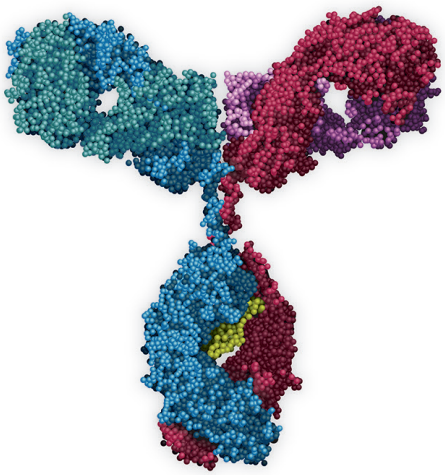
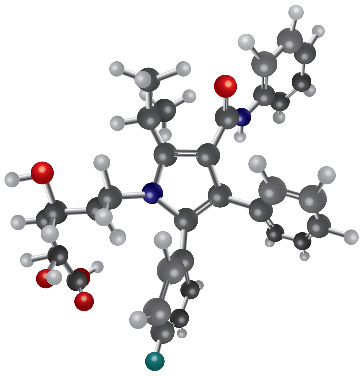
ANALYSIS GROUP ECONOMIC, FINANCIAL and STRATEGY CONSULTANTS

HEALTH CARE BULLETIN

Fall 2016

The Biosimilar Revolution Is Just Beginning in the U.S.

High molecular weight biologics like Herceptin are more complex than traditional, small-molecule chemical drugs like Lipitor. This complexity increases the costs, challenges, and risks of developing and manufacturing biosimilars.

Biologic	Traditional Drug
	
Herceptin (breast cancer) molecular weight = 185,000 daltons	**Lipitor (hypercholesterolemia)** molecular weight = 559 daltons

The entry of biosimilars to the U.S. market is still in its infancy, but their potential for widespread introduction represents one of the most significant events to hit the drug industry in decades, with many top-selling biologic drugs expected to be affected over the next few years. The Biologics Price Competition and Innovation Act (BPCIA) of 2009 paved the way for biosimilar entry, and the Food and Drug Administration (FDA) Biosimilar Product Development Program currently includes more than 50 biosimilars, referencing more than 15 different innovative biologics. To date, four of those biosimilars have been approved:

1. Zarxio (brand reference product Neupogen) in March 2015
2. Inflectra (brand reference product Remicade) in April 2016
3. Erelzi (brand reference product Enbrel) in August 2016
4. Amjevita (brand reference product Humira) in September 2016

The global market for biologic drugs has been forecast to exceed $390 billion annually by 2020, and some analysts predict substantial cost savings after more biosimilars are approved and introduced, as was the case with the introduction of generics. Indeed, one goal of the BPCIA was to try to achieve the level of cost savings realized from the widespread adoption of generics.

However, the development and approval processes for biosimilars, which are large-molecule biologics, are very different from those for generics, which are small-molecule chemical drugs. Consequently, biosimilar competition may share more features with traditional brand-brand drug competition than with brand-generic competition. In fact, the high costs of development (e.g., the FDA requires costly Phase III trials to approve a biosimilar) and manufacturing for biosimilars are likely to limit entry to a relatively small number of **(continues on page 2)**

Features

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The Biosimilar Revolution (continued from page 1)

competitors, in contrast to the experience with small-molecule generics.

For example, based on the limited experience of biosimilar entries to date, penetration rates may be much more modest than for generics, and the price discounts may be substantially less. Research by Duke University Professor Emeritus Henry Grabowski and his co-authors at Analysis Group found that branded small-molecule drugs facing generic entry lose, on average, in excess of 75 percent of their sales within six months. In addition, generic price discounts average more than 40 percent relative to the brand's price.

The share capture and price discount achieved six months after the introduction of Zarxio, however, have been much lower. The branded drug Neupogen lost only about 10 percent of its share, and Zarxio's price discount was 15 percent. This is consistent with the experience following the earlier entrance of Granix, a quasi-biosimilar. (See table.)

Comparison of U.S. Biosimilar and Generic Drug Average Share of Sales and Price Discount (Six Months After Launch)

	Share of sales vs. originator	Price discount vs. originator*
Generic Drug Average	≥75%	≥40%
Zarxio (biosimilar Neupogen)	~10%	15%
Granix (quasi-biosimilar Neupogen)	5-10%	~11-23%

* Public price (e.g., WAC), not including contracted discounts/rebates
Source: Estimates based on publicly disclosed information

One reason for the difference from generics is that biologic drugs are substantially more complex than small-molecule drugs, as they are derived from living organisms. This greater complexity often creates substantial scientific and manufacturing challenges, and can greatly increase the costs and risks associated with developing and producing biosimilars.

