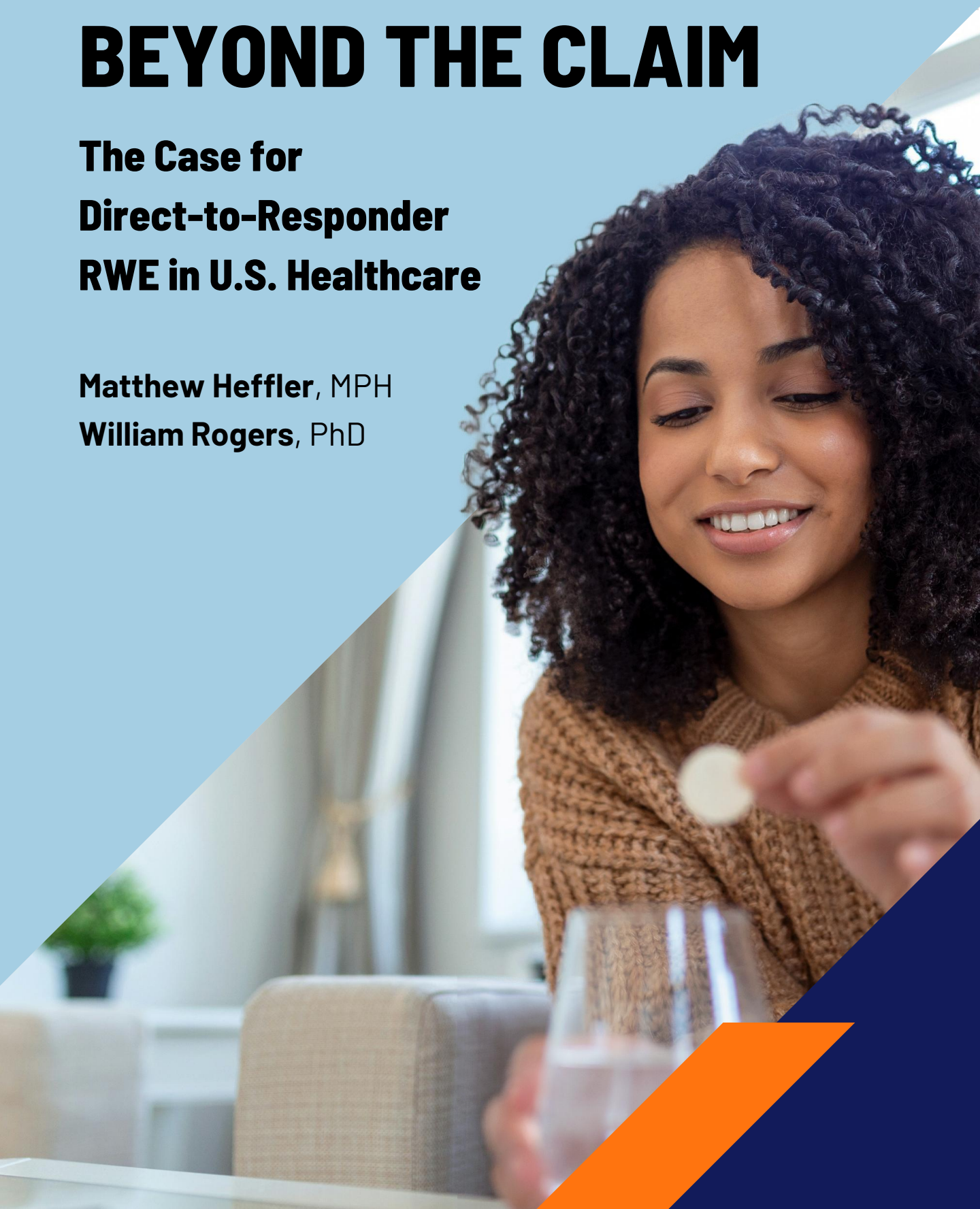
BEYOND THE CLAIM

The Case for Direct-to-Responder RWE in U.S. Healthcare

Matthew Heffler, MPH
William Rogers, PhD



Introduction

Real-World Evidence (RWE) has become a cornerstone of modern healthcare research, offering insights into how treatments and health interventions perform outside the controlled settings of clinical trials. In the United States, claims data—administrative records generated by insurance transactions—has long served as the primary source of RWE. Yet the structural realities of the American healthcare system introduce significant and often underappreciated gaps in this data.

