Administrative Claims Data: A Valuable Tool in Pharmaceutical Litigation

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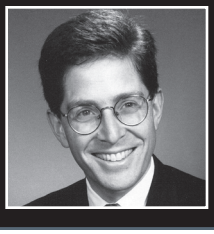
Many of us go to the doctor for a routine physical, occasionally rush to the emergency room to attend to our child's accidental injury, or fill a prescription at a neighborhood pharmacy. What is not so widely appreciated is that each of these encounters with the healthcare sector is systematically captured in administrative claims datasets, whether the insurer of record is Medicare, Medicaid, or a private entity (e.g., a self-insured employer). In many instances, the detailed information documented on medical and prescription drug claims (and sometimes even disability events) can be linked together to form a single comprehensive data file for each beneficiary. Of course, these data must be kept in a confidential format, because they include private information about the physical and mental health status of a great many individuals. But once appropriately de-identified to comply with the privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA),[1] they can provide a wealth of analytically valuable longitudinal information on the medical conditions and treatments of millions of anonymous people.

Proven Reliability

Testifying experts must meet high legal standards, and these require that the methodologies employed must be reliable. For over a decade, researchers at academic institutions, pharmaceutical companies, and government agencies have published scholarly research results in the peer-reviewed literature based on medical, pharmaceutical, and disability claims data to analyze a wide range of health economics issues. For example, investigations have been undertaken using claims-based research to study the economic burden of illnesses, the cost-effectiveness of various treatments, and optimal marketing and pricing strategies.

Academic and nonacademic researchers alike have relied on administrative medical and pharmaceutical claims data to identify groups of patients with specific diagnoses (e.g., diabetes in general or diabetic neuropathy in particular) who receive particular interventions (e.g., drug, procedure, laboratory test) at a chosen venue of care (e.g., inpatient care setting, physician's office). Using these data, researchers have followed such patients through time to map individual patterns of resource utilization (e.g., in terms of dollars spent), medical outcomes (e.g., number of days in the hospital), payment sources (e.g., insurance, out-of-pocket), and shifts in treatment (e.g., from one prescription drug to another). Where available, workplace disability records also have been linked to patients' medical and prescription drug claims files to assess the economic implications of illness or treatment on employee work loss.

Much of the value inherent in administrative claims datasets is derived from their large sample size, population-basis, longitudinal dimension, and anonymous patient-level specificity, as well as their widespread availability. Unlike survey-based approaches, administrative claims data are objective and, as an archival source, are not subject to recall bias. These data also are well-recognized in the fields of health economics, epidemiology, and pharmacoeconomics, and have a proven track record illustrated by many hundreds of publications in outlets ranging from prestigious peer-reviewed publications to trade magazines. While these data have limitations (e.g., potential for data entry errors or incorrectly-specified



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diagnoses, generally no measure of the clinical severity of the patient's illness) that require appropriate expertise to reach accurate and defensible conclusions, their richness far outweighs their limitations, particularly in the context of carefully conducted analyses.

Given their proven reliability and widespread application as a research standard, administrative claims data can be effectively used to analyze economic outcomes and patterns of care in pharmaceutical and other related litigation. For example, in the pursuit of the Master Settlement Agreement with the tobacco industry, Medicaid claims data were used to estimate smoking-attributable healthcare expenditures on a state-by-state basis for periods of up to 20 years.[2]

Although originally gathered for payment and recordkeeping purposes, administrative claims datasets have been long-recognized as an important tool for medical, health outcomes, and pharmacoeconomic research. They have not yet become a standard source, however, on which to base analyses in litigation proceedings. Several possible litigation-related applications of administrative claims data in the context of pharmaceutical litigation include:

- market definition;
- fraud and abuse;
- class certification;
- product failure; and
- damages.

While each of these uses is illustrated here in the context of pharmaceutical litigation, it is easy to extend these applications to other healthcare arenas (e.g., medical devices, hospital care, physician services).

Market Definition

Antitrust and intellectual property litigation often requires an economic definition of the relevant product market. Widely-used data sources for such assessments (e.g., IMS, Scott-Levin) typically provide detailed month-by-month information on total drug units sold and their prices. This aggregate approach can yield estimates of cross-price elasticities, which can be helpful in establishing the boundaries of a market. Information concerning patient-level encounters with physicians, however, can provide an additionally useful perspective at a much more disaggregated level.

Economic analysis of claims data permit development of a detailed profile of the duration of treatment with a specific drug, as well as switching patterns among drugs within a therapeutic class. They thereby provide insights for delineating the market beyond those available from more aggregate data. Specifically, claims data can be useful in distinguishing between a hypothetical economic market in which substitutions across individual brands (and their generic form, where available) are seldom observed, from another possible market definition in which substantial between-brand substitutions occur. Furthermore, administrative claims data can be helpful in assessing drug usage patterns, including both the brands and generics within a therapeutic class. Investigations along these lines can include attention to the medical diagnosis associated with any particular prescription, as well as the dollar amounts charged to the third-party payer and patient (e.g., in the form of an out-of-pocket copayment).

