Taren Grom

Executive INSIGHTS

CEOs, presidents, and executive management team members from across the industry — pharmaceutical, biotechnology, and service companies — discuss the most crucial factors driving change in the industry, as well as their strategies for meeting the challenges of business in the coming years.

WENDEL BARR is *CEO* of **Synteract**, a full-service contract research organization that supports biotechnology, medical device, and pharmaceutical companies in all phases of clinical development.

Within our industry, it is imperative to increase productivity. There is a general feeling that CROs need to deliver more of what sponsors value, with the most important objective being to take time and cost out of drug development while delivering high standards. Even though we may think we are absolutely good at something, it doesn't matter if the customer doesn't see value.

Our focus in 2013 will be to grow to meet customers' requirements by increasing the level of knowledge and strategic insight we provide to support their changing needs; execute projects to consistently meet or exceed customer expectations with quality deliverables; and leverage technology to get customers the data they need to get to decision points faster. Our objective is to further refine and enhance our integrated, intelligent approach to clinical development to reduce inefficiencies in the process, to better serve customers, and drive change in the industry.

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CHRIS BERGSTROM is *Chief Strategy and Commercial Officer* of **WellDoc**, which is developing the next generation of technology solutions to support the management of chronic disease.

Grabbing a foothold in the inevitable beyond-the-pill evolution will be an imperative. The pharma industry needs new products that require less capital and time to market than in the past. These products must be patient-centric, outcomes-driven, and also helpful to the provider. Further, they should leverage pharma's core competencies of physician marketing, quality systems, and scientific evidence. Innovative products, such as mobile integrated therapies, can accomplish this by helping patients and providers manage an entire disease. Through decision support and patient coaching, these products optimize treatment plans so patients can be on the right therapy, even if that drug is sold by a competitor, thus enabling pharma companies to trade their pill-pushing image for that of solution providers.

JOHN BLAKELEY is *Chief Commercial Officer* of **Greenphire,** which offers Web-based clinical payment technology platforms for use by research sites, research universities, sponsors, and CROs.

Continued pressure on margins and the lack of relative productivity in development pipelines is forcing the industry to slow down and look for more efficient and cost-appropriate methods for conducting research. Moving cost centers to the CRO environment is only part of the answer. The pharma industry should follow the examples of other mature industries and embrace technology solutions to drive more efficient and cost-controlled research.

There are many great examples in the industry where technology has proven to be more efficient and cost-effective. The EDC era has shown us that it is possible to realize strong gains from the adoption of technology. The industry should more openly embrace technological advancements that can drive cost-efficiencies and at the same time help to drive innovation.

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JAY BOLLING is *CEO* of **Roska Healthcare Advertising**, which executes professional and consumer advertising for a broad base of healthcare clients.

As an industry, we're losing sight of our customers. We're so focused on our brands, our rules, and our future, we've lost sight of our customers' needs. When was the last time we asked physicians what they wanted from us, rather than telling them what we wanted them to do? Are they focused on providing the best patient experience? Are they trying to build their practices? Are they even interested in product (clinical) data? And rather than trying to turn consumers into who we want them to be, do we ever ask them what they want — even if it has nothing to do with our therapy? Do we truly understand the fear and vulnerability that comes with being unwell? Are we connecting with them on a human level, the way we would if we were a trusted friend?

The future success of healthcare marketing will involve making a real difference in healthcare outcomes. To do this, we need to connect with our cus-

tomers on a human level by implementing marketing practices that are truly customer-centric, not brand-centric. The future success of marketing communications will be about this human connection; if it isn't, we'll lose our customers forever.

Instead of promotion or sales, let's start talking about customer engagement and measuring success accordingly.

First, look at why and how our customers want to engage with us, and then address what to do to connect with them and where we need to make that connection so it really sticks. From a consumer perspective, instead of focusing on GRPs (gross rating points) and product features/benefits, we need to focus on iterative storytelling, evolving our story to help consumers understand their disease, its diagnosis, the potential impact on their lives, and realistic expectations about treatment and its role in their wellness.