This paper explores how the U.S. healthcare landscape is uniquely characterized by three intersecting challenges:

- A fragmented, multi-payer insurance ecosystem
- High rates of patient dropout driven by cost and access barriers
- A large, structurally invisible over-the-counter (OTC) medication market

Together, these forces render claims based on secondary RWE systematically incomplete. Direct-to-Responder RWE—data collected directly from patients and consumers through representative survey panels—is not merely a supplement to claims data, but an essential corrective that restores the patient voice, captures OTC behavior, and ensures that the full spectrum of U.S. healthcare experience is represented in research.

The United States is one of only two countries globally (alongside New Zealand) that permits direct-to-consumer pharmaceutical advertising, creating a unique environment where patients actively seek specific branded treatments—a dynamic that shapes both OTC purchasing and prescription request behavior.

Navigating the limitations of claims data in the U.S.

The fragmented insurance landscape

Unlike single-payer systems common in many European countries or the UK's National Health Service, the United States operates through a fragmented multi-payer system comprising private insurers, employer-sponsored coverage, and government programs (Medicare for seniors, Medicaid for low-income populations). Research published in JAMA Health Forum, as part of the series Healthcare Affordability in the United States, has documented this fragmentation in detail[1]. Insurance coverage in the U.S. is not a monolithic status but a fluid, often interrupted condition. Millions of Americans cycle between employer-sponsored plans, marketplace coverage, Medicaid, and periods of no insurance within a single year. Each transition represents a break in the claims record—a gap during which healthcare utilization, medication adherence, and symptom burden can simply disappear from the data.

The consequences for RWE are profound. A patient who is prescribed biologic therapy under employer-sponsored insurance, loses that coverage during a job transition, manages symptoms with OTC medications for three months, and then re-enters the system under Medicaid, appears in the claims record simply as two separate entries without any of this key context.

This is not a marginal data quality issue. The Commonwealth Fund and other health policy researchers have documented that insurance churning disproportionately affects working-age adults with lower incomes, racial and ethnic minorities, workers in part-time or gig economy employment, and residents of states that did not expand Medicaid under the Affordable Care Act[1]. The Affordable Care Act (ACA), enacted in 2010, provided states the option to expand Medicaid eligibility. As of 2024, ten U.S. states have not adopted this expansion, leaving coverage gaps that vary significantly by geography – a dynamic unfamiliar in countries with universal coverage systems. These are precisely the populations whose healthcare experiences are most shaped by cost and access barriers—and most underrepresented in claims-based RWE.

Economic implications and patient drop-off

Financial barriers represent one of the most powerful forces shaping real-world healthcare behavior in the U.S.—and one of the most systematically undercounted by claims data. When patients cannot afford their medications, their copays, or their specialist visits, they do not generate claims. They simply exit the system, often silently and without any administrative footprint.

The scale of this phenomenon is substantial. A study published in Health Affairs[2]has found that cost-related medication non-adherence affects an estimated 20–30% of American adults in any given year. Patients skip doses, split pills, delay refills, or abandon prescriptions entirely based on out-of-pocket costs. Approximately one in four U.S. adults with a chronic condition report having not filled at least one prescription in the past year due to cost. These behaviors generate no claims—they are absences, not events.

Beyond medication adherence, financial barriers drive patients to defer or forgo care entirely. The Centers for Disease Control and Prevention (CDC)'s National Health Interview Survey consistently finds that roughly 10% of Americans report having delayed or forgone medical care in the past year due to cost[3].

For lower-income adults and the uninsured, this figure is substantially higher. These deferrals represent real health events—exacerbations, untreated comorbidities, delayed diagnoses—that shape disease trajectories but are systematically absent from claims data.