Fraud and Abuse

The ability to analyze person-level substitution behavior also can be useful in analyzing fraud and abuse cases, such as those connected with the Medicare system. For example, although this program does not now include a broad pharmaceutical benefit, some types of drugs (e.g., reimbursable injectibles administered in a physician's office) already are reimbursed within this system. As is the case with private sector claims data, reimbursement triggers not only a record of payment, but also a detailed description of the basis for that payment. In fact, the Medicare program constantly augments its own comprehensive administrative dataset with new claims identifying each prescribing physician, patient, venue of service, diagnosis, and treatment or procedure. (State Medicaid systems also record voluminous, comparable details in this context.)

Suppose, for simplicity, that there exists no medical reason to switch patients between two alternative pharmaceutical treatments that are each reimbursed under the Medicare program. In such a case, beneficiary-level Medicare claims data could help identify whether patients' treatments were, in fact, switched between the two drugs, and establish the precise timing of any such action. To the extent these medical decisions are closely tied to the timing and magnitude of financial incentives offered to specific prescribing physicians, they could be helpful in understanding the role of economic factors in the observed prescribing patterns. In this example, administrative claims data could help to establish a pattern of conduct that resulted in excessive reimbursement by the Medicare system to specific physicians.

Class Certification

An important aspect of class certification is the extent to which common issues predominate over individualized issues among plaintiffs in a proposed class. In pharmaceutical litigation, administrative claims data allow for detailed analysis of the characteristics of

users of a particular prescription drug in terms of a wide range of patient-specific distinguishing features, including the following:

- sociodemographic characteristics (e.g., age, gender, employment status);
- geographic location (e.g., zip code of patient residence);
- medical profile (e.g., comorbid conditions, concommitant drug usage pattern, medical procedure history);
- provider specialty (e.g., general practitioner, specialist);
- place of service (e.g., inpatient, outpatient, office visit); and
- payment characteristics (e.g., type of insurance, reimbursement to provider, amount paid out-of-pocket).

Of course, the actual extent of variation in these categories is an empirical issue that must be analyzed on a case-by-case basis to provide economic insight in this line of investigation.

Product Failure

Product failure cases raise a number of issues that can well be addressed by administrative claims data analysis, including assessments of causation and injury (i.e., that the product in question caused harm to those who used it). Because the size and scope of administrative claims datasets usually allow for the detection of even rare adverse events following use of a drug, they can provide a very useful basis for generalizing adverse event findings to the entire population.

Econometric modeling techniques that control for numerous plausible confounding factors, including many captured in claims datasets, can help to explain issues of causation and injury. In this way, the likely role of a specific drug on a particular health outcome of relevance to a litigation matter can be isolated. In addition, by comparing the demographic and medical profiles of patient groups who were prescribed treatment alternatives within a specific therapeutic class of drugs, it is possible to establish a baseline level of adverse events that exists among users of other drugs for which the same elevated adverse event risk is not at issue. This approach permits the experienced claims data analyst to appropriately quantify the excess risk associated with the use of one drug compared to another.

Damages

In the case of alleged injury resulting from a particular prescription drug, compensatory damages can be estimated to reflect the economic valuation of harm to the plaintiff that would not have been incurred "but for" the injury. An important aspect of the economic value of harm may be the additional costs incurred by those who were prescribed the drug, including all of the extra medical and disability costs associated with adverse events causally linked to its use.

Using administrative claims data, patients can be grouped within a therapeutic class based on drug use history. For example, in a litigation matter involving a new triptan drug for migraines (i.e., one that competes with incumbent products in this class), patients can be categorized based on their triptan usage patterns. After controlling for confounding factors, including patient demographic and medical characteristics, the health- and disability-related cost profiles can be assessed for patients who used the new triptan. These findings then can be compared with those found among users of pre-existing triptan alternatives, so that excess costs along these dimensions can be calculated.

Conclusion

Administrative claims data have been used widely as a basis for scientific publications in the medical, health economics, epidemiologic, and managed-care literatures. The well-developed methodologies for analyzing treatment patterns and health outcomes using these data can be applied to a variety of common litigation settings by drawing on the experience of pharmacoeconomic outcomes research. Such applications would require particular care in the context of litigation because of the high standards applied to data integrity, reproducibility, and analytic methods. Economic analysis in the context of numerous types of pharmaceutical litigation (as well as other areas of healthcare), including those involving market definition, fraud and abuse, class certification, product failure, and estimation of damages, can all benefit from appropriate application of administrative claims data analyses.

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[1] Health Insurance Portability and Accountability Act, Pub. L. No. 104-191 (codified at 42 U.S.C. §§ 1301 et seq.)

[2] T. Wyant & S.T. Parente, *Use of Medicaid and Medicare Administrative Claims Data in Litigation and Regulation*, Paper Presented at a Meeting of the Federal Committee on Statistical Methodology (Nov. 2003).