

Volume 18 • Number 9

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Printed in the U.S.A.

Volume Eighteen, Number Nine

## Innovation meets the market

There are 977 clinical trials under way for products that use regenerative medicine technology. There are more than 150 gene therapy drugs in Phase I, II and III clinical trials in progress as rare disease research enters into a new era of patient-focused innovation. Additionally, there are nearly 200 new drugs expected to be launched in the next five years, with a high number of these being new molecular entities (NMEs). There are currently more than 2,000 products in late-stage clinical development, a quarter of which are oncology therapies. Furthermore, the growing number of medicines receiving the FDA's Breakthrough Therapy Designation is contributing to an acceleration of approvals. Experts say this wave of innovation is similar to levels seen in the mid-2000s.

As this month's cover story explores, gene and cancer immunotherapies, RNAi therapies, smart medicines and digital therapies, as well as a host of other innovative remedies still in the pipeline, are hopeful entrants into the market to treat and even cure life-threatening diseases. But these innovations often come with unprecedented costs and are challenging our current healthcare system. The current system of health insurance, based on unit pricing, is not set up to address high-cost, and often one-time cell and gene therapies, or therapies such as digital "medicines" that have been clinically validated to demonstrate a change in behavior.



And just as R&D required new scientific approaches to tackling disease, there is call for new approaches to understand their value and how to pay for medicines to ensure patients can access the medicines they need, when they need them.

In a recent article posted by America's Biopharmaceutical Companies covering an event convened by The Atlantic, which was sponsored by PhRMA as part of its GoBoldly campaign, experts from across the healthcare system discussed the need to address barriers to patient access and ways to better pay for innovative treatments and cures.

Jamey Millar, senior VP of managed markets and government affairs at GlaxoSmithKline, was quoted as saying: "I think we're moving toward a value-based, outcomes-based marketplace where the various players in the value chain have to work together and partner."

Having a payment system better aligned with patient needs means removing barriers to their ability to access care, including by improving insurance benefit design. Almost everyone can agree that as new medicines evolve, the way these innovations are measured in terms of value must also advance to better consider the outcomes most important to patients.

Mr. Millar was joined by a diverse range of healthcare stakeholders, including Eleanor Peretto of the National Health Council and Leah McCormick Howard from the National Psoriasis Foundation. According to Ms. Peretto, "we're still doing things the way we used to, but we have all these new therapies...if all the stakeholders in the healthcare ecosystem could truly understand what being patient-centered is and act on it, that could make an incredible difference." Ms. McCormick noted: "Everyone needs to be willing to come to the table. We do a lot of talking about patients without actually including the patients."

We welcome your feedback on this important topic. Drop us a line at [tgrom@pharmavoiced.com](mailto:tgrom@pharmavoiced.com).

  
Taren Grom  
Editor

### Their word...

**DENISE MYSHKO**

Managing Editor



*Biopharmaceutical companies, payers, and providers are working together to find a reimbursement structure for new innovative therapies.*

**ROBIN ROBINSON**

Senior Editor



*As companies heed the call to serve a greater social purpose, agencies are creating philanthropic cultures that bring good to both staff and beneficiaries.*

**KIM RIBBINK**

Features Editor



*The oncology landscape is dynamic, with many new and more targeted therapies bringing new hope to patients.*

## 2019 Year in Preview Nov/Dec

- ▶ Advanced Diagnostics and Precision Medicine
- ▶ Bioprinting
- ▶ Creating Shared Value
- ▶ Genetic Testing and Human Data Rights and Access
- ▶ Gig Economy
- ▶ Innovative Medicine Launches
- ▶ Multi-stakeholder Commercial Models
- ▶ Rare Disease Innovation
- ▶ R&D Modeling and Simulation
- ▶ Voice Assistants
- ▶ Showcase: E-Solutions

PharmaVOICE (ISSN: 1932961X) is published monthly except joint issues in July/Aug. and Nov./Dec., by PharmaLinx LLC, P.O. Box 327, Titusville, NJ 08560. Periodicals postage paid at Titusville, NJ 08560 and additional mailing offices.

**Postmaster:** Send address changes to PharmaVOICE, P.O. Box 292345, Kettering, OH 45429-0345.

**PharmaVoice Coverage and Distribution:**

Domestic subscriptions are available at \$190 for one year (10 issues). Foreign subscriptions: 10 issues US\$360. Contact PharmaVoice at P.O. Box 327, Titusville, NJ 08560. Call us at 609.730.0196 or FAX your order to 609.730.0197.

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