But to achieve true consumer engagement, we must go beyond messaging, to integrating media, leveraging third-party partners, and measuring the effectiveness of everything we do.

To truly engage healthcare professionals, we need to understand their needs, problems, aspirations, and desires, and deliver an experience that truly adds value not just promotion about our products. To be successful, this physician experience must reflect how they see themselves and help them become who they truly want to be.

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ROBERT CHIOINI is *Founder, Chairman, CEO, and President* of **Rockwell Medical Inc.,** a fully-integrated biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD) with innovative products for the treatment of iron deficiency, secondary hyperparathyroidism, and hemodialysis.

Innovation of new technology that improves patients' quality of life while lowering healthcare costs will no longer be a nice to have, but a need to have.

Innovation of new technology and products that lower healthcare costs, partnerships between companies that marry innovation with infrastructure and delivery of healthcare, and stronger intellectual property laws outside of the United States to protect innovation are three major global trends that will impact the life-sciences industry.

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NICK COLUCCI is *President and CEO* of **Publicis Healthcare Communications Group,** a vertical network that integrates services across its global offices and brands to deliver on clients' needs.

There is a need for collaboration. More stringent reviews of me-too drugs by the FDA are pushing pharma into the territory of unmet need, which holds higher value for the patient population. While pharma companies continue to work out their pipeline directions, medical communication networks, such as Publicis Healthcare Communications Group, will expand to wellness, tackling all aspects of the consumers' drive toward a healthy lifestyle, and we will be drawing from our shared ideas and talents to create consumer touchpoints.

Agencies will need to diversify their portfolios and expand their capabilities to meet the needs of big pharma and the biotech industry, targeting niche diseases, cosmeceuticals, and other wellness products.

We will need to shift away from traditional sales promotion and focus more on CRM and direct-marketing models to the specific audiences our clients are targeting.

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LAURIE COOKE is *CEO* of the **Healthcare Businesswomen's Association,** a nonprofit organization dedicated to furthering the advancement and impact of women in healthcare worldwide.

As any executive team knows, an organization is only as good as its people. There is an abundance of data on the value of a diverse workforce and one of the most persuasive data points is the study published in Science in 2010 by an economist at Carnegie Mellon that states the collective intelligence of a group is significantly correlated to not the expected intelligence of the team members, but surprisingly, to the average social sensitivity of group members; distribution of conversational turn-taking; and proportion of females in the group.

This speaks volumes to the importance of gender diversity. The HBA E.D.G.E. in Leadership Study identified that best practice life-sciences companies exhibited both a culture conducive to women's advancement and well-executed programs. These companies had the following common best practices to support gender parity: unambiguous senior leadership support for change; merit and performance-based processes to ensure equity; measurement and accountability to drive behavior and results; advancement programs for high potential women; career and work flexibility models to retain top female talent; and recruiting practices to support representation of women.

Companies are advised to address these six key themes holistically to drive progress and change in their representation of women across the spectrum of their talent pipeline.

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KEITH DIONNE, PH.D., is *President and CEO* of **Constellation Pharmaceuticals,** a biopharmaceutical company in the field of epigenetics.

The last decade has challenged a pharmaceutical business model that worked for a long time. There is a continued need to re-think how companies approach their business, particularly in R&D. The companies that have been most proactive in focusing on innovative products are poised for success in the next decade. At Constellation, we have focused on epigenetics that we believe are the next generation of targets in cancer, immunology, and other diseases. One consequence of working in a novel target space is the need to create new paradigms for drug discovery, including earlier integration of chemistry and biology. The fruits of our innovative approach are now ripening and we are focused on delivering novel medicines to patients in the clinic.

We encourage calculated risk taking among employees and creating incentives, governance, and a culture that supports discovery and development of novel targets.

