MENTAL HEALTH: AN INSURANCE INDUSTRY PERSPECTIVE

How payers look at priorities for care in a time of policy uncertainty and growing concerns in the patient advocacy community

No group of stakeholders wields greater influence over patient access to medicines than payers making reimbursement and formulary decisions. Even in a time of policy upheaval in Washington, health plans must make sure members get the medicines they need. Insurers say they're committed to this role when it comes to mental health conditions, which affect one in five American adults. And they say their commitment won't change regardless of how the policy landscape may shift in Washington. In more than 15 hours of interviews with researchers at inVentiv Health, executives at managed care organizations covering more than 59 million lives talked about issues that are top of mind for patients, including medication access and psychiatric care. They understand the requirements to manage mental health conditions at parity with other physical health conditions. But their determination to solve problems goes beyond parity. The following report documents payers' views on the obstacles to effective mental health coverage and how to overcome them.

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INTRODUCTION

Advocacy organizations in mental health have watched with alarm as Congress and a new administration in Washington tackle the complex task of repealing and replacing the Affordable Care Act (ACA). The focus of attention, for many groups, is the future of state Medicaid expansion under the ACA. Medicaid is the primary funder of care for people with psychiatric conditions who have little or no income. For such individuals, "nothing matters more than the Medicaid expansion," Charles Ingoglia, senior vice president of the National Council for Behavioral Health told inVentiv Health in an interview shortly after the November 2016 presidential election. Ingoglia's views, and those of other advocacy groups, were published in a January 2017 inVentiv Health white paper titled "An Advocacy Rx for Progress in Mental Health."

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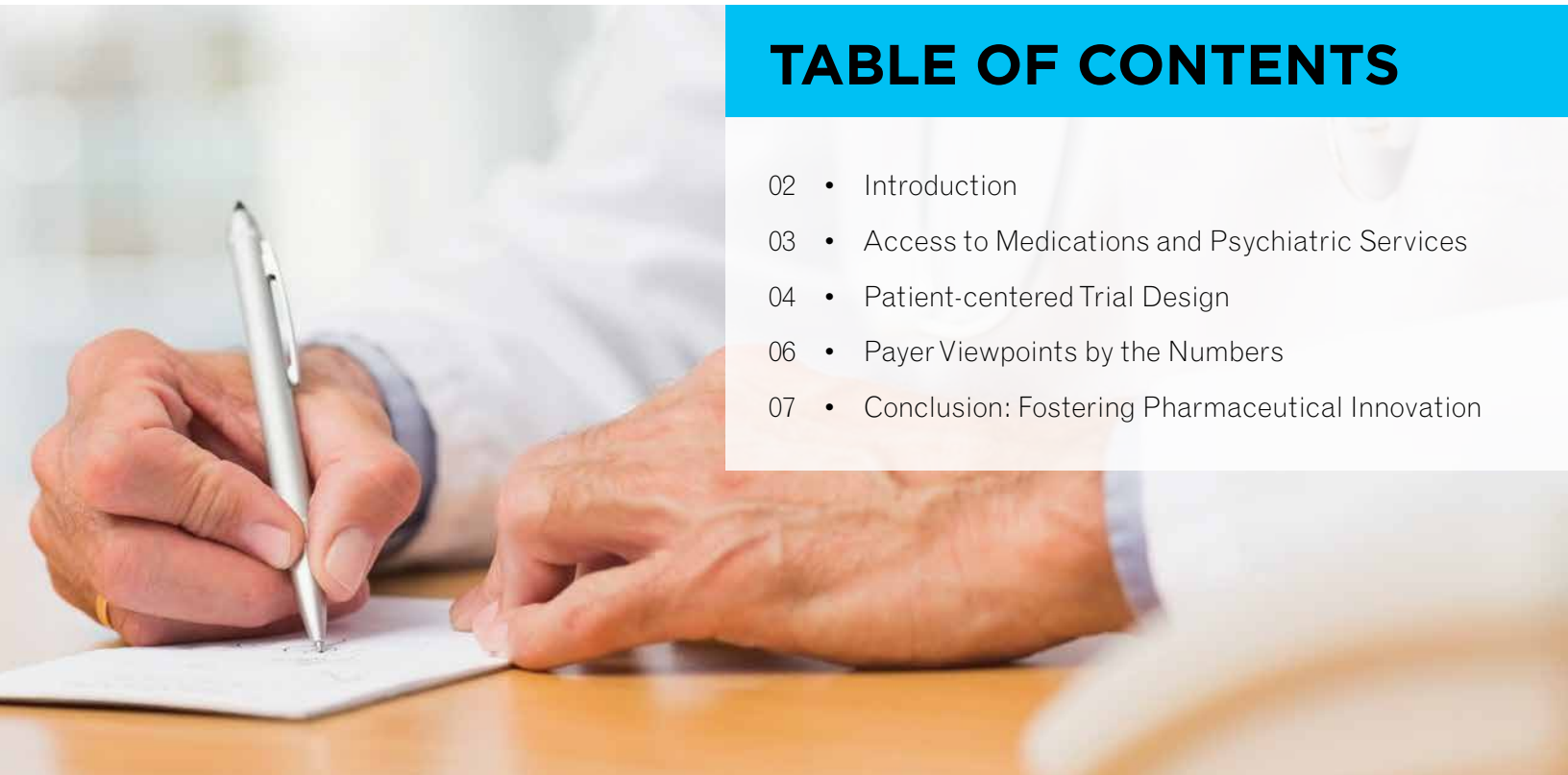
>
> **CHARLES INGOGLIA, SENIOR VICE PRESIDENT OF THE NATIONAL COUNCIL FOR BEHAVIORAL HEALTH**