The result is a systematic skew in claims-based RWE toward patients who are better insured, more financially stable, and more consistently engaged with the formal healthcare system. Research built on this data will, by construction, reflect the experiences of a more advantaged subset of patients and may generate conclusions that are structurally inapplicable to the patients with the greatest need and not representative of the real-world patient population.

The influence of the over-the-counter (OTC) market

OTC market scale and trends

The U.S. over-the-counter drug market represents a significant and rapidly growing segment of total healthcare utilization—one that is almost entirely absent from claims-based real-world data (RWD). By its nature, the OTC market operates outside the prescription and reimbursement infrastructure that generates administrative claims data. When a patient purchases ibuprofen for chronic pain management, melatonin for a sleep disorder, or a proton pump inhibitor for acid reflux, no claim is filed and no data record is created.

The transaction is complete, but from the perspective of secondary data analysis, it never happened.

The scale and regulatory framework of the U.S. OTC market differs substantially from other regions. In many European markets and the UK, certain medications available OTC in the U.S. remain prescription-only, and pharmacy-mediated sales create different data capture opportunities. The invisibility described here is particularly pronounced in the U.S. context.

> **In many European markets... certain medications available OTC in the U.S. remain prescription-only**

The U.S. Consumer Healthcare Products Association (CHPA) estimates the domestic OTC drug market at approximately $58 billion annually and could exceed $60 billion by 2027[4].

Multiple intersecting trends drive this growth:

Cost-conscious consumers

Those seeking less expensive alternatives to prescribed medications

Prescription only drugs switching to OTC

The increasing number of drug transitions by the U.S. Food and Drug Administration (FDA)

Direct-to-consumer advertising

Heavy investment in pharmaceutical advertising targeted at and delivered directly to the consumer

Cultural shift

A broader cultural shift in some demographics toward self-managed health practices

Several therapeutic categories within the OTC market are particularly large and relevant to conditions that are also the focus of pharmaceutical RWE. Sleep aids represent one of the most noteworthy growth areas: the OTC sleep aid market is estimated at approximately $800 million annually and growing at roughly 5% per year[5], driven by rising rates of reported sleep disturbance and increased awareness of sleep health. Analgesics and pain relievers, including nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, and topical agents; allergy medications; digestive health products; cough and cold remedies; and dermatological topical treatments (i.e., for dermatitis) are also major categories.

Impact on healthcare data representativeness

The invisibility of OTC utilization in claims data creates specific and consequential distortions in secondary RWE analysis, especially in areas such as the assessment of treatment patterns in certain therapy areas. When a patient transitions from a prescription medication to an OTC equivalent—whether due to cost, preference, the expiration of a prescription, or an Rx-to-OTC switch—claims data records the discontinuation of prescription use without capturing continuation of the patient's overall treatment. Analyses of adherence, treatment persistence, and medication switching built on claims data alone are prone to systematically mischaracterizing the behavior of a patient population that is actively managing its health through OTC channels.

The invisibility of OTC utilization in claims data creates specific and consequential distortions in secondary RWE analysis

The issue is not merely one of missing data points, but of systematically biased inference. Secondary-only RWE that cannot observe OTC behavior will tend to overestimate the proportion of patients who go untreated when prescriptions lapse, underestimate the resilience of self-managing patients, and mischaracterize the preferences and decision-making process through which patients navigate their treatment journey. These distortions have real implications for pharmaceutical manufacturers, formulary decision-makers, and health policy researchers who rely on secondary RWE to understand treatment landscapes and unmet needs.

Addressing gaps & elevating the patient voice with Direct-to-Responder RWE

Direct-to-Responder RWE providing representativeness

The most direct contribution of Direct-to-Responder RWE is the restoration of representativeness to research that is otherwise structurally biased by the characteristics of the insured, continuously-engaged patient population. This is not a matter of improving the precision of estimates at the margin—it is a matter of ensuring that research findings are inclusive of the entire patient population they aim to describe.

Direct-to-Responder research can reach patients during their claims "gaps", such as insurance cycling or switching to an OTC option, capturing medication-switching behavior, symptom severity, quality-of-life impacts, and the financial decision-making that drove their choices. These data are not merely supplementary to claims—they represent experiences that claims data structurally cannot observe or explain.