Going forward it will be important to expand innovative target discovery with innovation in clinical development, biomarkers, and collaborations set to advance breakthrough products to the clinic and ultimately to individual patients who can benefit from these advances. As an industry built on innovation we need to continue to identify new areas for drug discovery, increase

productivity with approaches that will improve our ability to predict success, and build win-win collaborations between pharma — development/marketing engines — and biotech — innovation and discovery engines.

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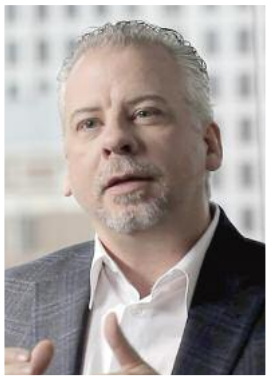

KERRY HILTON is *CEO* of **HCB Health**, a full-service advertising agency, built from the ground up to meet the evolving needs of modern healthcare brands.

CDHPs — consumer-directed health plans — will be offered by more than 70% of employers in 2013 to help contain costs. Plus, employers will offer their employees big incentives to quit smoking and other wellness initiatives. All of this is to accommodate the rising costs of healthcare as well as higher taxes to pay for the new healthcare law.

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YUICHI IWAKI, M.D., PH.D., is *President, CEO, and Founder* of **MediciNova Inc.**, a biopharmaceutical company founded upon acquiring and developing novel, small-molecule therapeutics for the treatment of diseases with unmet need, with a commercial focus on the U.S. market.

Life-sciences developers face a changing landscape in the near term and need to be prepared to face higher hurdles for success. Key business objectives in 2013 for any pharma company include assuring development going forward is aligned with the heightened requirements the market will demand for life-sciences products and services. These should include: addressing real unmet needs, clear positive differentiation with tangible outcomes improvement, and convincing demonstration of cost avoidance. The strategies should include early and frequent specification dialogue among developers, payers, and end users to successfully answer the question: "what problem are we solving with the right profile, data, and pricing?"

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RICK KEEFER is *President and CEO* of **Publicis Touchpoint Solutions Inc.**, which designs and implements healthcare sales, service, and communications teams to deliver customized cross-channel solutions.

The single most important business objective for every company in the life-sciences is to align its business model to meet the ever-changing demands of today's marketplace. It is a brave new world in healthcare. Companies — both manufacturers and suppliers — have to continuously evaluate and innovate.

Re-evaluating absolutely everything is a great first step in transforming any business model. Approaches that worked well for decades may not make sense in today's world. Many biopharma companies, for example, are dramatically changing how they do business by focusing on core competencies while outsourcing areas such as sales teams, research, and even complete commercialization of mature product lines.

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ILYSSA LEVINS is *President* of **Center for Communication Compliance (CCC),** a source for training, testing, and consulting in promotional regulatory compliance and risk communication.

The new business model for 2013 requires marketers to embrace regulatory, legal, and compliance colleagues as high-value partners instead of seeing them as policemen. Let's bust those myths of the proverbial sales prevention department and recognize that wise counsel from these three functions contributes to marketing excellence, including the transfer of balanced information that protects and enhances public health.

Today's pioneering marketers are teaming up with regulatory/legal/compliance to advocate for compliance education targeting agencies and internal marketing departments. They understand that education increases business opportunities for the brand by reducing regulatory knowledge gaps. Knowledge gaps result in unnecessary rewrites and longer review cycles, so fewer promotional materials go through the system.

Having to redline noncompliant material means these functions can't focus on optimizing the quality of promotional claims. And if sales reps are waiting for materials that need to be changed to meet the FDA's expectations, they won't have the most powerful promotional mix. Finally, when marketing loses money to untrained agencies forced to rewrite their own noncompliant materials — at a cost of more than $100,000 per brand, according to a benchmark study — they can't use that money to develop more campaigns.