While defending Medicaid is a high priority, patient and advocacy concerns are broader than that. People with mental health conditions who are on private or employer-funded plans also have faced significant barriers in seeing psychiatrists and getting coverage for newer and more expensive medications. These problems existed for many years prior to the ACA, and have persisted in the seven years since the law was enacted.

Advocacy groups who spoke with inVentiv Health last fall share two goals that have particular relevance to payers. First, individuals who may be taking medications over many years would like to improve access to drugs they need at a time of rising premiums and deductibles. Second, most advocacy organizations want to expand the involvement of patients in the early stages of clinical trial design. While payers aren't directly involved in this process, "pharmaceutical companies test products with an eye on endpoints and real-world evidence that matters to health insurers," said one advocacy leader. In addition, many patient groups are searching for new ways to foster innovation leading to better psychiatric treatments. It's a goal that has the full support of the payer community—as long as drugmakers can demonstrate better outcomes to justify the higher prices payers will be asked to shoulder.



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ACCESS TO MEDICATIONS AND PSYCHIATRIC SERVICES

Most payers interviewed by inVentiv Health reported that mental health is a moderately expensive condition—well below the spending norm for cancer, or for illnesses such as hepatitis C, where costs are driven by branded, specialty drugs. Costs in mental health are concentrated in hospitalizations and inpatient care, rather than on the pharmacy side. One reason is the wide availability of generics in categories such as atypical antipsychotics for schizophrenia and SSRIs for depression.

The availability of generics also explains why relatively few payers we interviewed saw a need to "actively manage" or restrict pharmaceutical benefits. Just under a quarter of payers said they employed step edits (also known as "fail first" policies) to make sure patients try generic treatments before using more expensive, branded medications. Only one payer employed a double-step restriction on the branded products within his plan, requiring patients to try and fail two generic options.

> Prescribing decisions should be left to the physician.
>
> **PAYER RESPONDENT**

In addition to the relatively low cost of drugs, the unpredictable nature of mental illness and the variety of individual patient needs have persuaded many payers to avoid restricting access. "Prescribing decisions should be left to the physician," one payer told us, expressing a strong consensus view. Most executives said they didn't anticipate changing their approach in the near future—regardless of what happens to the ACA.