The same logic applies to patients who have never engaged with the prescription system for a given condition: those who manage chronic pain exclusively with OTC analgesics, those who address sleep difficulties with melatonin and behavioral strategies rather than prescription sleep aids, and those who self-treat allergic rhinitis with OTC antihistamines rather than seeking specialist care. These patients represent a substantial proportion of the true disease population. RWE that excludes them will systematically underestimate disease burden, overestimate treatment rates, mischaracterize the spectrum of patient experience, and not consider patient preferences.

RWE providing context: Uncover the 'why'

Claims data is an invaluable source of information about what has happened within the formal healthcare system, and that importance should not be discounted. However, it cannot provide the reasoning, context, and decision-making that produced those transactions—or the reasoning that led patients to exit the system entirely.

This distinction between behavior and context is particularly consequential when prescribing patterns and patient preferences diverge. Claims data may show high rates of prescription for a particular therapeutic class in a given patient population. Without patient-reported data; however, it is impossible to determine whether those prescriptions reflect patient preferences, physician habits, formulary structure, or cost-driven substitution. Direct-to-Responder RWE can reveal that patients who appear—based on their prescription records—to be stable and satisfied users of a medication are, in reality, highly ambivalent: tolerating side effects because they cannot afford alternatives, using medications inconsistently due to cost, or planning to transition to OTC alternatives at their next coverage gap.

The implications of this divergence are material. Pharmaceutical manufacturers who rely exclusively on claims data to understand treatment patterns and patient preferences risk fundamentally misreading the competitive landscape for their products. They may overestimate patient satisfaction with existing therapies, underestimate the role of cost barriers in apparent adherence, and fail to identify the patient segments most receptive to new treatment options. Similarly, they may be missing out on key messages that could be highly impactful in medical science liaison (MSL) interactions.

Direct-to-Responder RWE can capture the patient's perspective on these dynamics with precision: attitudes toward current treatments, the role of cost in medication choices, awareness of and interest in therapeutic alternatives, preferences regarding administration and key product benefits, and the degree to which treatment decisions are driven by patients versus physicians.

This research reveals a healthcare landscape that is meaningfully different from what claims data suggests—one in which patient agency, financial constraint, and access barriers play a far larger role than administrative records can capture.

The importance of patient voice in healthcare research and delivery

The case for Direct-to-Responder RWE is ultimately a case for the systematic inclusion of patient voice in healthcare research. Claims data, however comprehensive, is a secondary artifact of administrative processes designed to facilitate payment—not to capture patient experience. It records what the system did, not what the patient needed, preferred, or experienced.

When patients are given the opportunity to report their own experiences, **the picture of healthcare needs that emerges is often substantially different**

When patients are given the opportunity to report their own experiences—their symptom burden, their treatment preferences, their financial constraints, their quality of life, their goals for care—the picture of healthcare needs that emerges is often substantially different from the one presented by administrative data. Research in health economics and patient-centered outcomes has consistently demonstrated that patient-reported outcomes and administrative claims tell different, complementary stories, and that neither alone is sufficient for a complete understanding of the healthcare landscape.

This kind of evidence has direct implications for healthcare delivery. Pharmaceutical manufacturers can use patient-reported data to identify unmet needs that their pipeline should address, understand the patient journey in ways that inform patient support programs, and communicate the value of their therapies to physicians and payers in terms that resonate with real patient experience. Payers can use patient-reported data to identify coverage policies that create barriers without improving outcomes as areas for improvement. Health systems can use patient-reported data to design care models that address the factors—cost, access, complexity, communication—that drive patients out of the formal system.

Most fundamentally, the inclusion of the patient voice in RWE is a matter of scientific integrity. Research that excludes the perspectives of the uninsured, the underinsured, the cost-constrained, and the self-managing is not neutral—it is biased in ways that tend to benefit those who are already advantaged by the system. Direct-to-Responder RWE is the vehicle through which that bias can be identified and corrected.

