BY DENISE MYSHKO

R&D PIPELINES

A RENEWED FOCUS ON THE PIPELINE

Dr. John Arrowsmith
Thomson Reuters
"Clinical groups are no longer accepting candidates solely from within their own company; they are seeking out the best candidates."

John Blakeley
ERT
"The lack of pipeline depth and breadth still remains within many large pharma companies."

The decreasing productivity of R&D takes center stage as companies look to address the efficiency and productivity of their efforts and bring innovation back to the pipeline.

Despite steady and significant increases in R&D spending, the number of new molecular entities (NMEs) and biologic license applications (BLAs) approved have been declining over recent years.

Current biopharma R&D operating models lack the flexibility required to effectively apply research capacity to meet shifting demand, according to executives at Deloitte. As a result, R&D is plagued by operational and governance constraints that drive costs up and limit choices at key stage gates, creating a variable and unsustainable flow of low-value products through the pipeline.

To rebuild sustainable pipelines with high-value products, R&D organizations must focus on actively balancing resources across the pipeline to consistently align capacity with demand and create choices that will differentiate products, according to recent studies by Deloitte. In many organizations this will require wholesale operational, structural, and cultural transformation. Deloitte researchers say this change needs to occur now, as other options such as M&A, licensing, outsourcing, and cost-cutting alone cannot support long-term growth.

> There are currently more than 2,900 medicines in clinical trials or awaiting review by the FDA, compared with 2,400 in 2005.
>
> SOURCE: PHRMA

Doug Fambrough, CEO of Dicerna, agrees that there is an urgent need for novel drugs to fill weak pharma pipelines and sustain revenue.

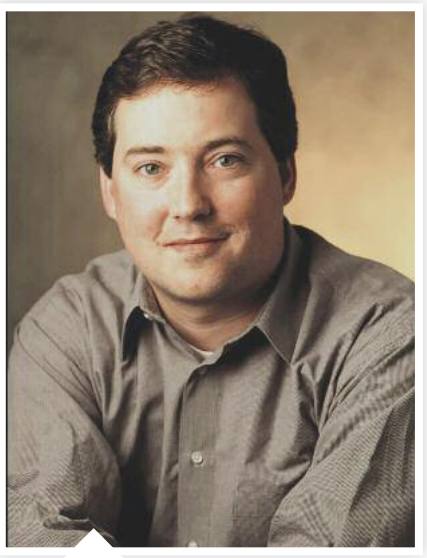
"The need for efficiency and productivity is driving an externalization of R&D from large organizations to smaller, more nimble organizations," he says. "The decreasing productivity of R&D results in fewer drugs making it through development and those that do face increased regulatory hurdles and higher market barriers, such as reimbursement hurdles, formularies, NICE, etc."

A general decline in success rates for new drugs also has taken its toll on productivity, and indicative of this is a doubling of Phase III terminations in the period 2007 to 2009 compared with those during the 2004 to 2006 period, according to research done by CMR International, a Thomson Reuters business.

John Arrowsmith, Ph.D., scientific director at Thomson Reuters, says fewer than one in 10 clinical candidates make it to market.

James Datin
Safeguard Scientifics
"Biotech companies are still willing to put products into their pipeline, but are only funding those that have the most potential and are closest to approval."

Nicholas Landekic
PolyMedix
"The big pharma companies have largely lost the ability to innovate, and investors do not have the appetite to finance innovation at small companies."



Doug Fambrough
Dicerna
"The need for efficiency and productivity is driving an externalization of R&D from large organizations to smaller, more nimble organizations."

"This has been true of the pharmaceutical industry for a long time," he says. "But new pricing pressures brought on by insurers and regulators have made it impossible for the industry to afford this high failure rate any longer. As a result, the industry is responding by demanding more productivity and innovation from its employees. In addition, pharma companies are going externally to fill their pipelines with quality candidates and more emphasis is being placed on licensing deals with biotechs and academia."

The lack of pipeline depth and breadth still remains within many large pharma companies, says John Blakeley, executive VP at ERT.

"In the smaller companies the tough economic environment of the past two years means that money remains in short supply compared with 1998," he says. "These points, combined with the fact that large pharma has also not yet fully addressed the question of drugs coming off patent, mean that there is still some uncertainty in the market."