Because it is more difficult to characterize the structure of biologic drugs than chemical drugs, the development and

production of biosimilars introduce more variability. This variability between innovator and biosimilar drugs makes it unlikely that the FDA will initially approve many biosimilars as interchangeable with their reference innovator biologic. If this is the case, pharmacies will not be allowed to automatically substitute a biosimilar for the innovator biologic, and payers may be reluctant to push for automatic substitution or implement formulary/managed care mechanisms that encourage switching between the innovator and biosimilar.

In addition, manufacturers will likely use distinct "brand" names for their biosimilars, and may need to invest substantially in marketing and sales to encourage their adoption. In fact, current biosimilars in the United States and Europe are developed and marketed as branded competitors with distinct names.

The FDA is still reviewing how best to address the issue of interchangeability for new biosimilars in the United States. Given the potential safety concerns, it is likely to wait for more information on the experience of the first set of biosimilars before taking a strong stance in favor of interchangeability. This will likely take several years.

As a result of all these factors, we expect biosimilar adoption to be more gradual than has been seen with the rapid shift to generics for many small-molecule drugs. ■

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ADAPTED FROM "CAN THE LIFE SCIENCES INDUSTRY BANK ON BIOSIMILARS?" BY PAUL E. GREENBERG, TAMAR SISITSKY, AND RICHARD A. MORTIMER, PUBLISHED ON LAW360.COM, APRIL 13, 2016; AND "THE POTENTIAL FOR LITIGATION IN NEW ERA OF BIOSIMILARS," BY CHRISTIAN FROIS, RICHARD A. MORTIMER, AND ALAN WHITE, PUBLISHED ON LAW360.COM, SEPTEMBER 20, 2016.

Uncertainty in the Litigation Landscape for Biosimilars

In recent years, there has been widespread litigation related to intellectual property disputes and alleged antitrust violations surrounding generic entry across a wide range of therapeutic classes. Will the entry of biosimilars in the U.S. lead to a similar wave of related litigation?

A few biosimilar applications have already triggered patent infringement lawsuits. These led to related disputes, such as whether the so-called "patent dance" exchange of information is mandatory and whether the 180-day notice of commercial marketing can be used to further delay the introduction of a competing biosimilar following the expiration of a patent.

In addition, entry of biosimilars may result in product safety lawsuits or allegations of improper or misleading promotion. This is made even more likely when the FDA approves the biosimilars for approved indications of the reference brand when the manufacturer did not submit any corresponding trial data, as the FDA did for Zarxio, Inflectra, Erelzi, and Amjevita. This raises the specter of product safety concerns if some patients react differently to the biosimilar than to the reference brand biologic.

Taken together, the complex manufacturing process and array of associated patents, as well as the challenging nature of establishing "similarity" to the reference brand, broaden the potential for a wide range of lawsuits. ■

Viewing Recent Opioid Regulations in Context

In recent years, government agencies have grappled with the twin objectives of maintaining access to prescription opioids for those with a legitimate medical need while restricting inappropriate access.

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ADAPTED FROM "VIEWING RECENT OPIOID REGULATIONS IN CONTEXT," BY CRYSTAL PIKE, KENNETH WEINSTEIN, PAVEL DARLING, AND PAUL E. GREENBERG, PUBLISHED ON LAW360.COM, APRIL 1, 2016.

In the past decade, acute and chronic pain patients have benefited from innovation in opioid medicines, including new drug approvals and improved and longer-acting and abuse-deterrent formulations. During this period, opioid prescriptions have increased by more than 25 percent.[1] However, opioid-related deaths tripled between 2000 and 2015,[2] and the annual economic burden of opioid abuse is a staggering $78.5 billion.[3]

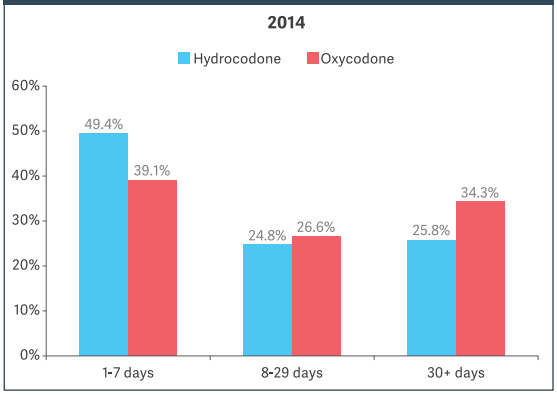
Consequently, state and federal agencies have been increasing efforts to curb the misuse and abuse of prescription opioids. In 2016, for example, the Centers for Disease Control and Prevention (CDC) published a new guideline recommending shorter durations for opioid prescriptions for chronic pain, and the FDA announced a "black box" warning for immediate-release opioids.

