation mainly through the influence of the clinical society namely AMA and its affiliate societies. This often undermines the real valuation of technically advanced tissue regenerative medical devices which need more input from the FDA and other scientific expertise from biological & biomaterial science.





# Government News

By Carl G. Simon, Jr., PhD

## U.S. ANNOUNCES NATIONAL STANDARDS STRATEGY

[The “United States Government National Standards Strategy for Critical and Emerging Technology” was released by the Biden Administration on May 4 2023.](#) The goal is to “safeguard American consumers’ technology and strengthen US leadership and competitiveness in international standards development.” The four key objectives are 1) investment, 2) participation, 3) workforce and 4) integrity & inclusivity. Under investment, the strategy calls for an increase in federal research and development spending to \$210 billion, an increase of \$9 billion over fiscal year 2023. The funding will be used to accelerate fundamental research to drive technical contributions to international standards and to foster the translation of these research results and measurement science into globally accepted specifications and features. The strategy instructs funding agencies to explicitly recognize as within scope participation in standards development by federal grantees and funding recipients, when appropriate. For example, National Science Foundation is currently updating its proposal and award policies and procedures to include participation in standards development activities. The strategy identifies eight key subject areas that include Biotechnologies “which will affect the health, agricultural, and industrial sectors of all nations, and which will need to be used safely and securely to support the health of our citizens, animals, and environment.”

## TWO REGENERATIVE MEDICINE WORKFORCE DEVELOPMENT REPORTS PUBLISHED

Two regenerative medicine (RM) workforce reports were published in 2023, [one from the US Government Accountability Office \(GAO\)](#) and [one from the US National Academies of Sciences Engineering and Medicine \(NASEM\)](#). Rapid growth in RM is driving increased demand for workers in the field but existing workforce and education data do not contain information specific to RM.

The GAO report was compiled by interviewing officials from Department of Health and Human Services (HHS) and eight relevant stakeholder organizations and by reviewing related reports and job postings. The GAO report found that the RM workforce occupies a wide range of jobs including research, development, biomanufacturing, clinical care and regulatory affairs. It was noted that many positions required a postsecondary degree as well as specialized training in laboratory techniques or topics specific to the field. There is a need for a nationally recognized core curriculum for RM. A shortage in laboratory technicians to support development and biomanufacturing of RM therapies and a shortage in data scientists was reported.

The NASEM report was compiled from input collected at a workshop of the Regenerative Medicine Forum, and it also noted a shortage in workers, especially at the technician level. The NASEM report highlighted the need for increased outreach and building of awareness of career paths in RM. NASEM also reported a need to expand training pathways at all levels, high school, undergraduate and advanced degrees. More training certification programs are needed, as an alternative to traditional degrees, with greater input from industry. Finally, the role of mentors was emphasized for providing guidance in choosing career pathways. Experienced professionals are encouraged to serve as mentors, and less experienced individuals are encouraged to seek out mentors.

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# AIMBE Appoints Executive Director

By Karen J.L. Burg, PhD, FNAI, FBSE, FAIMBE, PAESMEM 2021

The American Institute for Medical and Biological Engineering (AIMBE) announces the appointment of Dawn Beraud, PhD, as the Executive Director of AIMBE beginning July 2023. As a science policy leader with senior government experience and a keen understanding of Capitol Hill, Dr. Beraud brings to AIMBE her passion for helping scientists join the conversation and influence policy decisions.

With significant consideration given to the skills, experiences, and expertise needed to successfully guide AIMBE in its next phase of advocacy leadership, AIMBE has selected Dr. Beraud to serve in this important leadership role. Dr. Beraud's current position as director of the Office of Legislation, Policy, and International Activities at the National Institute on Aging (NIA) — and her 10-year history of serving the National Institutes of Health — have distinguished her as a leader in working with both Congress and academic leaders. Dr. Beraud skillfully communicated research plans and progress to congressional Members and their staff, which supported a more than 5-fold budget increase during her tenure. Her leadership skills, commitment to science policy, and experience with national policy leaders make her an exceptional individual for the role of Executive Director. We are confident that under her leadership, the organization's success and impact in achieving its critical advocacy mission will continue to flourish.

Dr. Beraud received a BS in psychology from the University of Florida and a PhD in neuroscience from Georgetown University.

"I am delighted to join this prestigious organization and to engage with the Fellows at the heart of AIMBE. With my leap

outside of federal service, I am looking forward to partnering with Fellows to advocate for policies that support your important work to advance medical and biological engineering for the benefit of society."

Over the next year, Dawn will begin the strategic planning process for AIMBE. "We are thrilled with the appointment of Dr. Beraud who will lead AIMBE and strengthen and solidify our advocacy mission," noted AIMBE President Joyce Wong, PhD.

Please join us in welcoming Dr. Beraud as AIMBE Executive Director!

The full press release can be found [here](#).



Dawn Beraud, PhD



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