Mr. Blakeley says because of this lack of pipeline breadth and depth, the pharma industry will increasingly seek more licensing deals, as well as continue with merger and acquisition activity.

"Bolder actions will be seen, such as the recent Sanofi-Aventis bid for Genzyme," he says. "Large sponsors will be watching the pipelines of smaller companies for strong candidates. At the point when a new chemical entity begins to look promising, there will be opportunities for combinations within the market to help continue the process. I believe that smaller companies will be developing drugs up to proof of concept and the larger companies will likely engage in licensing agreements for later-stage development and marketing."

Companies are under increased pressure to accelerate the pace of innovation as they face billions of dollars in losses from expired patent periods, and they are shifting away from blockbuster drugs and toward new sources of revenue, such as the development of vaccines

SUCCESS RATES

The top 10 pharmaceutical companies out of the world's top 50 have lower estimated overall clinical approval success rates than do smaller firms in that group, but nonetheless appeared to have some R&D productivity advantages, according to a new study completed by the Tufts Center for the Study of Drug Development.

Despite experiencing lower overall clinical success rates, the top 10 firms terminated a greater proportion of their failures in early-stage clinical testing, compared with the other 40 companies in the group, the study found. Failing early lets developers redirect resources into other projects and avoid more costly later stage failures.

The study also found that:

- Small molecules accounted for 85% of the drugs that entered the clinical pipelines of top 50 pharmaceutical firms in the 1993 to 2004 period.
- Large-molecule clinical approval success rates outpaced small molecules by almost 2:1 for each top-50 pharma size group examined.
- Across all top company size groups, transitioning compounds from Phase II to Phase III was a substantial hurdle.

Source: Tufts Center for the Study of Drug Development. For more information, visit csdd.tufts.edu.

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But what should the ideal strategy involve? A robust, patient-centric and data-driven plan that combines historical data from similar studies, a detailed protocol review and a full feasibility assessment should lie at the core of your strategy. And because studies can last up to 40 percent longer than planned,[2] your enrollment targets should be realistic too, while any recruitment milestones must be identified and corresponding contingency actions planned.

> *Because studies can last up to 40 percent longer than planned, your enrollment targets should be realistic.*

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> *Patients aren't just numbers – they're real people. And each has their own reason for enrolling.*

But having a sound strategy is only half the challenge. That's because patients aren't just numbers – they're real people. And each has their own reason for enrolling – from hope for their own health or the health of future generations to more practical benefits such as access to close monitoring and care. Only by understanding these reasons and using tools that resonate will you be able to engage patients and build a strong relationship that will aid retention and compliance.

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1. Adams, C.P. and Brantner, V.V. "Spending on new drug development," Health Economics, volume 19, issue 2, pages 130-141, February 2010.
2. Hess, J. and Litalien, S. "Web-based Patient Recruitment," Cutting Edge Information, October 2005.

Sanjeev Wadhwa
Computer Sciences
"There is increasing competition for in-licensing, and innovation is likely to come from unexpected places."

Rick Heinick
Schaffer Consulting
"There is a need to increase the flow of information across scientific disciplines, therapeutic classes, and the commercial organization."

or supplements, says Michael Naimoli, worldwide managing director at Microsoft Health and Life Sciences.

FINDING INNOVATION

To be successful, companies need to embrace a multidisciplinary approach that includes science and business, says Rick Heinick, senior partner and head of the M&A practice at Schaffer Consulting.

"Pharmacology, biostatistics, and physiology are not always in unison," he says. "There is a need for increased flow of information across scientific disciplines, therapeutic classes, and the commercial organization. The current structure has to be simplified."

Mr. Heinick says in general, companies need to acquire the portfolio to achieve speed to market.

"The best acquisitions are when the acquiring company has particular expertise that matches the market experience in the pipeline they are acquiring," he says. "Today, big pharma is steadily acquiring small biotechs, but often for the wrong reasons. Big pharma is very marketing-oriented while biotechs are more R&D-oriented. They need to make sure they don't lose pipeline value when integrating."