Payers were divided on their disposition toward injectable drugs versus oral medications. Some felt that benefits such as longer activity and greater likelihood of patient compliance justified paying a higher price. That doesn't mean they encouraged broad use of more expensive treatments. Indeed, a number of payers were skeptical about the advantages of injectables, even when it comes to claims of improved medication adherence.

Quality care also hinges on "network adequacy"—the individual's ability to locate and consult with in-network professionals. Unfortunately, in many parts of the US, the number of psychiatrists participating in health plans has been steadily declining. Advocacy groups believe insurers could address the shortage by raising reimbursement rates. Several payers we spoke with agreed that this might make a difference. The majority, however, believe the burden is on society to find incentives that will bring more doctors into the field. They also noted that shortages of psychiatrists are no worse than shortages of in-network dermatologists, neurologists, and other specialists. "This is not, fundamentally, a reimbursement issue, and is not something managed care organizations necessarily can solve," we were told.

ON THE ISSUE OF PSYCHIATRIST SHORTAGES, ONE PAYER NOTED,

> "This is not, fundamentally, a reimbursement issue, and is not something managed care organizations necessarily can solve."

One hopeful message emerged from our discussions of network adequacy. Many payers said their organizations are making rapid strides in the use of telemedicine, including videoconference technology that enables a relatively small number of in-network specialists to engage with a large number of patients over a wide geographic area. Payers said this technology could make a difference with conditions such as major depression, but were less sanguine about psychosis. "Telepsychology has been around a long time," said one payer, a licensed physician. A camera can make the process incredibly efficient, "but imagine when you are working with a patient who has been diagnosed with schizophrenia and is experiencing paranoia. The patient must feel comfortable."

PATIENT-CENTERED TRIAL DESIGN

Advocacy groups in mental health, as in other disease categories, have long argued that clinical trials should be designed with more input from patients. Consider the risks and benefits of a new antidepressant, for example. From patients, the trial sponsors may learn that a lower dose is optimal, even if the mood-altering benefit is less. Why? Because the patient's worries about weight gain, cognitive impairment, or other side effects may outweigh the desire for a stronger "kick" from the drug. Without patient input, the manufacturer would never know.

Payers we interviewed understand the argument. Ultimately, however, they're interested in trial endpoints that prove the drug delivers on its promise. They recognize that subjectivity is unavoidable when assessing drugs designed to reduce symptoms of mental distress. Even so, nearly all payers we spoke with said they did not wish to see clinical trials of psychiatric drugs place greater weight on patient-reported outcome (PRO) measures.

Our conversations, which followed a discussion guide rather than a formal survey, did not elicit payers' thoughts about rigorously validated PROs, including tools developed under the PRO Measurement Information System (PROMIS®) initiative sponsored by the National Institutes of Health. In our discussions, payers' objections focused on traditional, FDA-defined PROs—namely, reports that come directly from patients without amendment or interpretation by a clinician. For a deeper look at the concerns of patients and advocacy groups, please see our companion white paper, "An Advocacy Rx for Mental Health."

Payers also took a dim view of quality-adjusted life years (QALY) data, a measure of disease burden that seeks to capture both quality and quantity of life lived. In our research, not one payer said QALY data would matter when discussing a drug's value at a pharmacy and therapeutics (P&T) meeting. As one interviewee explained, the measure is not helpful because any product would have to show a value of $50,000 per member per year—an unrealistic goal in most categories, and especially in mental health.

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Many payers expressed skepticism toward comparative effectiveness research (CER), an analytical tool that has meaning to many patient advocates. The snag, in this case, has less to do with subjectivity than logistics. With so many generic products on the market, payers said few biopharma companies would want to spend money on head-to-head trials. Lack of predictability in patient response also presents challenges, payers said. And even when a study appears to show that drug A yields better outcomes than drug B, it's hard to project those data into a real-world setting to see how it will affect costs. "There is rarely a large spread between the reported efficacy of products," one payer explained. "It's frequently something like 42% improvement vs 37% improvement, and what does that even mean?"