It's time to champion regulatory/legal/compliance functions for their contributions to more efficient promotional processes and more effective promotional materials. The outcome: marketers achieve commercial objectives and manage risk at the same time.

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RICK MORRISON is *Founder and CEO* of **Comprehend Systems,** which offers clinical data visualization, analytics, and reporting software to improve the way clinical researchers access, understand, explore, and analyze data.

The industry needs to figure out how to better deploy and use its resources, as more and more companies are cost-constrained and are experiencing so many outside pressures to become leaner and more efficient. There is a lot of waste involved with the "way things have always been done" model, and this will have to change. Broadly, the strategies that will facilitate this are technology adoption and evolving the relationships that sponsors and biotech companies have with their vendors.

Technology will allow companies to run more efficiently, cheaper, and more effectively. Vendor relationships must evolve to become more account-

able. The onus is now on companies that provide services to sponsors to add value.

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SANJAY PINGLE is *President* of **Physicians Interactive,** a division of Skyscape.com Inc., a resource for healthcare information, medication samples, and mobile decision support tools to medical professionals.

A key strategic imperative in 2013 will be to focus on integration as opposed to innovation — listening to what healthcare professionals need from life-sciences companies and where they need it.

The objective is to incorporate existing value-added information and services into the physician's digital workflow in ways that improve the quality of care. This includes creating access to relevant information and services within electronic health records (EHRs), ePrescribing (eRx), the Web, and mobile/tablet channels. Those services will help to reduce patient cost, increase therapy compliance, create goodwill between physicians and patients, all while building better patient-physician interactions around life-sciences products.

Life-sciences companies will be able to increase engagement and better control promotional costs via the use of EHR, mobile, electronic sampling, and Web-based nonpersonal communication channels.

KEN RIBOTSKY is *President and CEO* of **Brandkarma,** which offers healthcare companies strategic and creative marketing for specialty pharmaceutical, biotech, medical device, diagnostics, and OTC brands.

The life-sciences industry has to be more focused than ever on ways to provide personalized solutions to diseases. Knowing what will work on a particular individual is critical, especially when there is a broad risk versus return ratio. For our company's part, personalization is also important, but of course we are looking at it from the perspective of personalized and targeted communications.

Agencies need to help clients tailor relevant messages to specific stakeholders. The age of one-size-fits-all is long gone. Traditional marketing sees all targets in one demographic as a monolithic entity. The future of targeting is about understanding the personas of those you want to reach — what's important to them and how they see themselves. This way, marketers can create messages that resonate with an individual. And this could be very different from what their neighbor responds to, even when they are both in the same exact demographic.