The smartest thing big pharma companies can do right now is buy promising early- and mid-stage biotech companies, says Nicholas Landekic, president and CEO of PolyMedix.

"Rather than looking for a $60 billion mega-acquisition, big pharma companies can pay a fraction of that for several promising companies with solid, fundamental pipelines, use the rest of the money to actually develop the products and in five years create real value instead of facing the same dry pipeline problem all over again," he says. "Unfortunately, this requires corporate compensation structures that provide rewards for building long-term value beyond just the current year, and few companies have that."

BEST PRACTICES FOR PIPELINE DEVELOPMENT

Currently pharma companies search for and pick winners after a viable product has already been developed, says Sanjeev Wadhwa, partner, director life-sciences R&D, at Computer Sciences Corp. (CSC).

"There is increasing competition for in-licensing, and innovation is likely to come from unexpected places," he says. "Pharmaceutical companies will need to search and cover a broader range of early-development activities, allowing products to evolve while retaining an interest. External innovation will need to be sourced from a much larger geographic footprint than today with a focus on determining the landscape of technologies and people, influential innovators, IP sources and capabilities, and competitor portfolios."

Mr. Wadhwa suggests companies need to take a venture capital portfolio approach.

"The outside world, using collaborative networks and observational data, is continuously motivated and positioned to know more — or claim to know more — about a product's comparative effectiveness and risks than the developer does," he says. "In the future, pharma will need to cast the net wider to search for innovation."

The result, he says, will be a turn toward in-licensing as a potent solution.

"In-licensing complements internal R&D efforts by allowing companies to react more rapidly to industry trends," Mr. Wadhwa says. "This trend also benefits smaller firms, which often lack the capital to support the expensive

Michael Naimoli

Microsoft

"Companies are under increased pressure to accelerate the pace of innovation as they face billions of dollars in losses from expired patent periods."

R&D process estimated to cost around $900 million and last up to 10 years per product."

As a result, large biopharmaceutical companies are competing intensely with each other to form alliances with small biotech firms and other research organizations.

"For example, traditionally pharmaceutical companies would in-license compounds in Phase II and drive them through the final testing and marketing stages," Mr. Wadhwa says. "But an increasing number of agreements are now being negotiated for compounds in early stages of development where costs and competition are low. Pharmaceutical companies are even beginning to offer high-success dependent payments for substances in early stages despite the six to seven years it generally takes to transition a drug from this phase to a marketable product."

> In 2009, 26 new molecular entities (NME) were launched, which is an increase of five from 2008. Half of these NME launches were by major companies.
>
> SOURCE: THOMSON REUTERS

Moreover, biopharma companies are also seeking alliances with small biotech firms, thus fueling market competition.

The prioritization of products also is a top factor for biotech firms, says James Datin, executive VP and managing director, life-sciences group, at Safeguard Scientifics.

"In 2000, the average biotech company was working on developing three products; today, it's one-and-a-half, on average," he says. "Biotech companies are still willing to put products into their pipeline, but are only funding those that have the most potential and are closest to approval."

Mr. Landekic says pharma needs to maintain a relentless discipline on the "need to have" and not on the "nice to have."

"While drug development will always be the most expensive and difficult endeavor in commerce, it is amazing how much time and money can be saved if companies can stay objective and focused on the critical path," he says.

He also suggests that companies return to drugs with acute courses of therapy.

"For years big pharma only wanted chronic therapy drugs, because of the cash flow annuity once a patient is acquired," Mr. Landekic says. "The flip side is that chronic therapies also cost much more money and take much more time to develop, with the risk of late-stage blow ups. Companies can get better bang for their buck with innovative acute therapies that offer tangible advantages, and take less time and cost much less money to develop." ✦

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JOHN ARROWSMITH, PH.D. Scientific Director, Thomson Reuters, which delivers information to decision makers in the financial, legal, tax and accounting, healthcare, science, and media markets. For more information, visit lifesciencesconsulting.thomsonreuters.com.

JOHN BLAKELEY. Executive VP, ERT, a global provider of technology and services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit ert.com.

JAMES A. DATIN. Executive VP and Managing Director, Life Sciences Group, Safeguard Scientifics Inc., which provides growth capital for life-sciences and technology companies in the molecular and point-of-care diagnostics, medical devices, regenerative medicine and specialty pharmaceuticals, and technology companies. For more information, visit safeguard.com.