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PAYER RESPONDENT

Pharma companies are aware of insurers' concerns regarding CER, according to Cutting Edge Information, a business intelligence firm that recently surveyed manufacturers on this matter. "Among companies we spoke with, there was recognition that payers are skeptical of CER models built internally by drug manufacturers," says Cutting Edge Senior Consultant Jacob Presson. "Teams responsible for developing this information are struggling to find alternatives that are worth the significant investment these trials require."

The recent rush by biopharma companies to generate health economics and outcomes research (HEOR) is also viewed through a cynical lens. Payers characterized these types of studies as biased—not in their design, but in their

reporting. As one payer phrased it, "No manufacturer has ever publicized a study that didn't show their product saving payers stacks of money, but these savings are rarely, if ever, realized within the payer's own plan." Pharmaceutical companies may not be surprised by the skepticism, but they say the intention of these economic models is to support a conversation.

Given prevailing skepticism, what clinical trial enhancements would make a difference to payers? Many told us trials of psychiatric drugs are too short, typically tracking patients for as few as six weeks. But patients often take the drugs for more than a decade. Payers would like to see products that demonstrate benefits after months, or even years, of use.

Once drugs clear the FDA, rigorous phase IV (post-marketing surveillance) studies are highly desirable, payers told us, and could sway a P&T committee in matters such as the use of step edits or formulary placement. The good news is, "the number of post-marketing studies conducted in support of psychiatric products is on the rise, with an emphasis on cost effectiveness and long-term effectiveness," said Presson at Cutting Edge.

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> **JACOB PRESSON,**
> **CUTTING EDGE SENIOR CONSULTANT**

PAYER VIEWPOINTS **BY THE NUMBERS**

In interviews with inVentiv Health, 13 insurance industry leaders spoke frankly about hurdles confronting Americans with mental health conditions.

In interviews, payers acknowledged patients face access issues...

85% said "network adequacy" problems exist in their areas, including shortages of psychiatrists and psychologists

100% noted that shortages of specialists aren't unique to mental health

92% said these problems require "societal" changes, and can't be fixed simply by raising reimbursement rates

...yet relatively few insurers required prior authorizations, a method of restricting use of branded medications

54% applied prior authorizations to assure appropriate use of certain branded products

15% imposed National Drug Code (NDC) blocks—the most stringent form of restriction—on some branded drugs that had generic versions available

23% of payers had step edits requiring patients to "fail first" on generic drugs before using branded medications

Payers appreciate well-vetted outcomes data, but many questioned the need for wider use of patient-reported outcome (PRO) measures