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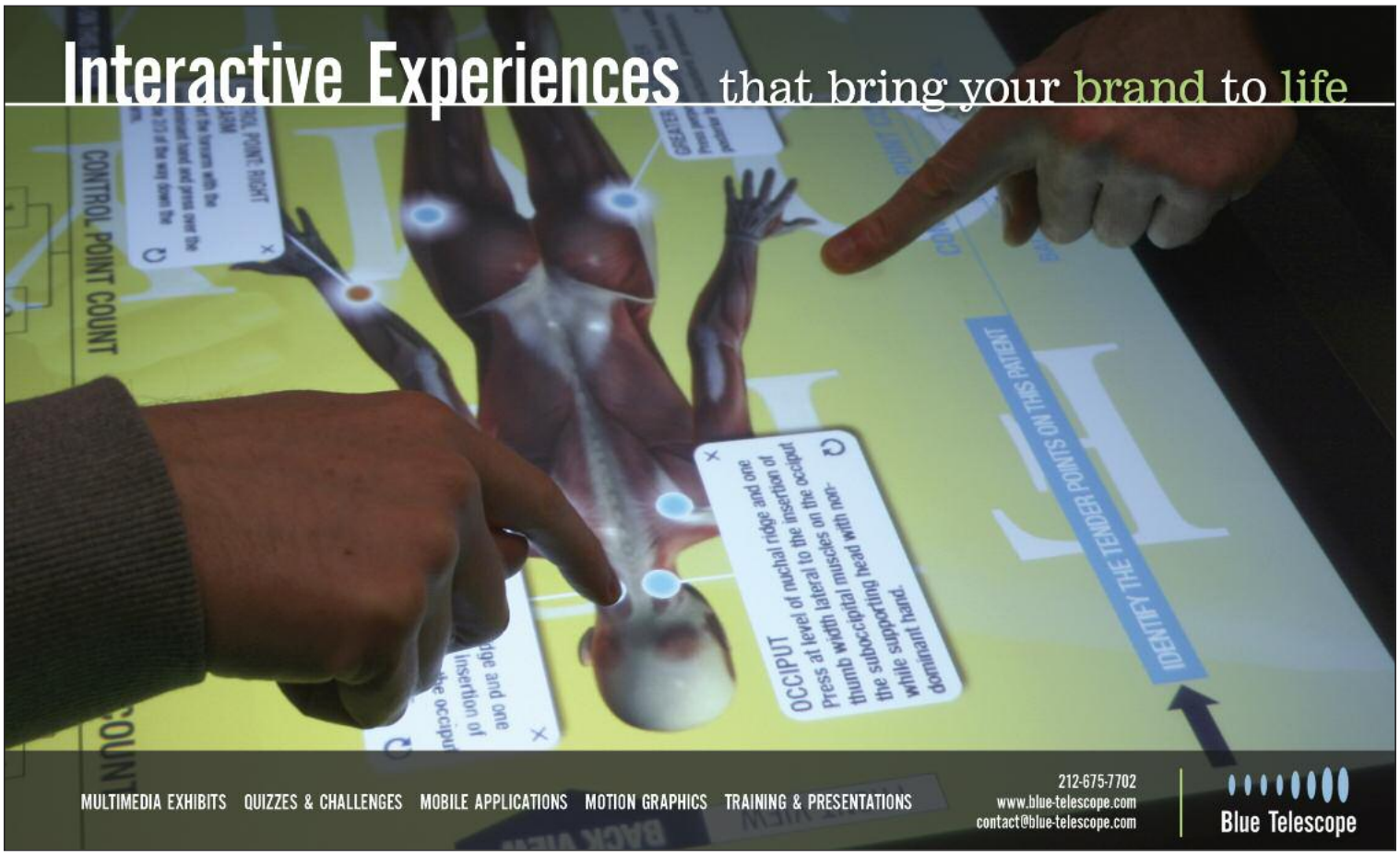
GREG SEMINACK is *President* of **CFS Clinical,** a specialty provider focused on the business and financial management activities for clinical trials.

There is a great opportunity to increase efficiencies in the processes and technologies surrounding the business side of clinical trials. Moreover, there is significant opportunity in making better connections between subjects, sites, and sponsors. Making it easier to



do business by developing best practices and leveraging technology to support the process will help reduce the time to complete a trial, improve the subject's relationship with the site, and improve the sponsor-site relationship. These improvements all lead to better subject retention, lower costs, greater transparency, and better overall managed clinical trials. In addition, instead of sponsors and CROs using software platforms, which require knowledge transfer, implementation, training, and managing a workforce, there is opportunity in providing global outsourced, turnkey services for these non-core services.

The challenges we face as a service provider in these transformational times are many. Clinical trial portfolios have been in a state of flux over the past several years as the economic model has forced change. When and if a clinical trial gets initiated or canceled has never been harder to determine. Obtaining visibility to our clients' requirements so we have the resources trained and ready to be deployed stands on top of our list of challenges.

Of course, while this unpredictability is challenging for service providers, it also creates opportunity as sponsors look to outsource to reduce fixed headcount and become more agile to navigate the fluid business demands. This paradigm change essentially shifts the workforce to the outsourced providers, and those providers that can best manage this new dynamic through efficiency will be the winners in the long run.