DOUG FAMBROUGH. CEO, Dicerna Pharmaceuticals, a private, venture-backed, second generation RNA interference (RNAi) company developing novel therapeutic agents in multiple therapeutic areas. For more information, visit dicerna.com.

RICK HEINICK. Senior Partner and head of the M&A practice at Schaffer Consulting, where he advises CEOs and their teams on M&A integration and transformational change. For more information, visit schafferconsultingllc.com.

NICHOLAS LANDEKIC. President and CEO, PolyMedix Inc., which is developing novel, first-in-class therapies for serious, life-threatening, acute disorders. For more information, visit polymedix.com.

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» R&D PIPELINES

ENHANCING THE PIPELINE: A COMPANY BY COMPANY APPROACH

The following examples illustrate how a few biopharma companies are addressing efficiency and bringing innovation to their pipelines.

There are an estimated 550 projects in development from the top 50 companies that have the potential to add a value of more than $78 billion in additional revenue to the current pharmaceutical market by 2015, according to a recent report from Kalorama Information.

Drugs in the oncology segment are expected to make a significant impact to current markets, increasing competition and providing advanced alternatives to current therapies. Cancer drugs in development could possibly make up almost 33% of the potential value.

Here is a look at some of what our experts are doing to enhance their pipelines.

America's pharmaceutical research and biotechnology companies invested a record $65.3 billion on the research and development of medicines and vaccines in 2009. This represents an increase of more than $1.5 billion in R&D compared with 2008.

SOURCE: PHRMA

DAIICHI SANKYO

Companies will need to overcome the challenge of increasing complexity and cost related to discovering, developing, and commercializing pharmaceuticals, says Glenn J. Gormley, M.D., Ph.D., chief science officer, co-head, research and development, Daiichi Sankyo, and global head of development and president of Daiichi Sankyo Pharma Development (DSPD).

"Daiichi Sankyo is well-equipped to meet such challenges and continues to focus on addressing unmet medical needs through portfolio expansion and diversification, internal discovery and potential partnerships, and licensing activities and acquisitions," he says. "We have a long history of commitment to cardiovascular disease, and we're looking toward a new area of R&D commitment in oncology, where there continues to be a large unmet need for new treatment options.

"At Daiichi Sankyo, we are proud to be building on our legacy of innovation, particularly in cardiovascular disease, while entering new areas like oncology," Dr. Gormley continues. "We continue to look for new and innovative ways to grow through internal science and discovery, as well as external business development and licensing activities."

DICERNA

Doug Fambrough, CEO of Dicerna, says Dicerna, a biopharmaceutical company, continues to focus internally on developing its Dicer Substrate Technology for cancer indications and on developing drug delivery systems, while continuing to build on a robust strategic partnering program.

Doug Fambrough
Dicerna

"We welcome external collaborations, not only to support and grow our own programs but to help realize the great promise that we see for the application of DsiRNAs across a wide range of disease areas," he says. "The company has made tremendous progress in 2010 on the partnering front, having formed major alliances with Kyowa Hakko Kirin — a potential $1.4 billion oncology target-based deal — and Ipsen — peptide delivery collaboration, oncology, and endocrinology targets."

GEOVAX

At GeoVax, the company plans to capitalize on the use of federally funded IPCAVD (Integrated Preclinical/Clinical AIDS Vaccine Development Program) grants, says Robert McNally, Ph.D., president and CEO of GeoVax.

Dr. Robert McNally
GeoVax

"In the next five years and in the long-term, we plan to expand GeoVax's corporate HIV vaccine technology to include variations suitable for

the developing world where there is a great need for this technology," he says.

MILLENNIUM: THE TAKEDA ONCOLOGY COMPANY

Millennium Pharmaceuticals, The Takeda Oncology Company, has undertaken several measures over the past few years in an effort to further enhance its pipeline and development productivity.

"We have implemented a comprehensive outsourcing strategy for several development areas," says Claire Thom, Pharm.D., senior VP, portfolio management, at Millennium: The Takeda Oncology Company. "Millennium has initiated a strategic translational medicine team and allocated resources internally via a rigorously applied prioritization process.