Conclusion

The United States healthcare system has distinctive characteristics: its fragmented, multi-payer insurance architecture; its high rates of cost-driven patient dropout; and its large, structurally invisible OTC market create gaps in claims-based RWE that are not incidental, but structural. These gaps are not distributed randomly across the patient population; they systematically exclude the patients who are most affected by cost and access barriers, most likely to self-manage, and most underserved by the formal healthcare system.

Direct-to-Responder RWE can address these gaps. By reaching all Americans, regardless of insurance status, coverage continuity, or engagement with the formal healthcare system, Direct-to-Responder research captures the full spectrum of patient experience. By enabling the direct collection of patient-reported outcomes, preferences, and behaviors, it recovers the contextual richness that claims data, by its nature, cannot provide.

In an era of increasing sophistication in healthcare data analytics, the temptation to treat comprehensive claims databases as a complete picture of real-world healthcare is understandable but ultimately misleading. The most complete picture requires multiple data sources, each contributing what the others cannot. Direct-to-Responder RWE is not merely a supplement to claims data—it is an essential source of truth that ensures research reflects the full reality of how Americans navigate health, illness, cost, and care.

Direct-to-Responder recovers the contextual richness that claims data, by its nature, cannot provide.

For pharmaceutical manufacturers, payers, health systems, and policymakers alike, the integration of Direct-to-Responder RWE into their research programs demonstrates a commitment to seeing patients as a whole, including those whose experiences the formal system has been least equipped to record.

How Ipsos can help

Healthcare at Ipsos' Real-World Evidence practice combines deep methodological expertise with access to representative patient and consumer panels. Our Direct-to-Responder research solutions enable pharmaceutical manufacturers, payers, and health systems to:

Capture patient-reported outcomes (PROs) and quality-of-life (QoL) data from populations underrepresented in claims databases

Understand over-the-counter (OTC) utilization patterns and self-management behaviors

Generate evidence that reflects the full spectrum of U.S. healthcare experience

Need help building an evidence strategy that is flexible and reflects the complexities in the real world? Ipsos' team of experts spanning RWE, Market Access, Health Economic and Commercial consultants can support your integrated evidence planning (IEP) process to ensure success for products at any stage of the product lifecycle.

Want to know more about Ipsos' capabilities, or to discuss the content in this article, reach out to us at RWE@Ipsos.com.

References

1. Levitt L. How unaffordable is health care? JAMA Health Forum [Internet]. 2026 Jan 8;7(1):e256929. Available from: https://doi.org/10.1001/jamahealthforum.2025.6929
2. Doty MM, Tikkanen RS, FitzGerald M, Fields K, Williams RD. Income-Related inequality in affordability and access to primary care in eleven High-Income countries. Health Affairs [Internet]. 2020 Dec 21;40(1):113–20. Available from: https://doi.org/10.1377/hlthaff.2020.01566
3. National Center for Health Statistics. 2023 National Health Interview Survey (NHIS) Survey Description. 2024 Jul. Available from: https://ftp.cdc.gov/pub/health_Statistics/NCHs/Dataset_Documentation/NHIS/2023/srvydesc-508.pdf
4. Consumer Healthcare Products Association (CHPA). U.S. OTC Drug Market Data and Projections. Washington, DC: CHPA; 2023–2024. Available from: https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics
5. Knowledge Sourcing Intelligence, 2025. OTC sleep aids medication market size, share, opportunities, and trends — forecasts from 2025 to 2030 (Report No. KSI061617252). Available from: https://www.knowledge-sourcing.com/report/otc-sleep-aids-medication-market

THANK YOU

ABOUT HEALTHCARE AT IPSOS

A globally connected team in over 30 countries worldwide, we provide insights, evidence and guidance across the healthcare product lifecycle. We empower our clients to align commercial success with what matters most: **Improving patients' lives.**

For more information, please contact:

Matthew Heffler
Vice President, Healthcare (US)
Matthew.Heffler@Ipsos.com

William Rogers
Global Head (SVP), Real-World Evidence, Healthcare
William.Rogers@Ipsos.com

Learn more at:
www.Ipsos.com