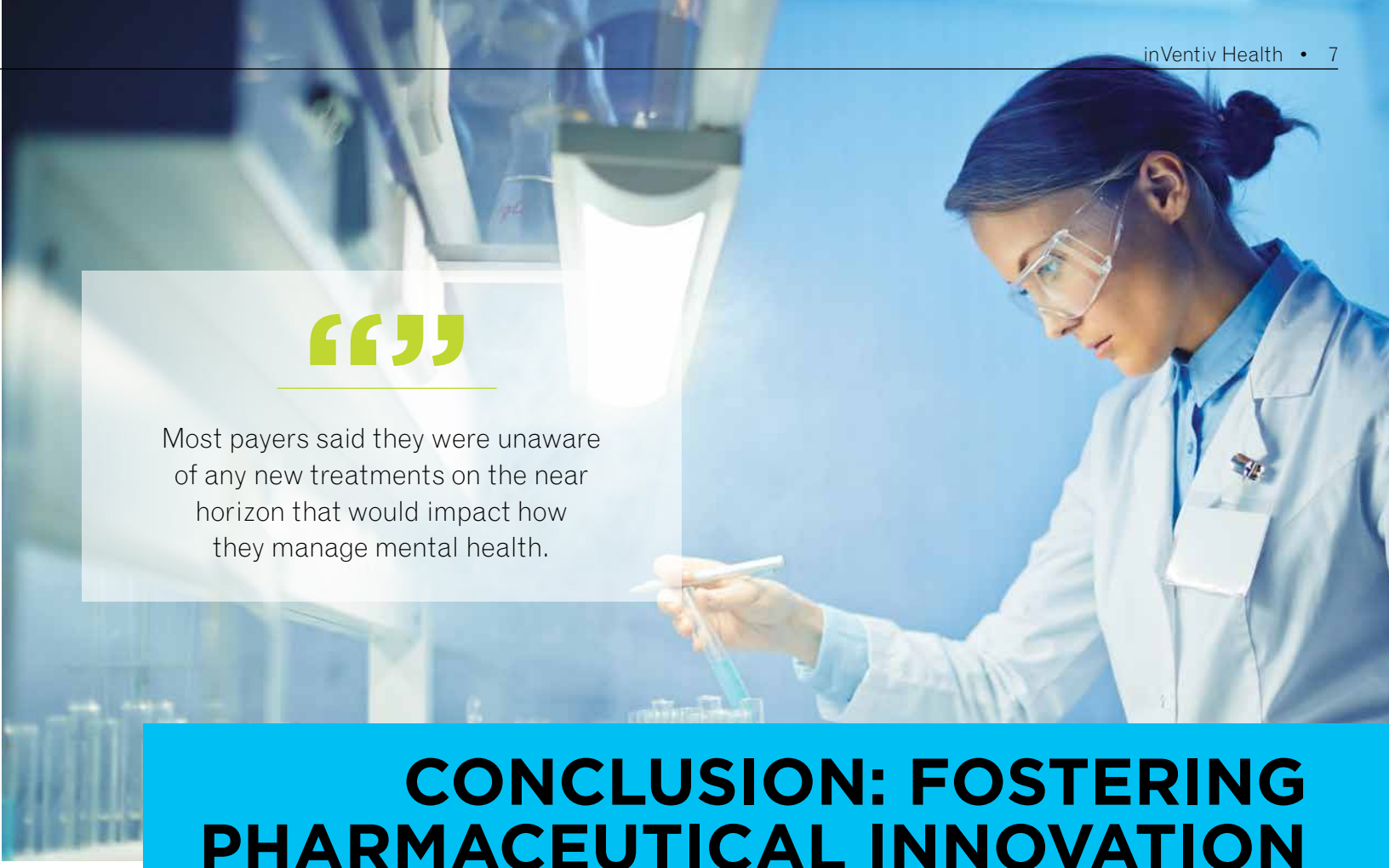
92% didn't want to see wider use of patient-reported outcome (PRO) measures

62% said comparative effectiveness studies, while generally useful, lose applicability in markets like mental health that are crowded with alternatives

69% wouldn't place much stock in health economics and outcomes research (HEOR) generated solely by a product manufacturer without third-party corroboration

100% said they had no interest in seeing quality-adjusted life years (QALY) data

*Payers were not asked their opinions on PRO Measurement Information System (PROMIS®) or other tools designed to standardize and validate the interpretation of patient responses.



> Most payers said they were unaware of any new treatments on the near horizon that would impact how they manage mental health.

CONCLUSION: FOSTERING PHARMACEUTICAL INNOVATION

In terms of pharmaceutical development, several payers expressed concern that the mental health category has been stagnant for several years. Most said they were unaware of any new products on the near horizon that would impact the marketplace or how payers manage the category.

The perceived innovation deficit isn't limited to treatments. Advanced assays for early detection of mental illness are woefully lacking when compared with areas such as heart disease, diabetes and cancer. It's unfortunate, payers say, because early detection makes an enormous difference in patients' lives and costs. While simple questionnaires to detect depression are becoming standard in primary care, "I don't know of good screening tools for other behavioral health conditions," one payer told us. "Is that because people have lobbied harder for the use of these tools with depression? Or is bipolar disorder intrinsically harder? We have to answer that question."