"Finally, our business development team works hard to bring in external opportunities to supplement our in-house discovery output," Dr. Thom adds.

Over the next five years, Millennium will continue with its strategic business development initiatives as a way of ensuring pipeline growth, she says.

"In addition, I see the company improving its internal path to proof of concept, as well as our discovery advancement criteria and internal governance over the process," Dr. Thom says.

NOVARTIS

Mark Fishman
Novartis Institutes for BioMedical Research (NIBR)

According to Mark Fishman, president of NIBR, eight years ago Novartis Institutes for BioMedical Research (NIBR) set a course for research that remains unchanged: focus on patient need, sound science, and early clinical insights.

"Our R&D philosophy is founded on two pillars: an unwavering commitment to address unmet medical need and the pursuit of fundamental disease mechanisms," he says. "Unmet medical need does not refer to the market size, but rather a patient or a group of patients who need a medicine. Our research approach centers on studying diseases with smaller patient populations that share pathways with diseases of larger patient populations. By targeting relatively homogeneous diseases, we get robust data with relatively few patients and can rapidly establish the potential for the compound and its target. This approach has improved the success rate from discovery through development."

NUPATHE

Jane Hollingsworth
NuPathe

At NuPathe, a specialty pharmaceutical company focused on diseases of the central nervous system, the company's pipeline is powered by proprietary technology platforms, including SmartRelief, a transdermal medication delivery technology based on iontophoresis, and long-acting delivery (LAD) technology.

"NuPathe's most advanced product candidate, Zelrix, is a single-use, transdermal sumatriptan patch being developed for the treatment of migraine," says Jane Hollingsworth, CEO of NuPathe.

"In addition to Zelrix, NuPathe has two proprietary product candidates in preclinical development: NP201 for the continuous symptomatic treatment of Parkinson's disease, and NP202 for the long-term treatment of schizophrenia and bipolar disorder.

"We have focused on innovation with critical analysis of the risks associated with each development project," Ms. Hollingsworth continues. "This approach is essential for success since the risk/benefit ratio of each major decision along the way needs to be carefully and thoughtfully considered."

REGULUS

Dr. Kleanthis Xanthopoulos
Regulus Therapeutics

Kleanthis Xanthopoulos, Ph.D., president and CEO of Regulus Therapeutics, a biopharmaceutical company focused on microRNA therapeutics, says his company's strategy is to establish a limited number of significant and credible partnerships with companies that have specific therapeutic area expertise to help drive the development of novel microRNA therapeutics.

"At Regulus, we are maintaining a significant 'brain trust' of outstanding talent within the company, outsourcing activities that can be done more efficiently elsewhere and always staying focused on high pay-off activities," he says.

ROCHE

Jean-Jacques Garaud
Roche

According to Jean-Jacques Garaud, global head of pharma research and early development (pRED) at Roche, it is essential for the pharmaceutical industry to have a much better understanding of disease biology in order to enhance R&D productivity.

"To address this, we are conducting more research in the area of translational medicine not only in-house but also via our translational research hubs, so that we understand the key mechanisms and pathways associated with diseases," Mr. Garaud says.

Roche, he says, has additionally implemented diagnostics into its overall research and development plans to identify biomarkers early in the discovery process (and to

GLOBAL PHARMACEUTICAL MARKET R&D IMPACT

Therapeutic Category	No. of Late-Stage Projects	Potential Impact by 2015 ($ in Billions)
Cardiovascular/Blood	72	$13
Neurotherapeutics	81	$9
Infection	45	$5
Oncology	149	$26
Respiratory/Inflammatory	50	$7
Gastrointestinal	12	$2
Other*	141	$16
Total	550	$78

*Other includes: dermatology, other than antifungals; fertility; hormones; diabetes treatments; osteoporosis; renal disease; ocular treatments, other than infection; and other areas not included in one of the six general segments.

Source: Kalorama Information.
For more information, visit kaloramainformation.com.

effectively stratify patients for its clinical trials) that will translate into viable clinical outcomes."