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MICHAEL SHERMAN is *Chief Financial Officer* of **Endocyte,** a biopharmaceutical company developing targeted therapies for the treatment of cancer and other serious diseases.

As an industry we must continue to make progress in finding more efficient and effective approaches to drug development. This means pursuing more rapid, lower cost, and lower risk methods that lead to products that have a meaningful impact on patient care and, therefore, will be valued and reimbursed.

Endocyte has fully embraced the principals of personalized medicine, which delivers the right drug to the right patient, as our mechanism to address this challenge. Resources are conserved at multiple areas along the drug development spectrum.

In addition, for oncology specifically, comparatively low historical rates of drug efficacy in this area create a demand for more targeted therapeutics, which, in combination with a companion diagnostic, are more likely to demonstrate efficacy as treatments are used in the correct patient.

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AL TOPIN is *President* of **Topin & Associates**, a full-service, independent healthcare advertising agency.

Let's make 2013 the year we all focus on impacting the most important, but vulnerable, link in our industry's communication chain. All the R&D investments, scientific breakthroughs, and marketing planning may be wasted unless we begin to improve the value of the conversation between the physician and the patient.

The conversation that occurs in that moment of truth when a patient is diagnosed and/or treatment is prescribed is the most critical driver of outcomes, positive and negative.

Pharmaceutical companies, payers, even legislators, have a critical stake in the clarity of communication that takes place in that examination room. If patients leave without fully understanding their newly diagnosed condition, if they do not understand their prescribed treatment and their own role in maintaining that treatment, there is no DTC ad, DTP brochure, or well-trained sales rep who can alter the course to a negative outcome.

Yet today, we are well aware that time-constrained physicians enter the exam room with visions of black-box warnings and REMS programs swirling in their heads while they are about to give their patient difficult news and/or a complicated treatment program. And patients now meet their doctor literally armed with information about their symptoms from the Internet — both accurate and anecdotal — and a strong-willed intention to maintain control of their medical situation.

This is not a formula for clear communication or scenario in which a sheet of information and a simplified check list will drive understanding and compliance.

So if all of us in the industry want to impact outcomes in the coming year, we must find new pathways and programs to bolster physicians and patients in this critical conversation. Pharmaceutical companies must go beyond their focus on writing a script and address the patient's unmet needs, the rest of the office staff and the patients' caregivers. Sales reps must do more than talk product and science; they must deliver the support that helps maximize outcomes for their products.

Let's make 2013 the year we all focus on the conversation between the physician and the patient — and make sure that this critical moment of truth serves the best interests of all.

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SCOTT WEINTRAUB is *Chief Marketing Officer* of **Healthcare Regional Marketing**, a strategic healthcare marketing and deployment organization.

The industry has had a lot of recent conversation about localization, but there has been very little organization or unity toward actually accomplishing best practices. A lot of the conversation centers around data: acquiring it, interpreting it, and acting on it with a local focus. However, it's clear from the inaction that healthcare companies don't know what to do with it once they have it.

It's time for healthcare to realize that both doctors and patients — and future patients — those who are not ill but who are mindful of caring for themselves and involving a professional to do it — are connected and self-educated about their healthcare.

Developing the best ways to employ the wealth of data that are available to ensure that the right doctors are with the right patients having the most fruitful conversations is critical.

It's a simple approach, but a partner needs to understand how to synthesize national performance data, qualitative data, and brand objectives into localized plans. Then it's important to identify what actually drives business success on an MSA or district level: is it efficacy; is it access; is it due to the prevalence of the disease that your brand affects?

Next, group all the similar districts according to their drivers, even if they aren't contiguous. This enables scalability.

Finally, determine what resources are already on hand that can be used to successfully bring to bear against those drivers. This will also expose where resource lacks, so a plan can be developed for specific tools and practices to affect very specific localities. PV

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