Even if screens existed, payers noted additional obstacles to overcome. Often, signs of schizophrenia and bipolar disorder first appear in late adolescence and early adulthood. These are among the age groups least likely to show up for an annual physical or primary care visit where, logically, doctors would use these early diagnostic tools.

Is the lack of early screening for schizophrenia something the insurance industry can solve? Payers don't believe so. Indeed, many of the issues that matter most to patient advocacy groups need to be elevated to bigger forums that are empowered to steer public policy, payers say.

The tragic fact is that serious mental illness is often accompanied by impoverishment, homelessness, and a crippling assortment of comorbidities. Examining these consequences through the lens of health insurance is like using a magnifying glass to study a forest. Payers interviewed by inVentiv Health consistently and repeatedly expressed sympathy for patients and their families. What they were unable to provide—because no single stakeholder possibly can—was off-the-rack solutions to the monumental challenges mental health conditions pose in an era of cost control and policy uncertainty.

However, payers told us, they are finding more occasions to have frank discussions with patient advocates, pharmaceutical executives, physicians and policymakers at state and federal levels. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) organizes events that bring all of these stakeholders together, and cross-industry attendance is also increasing at meetings of the Institute for Economic and Clinical Review (ICER). "In face-to-face meetings at these events, we're learning about the consequences of an illness from each individual perspective," one payer told us. It's hard to think of a time when such moments of convergence have mattered more.

ABOUT INVENTIV HEALTH

inVentiv Health is a global professional services organization designed to help the biopharmaceutical industry accelerate the delivery of therapies to market. Our combined Clinical Research Organization (CRO) and Contract Commercial Organization (CCO) offer a differentiated suite of services, processes and integrated solutions designed to improve client performance.

At critical points across the process, we're able to help clients navigate obstacles to effective mental health drug development and commercialization.

NEUROSCIENCE EXPERTISE FOR PHASE I-IV CLINICAL DEVELOPMENT

inVentiv Health has extensive expertise with neuroscience indications, including the design, execution, analysis and interpretation of studies in a variety of neuroscience disorders. We integrate outstanding scientific and medical support with effective, therapeutically specialized operational teams to achieve the best possible scientific design and study execution for our clients. This includes psychiatric trials involving more than 1,800 sites and 16,000 globally. Our team of physicians, neurologists and neuroscience investigators share their deep insights to bring innovative science to our trials.

For more information, please contact **Eileen Harvey** at **eileen.harvey@inventivhealth.com**.

MARKET ACCESS RESEARCH

The dedicated market access research team at inVentiv Health Research and Insights uncovers unprecedented insights into what payers and other key access stakeholder are looking for from a manufacturer across the clinical and commercialization process. We're able to do this by leveraging our proprietary market access panel to provide clients with quick access to a broad range of market access stakeholders, including our group of payers that represent more than 90% of total covered lives in the US. We apply our extensive payer experience to ask this panel, better, more nuanced questions that produce actionable insights, leading to meaningful results.

For more information, please contact **Kelly White** at **kelly.white@inventivhealth.com**.

ADVOCACY PATIENT ENGAGEMENT SOLUTIONS

Our team brings decades of experience in advocacy consulting for pharmaceutical, biotech and device companies, and patient and advocacy organizations. As a result, our experts are adept at bridging the gap between patients and companies to find mutual solutions and support new and existing treatments that improve patient care. Traditionally, the patient voice has been limited to discrete points later in the product development lifecycle. inVentiv Health helps clients infuse the patient voice throughout clinical development and commercialization with input mechanisms providing a continual feedback loop.

For more information, please contact **Jeanine O' Kane** at **jeanine.okane@inventivhealth.com** or visit **inventivhealth-pr.com/advocacy**.

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