SANOFI-AVENTIS

Sanofi-Aventis' R&D strategy includes pooling expertise and creativity from a range of internal and external sources — biotech companies, universities, research centers, and specialty pharmaceutical companies — to speed the discovery and development of innovative health solutions for patients, says Paul Chew, M.D., senior VP, U.S. chief medical officer/chief scientific officer, at Sanofi-Aventis US.

Dr. Paul Chew
Sanofi-Aventis US

"Our strategy is to leverage our internal expertise along with external collaborations as this will be the engine to help drive success," he says. "Sanofi-Aventis will continue to create partnerships wherever the best science and the best technology may be. We are moving a step further from being a preferred partner to building a preferred network through an open innovation strategy where Sanofi-Aventis is a networked organization at the center of the innovation engine." ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

CLINICAL TRIALS GROW IN COMPLEXITY

Growing clinical trial complexity continues to challenge the ability of pharmaceutical and biotechnology companies to contain the ever-rising cost of developing new drugs, according to the Tufts Center for the Study of Drug Development.

The study found that the median number of procedures per clinical trial increased by 49% between 2000 and 2003 and between 2004 and 2007, while the total effort required to complete those procedures grew by 54%.

The rise in the number of eligibility criteria used to screen volunteers has contributed to a decline in volunteers enrolling in clinical trials. And once volunteers enroll, the larger number of procedures per protocol is dissuading study volunteers from staying in trials through to completion.

The analysis also found:

- Wide variability exists in complexity and execution burden per protocol between therapeutic areas and clinical study phases, indicating opportunities to streamline design.
- Between 2002 and 2007, protocols targeting diseases in oncology, immunology, and the central nervous system experienced the most rapid growth in the total number of procedures and in the burden to execute those procedures.
- Overall growth in complexity and execution burden grew at the slowest rate for protocols in Phase III studies, as companies, looking to contain costs, gathered more data in early phases of clinical research.

Source: Tufts Center for the Study of Drug Development. For more information, visit csdd.tufts.edu.

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PAUL CHEW, M.D. Senior VP, U.S. Chief Medical Officer/Chief Scientific Officer, Sanofi-Aventis US, a global pharmaceutical company that discovers, develops, and distributes therapeutic solutions to improve the lives of everyone. For more information, visit sanofi-aventis.us.

MARK FISHMAN. President, Novartis Institutes for BioMedical Research (NIBR), the global pharmaceutical research organization for Novartis committed to discovering innovative medicines that treat disease and improve human health. For more information, visit nibr.com.

JEAN-JACQUES GARAUD. Global Head of Pharma Research and Early Development (pRED), Roche, which addresses unmet medical needs from early detection and prevention of diseases to diagnosis, treatment, and treatment monitoring. For more information, visit roche.com.

GLENN J. GORMLEY, M.D., PH.D. Chief Science Officer, Co-Head, Research & Development, Daiichi Sankyo; Global Head of Development, President, Daiichi Sankyo Pharma Development (DSPD), a member of the Daiichi Sankyo Group, which is dedicated to the creation and supply of pharmaceutical products to address the unmet medical needs of patients in both mature and emerging markets. For more information, visit dsi.com.

JANE H. HOLLINGSWORTH. CEO, NuPathe, a specialty pharmaceutical company focused on the development and commercialization of branded therapeutics for diseases of the central nervous system, including neurological and psychiatric disorders. For more information, visit nupathe.com.

ROBERT T. MCNALLY, PH.D. President and CEO, GeoVax, a biotechnology company developing human vaccines for diseases caused by HIV-1 (Human Immunodeficiency Virus - AIDS) and other infectious agents. For more information, visit geovax.com.

CLAIRE THOM, PHARM.D. Senior VP, Portfolio Management, Millennium: The Takeda Oncology Company, which is focused exclusively in oncology to improve the treatment of cancer around the world. For more information, visit millennium.com.

KLEANTHIS XANTHOPOULOS, PH.D. President and CEO, Regulus Therapeutics Inc., a biopharmaceutical company leading the discovery and development of a new class of high-impact medicines based on microRNAs. For more information, visit regulusrx.com.

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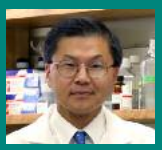

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