To put the CDC guideline in the context of existing treatment patterns, Analysis Group analyzed a large set of medical claims data for privately insured patients, with a focus on the past 10 years of oxycodone and hydrocodone prescriptions. Our analysis yielded three main conclusions:

- Adopting the more stringent CDC guideline will likely result in a significant reduction in average days supplied per prescription. The CDC advises that, for acute pain, more than a 7-day supply of opioids "will rarely be needed." Our analysis found that 50 to 60 percent of oxycodone/hydrocodone prescriptions exceed the 7-day recommendation, with 25 to 35 percent having a 30-day supply. **(See figure.)**
- The guideline recommends limiting the duration of treatment for chronic pain and reevaluating the need for continued treatment at least every three months. With more than 20 percent of oxycodone/hydrocodone patients in our data having three or more claims annually, time will tell whether the guideline results in a reduction in the proportion of long-term patients.
- While the CDC guidelines do not explicitly address pills per prescription (other than to note that the lowest effective dose is optimal), this is an important consideration for diversion. In our analysis, 35 percent of oxycodone prescriptions and 25 percent of hydrocodone prescriptions exceed 90 pills, with 80 percent of patients receiving three or more pills per day.

Given recent regulatory changes, more research concerning the impact of these changes on abuse/overdose and adequacy of care for patients with legitimate medical need is important. ■

Share of Hydrocodone and Oxycodone Claims by Days Supplied



Notes: Hydrocodone/oxycodone claims were identified based on NDCs within the opioid class of drugs. GPI code 65xxx. Analysis excludes drug claims for beneficiaries younger than 18 years. **Source:** OptumHealth Reporting and Insights database

[1]Substance Abuse and Mental Health Services Administration, *Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health*, Sept. 2105

[2]CDC Morbidity and Mortality Weekly Report, *Increases in Drug and Opioid Overdose Deaths — United States, 2000-2014*, January 1, 2016/64(50); 1378-82

[3]As of 2013. Curtis S. Florence, Chao Zhou, Feijun Luo, Likang Xu. "The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States," 2013. *Medical Care*, 2016; 54 (10): 901 DOI: 097/MLR.0000000000000625

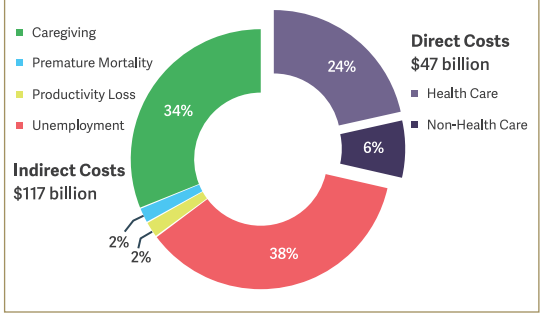
Economic Burden of Schizophrenia in the U.S. Exceeded $155 Billion in 2013, New Study Finds

The estimated economic costs of dealing with schizophrenia from a societal perspective in the United States totaled $155.7 billion in 2013, according to a new Analysis Group study.

The figure is even more notable when compared with total economic costs of $62.7 billion in 2002, as determined by the Analysis Group team in a similar study published in 2005.

The new study, "The Economic Burden of Schizophrenia in the United States in 2013," is by an Analysis Group research team including Managing Principal Eric Wu, Vice President Annie Guérin, and Senior Economist Martin Cloutier.

Economic Burden of Schizophrenia, 2013



Note: Percentages add up to more than 100 percent because they have been calculated after accounting for cost offsets. **Source:** Analysis Group, "The Economic Burden of Schizophrenia in the United States," 2016, prepared for Otsuka America Pharmaceutical

Why the dramatic increase?

Most importantly, the prevalence of schizophrenia is now better documented than it was a decade ago. In the new study, the researchers based their estimates on a prevalence estimate of 1.1 percent, versus 0.5 percent in the original study. The conservative prevalence estimate used in 2005 was based on a retrospective claims analysis and epidemiological survey studies. In the new study, the prevalence estimate was based on more sophisticated and recent data from the National Institute of Mental Health.

Several structural changes over the past decade also likely impacted the economic burden of schizophrenia: coverage changes in Medicare programs (e.g., coverage for outpatient prescription drugs beginning in 2006), new legislation on health care coverage (e.g., Patient Protection and Affordable Care Act, 2010) and coverage quality (e.g., Mental Health Parity and Addiction Equity Act, 2008), changes in pharmacologic therapy (i.e., introduction of new drugs and availability of some generic atypical antipsychotics), and a continuing trend of deinstitutionalization.

Indeed, perhaps driven by the continuing deinstitutionalization of patients, this new study found substantially greater caregiving costs to family members as part of the "re-integration" focus of the Americans with Disabilities Act. The indirect costs of unemployment (38 percent of the $155.7 billion total) and caregiving (34 percent) contribute even more to the total societal costs of schizophrenia than direct health care costs (24 percent). **(See figure.)**

Although literature suggests that a push for increased family intervention for schizophrenia patients can be beneficial, and in fact is recommended by many international clinical guidelines, the authors note that this intervention comes at a high economic cost to caregivers. ■

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ADAPTED FROM "THE ECONOMIC BURDEN OF SCHIZOPHRENIA IN THE UNITED STATES IN 2013," BY A TEAM OF RESEARCHERS INCLUDING ERIC WU, ANNIE GUÉRIN, AND MARTIN CLOUTIER, PUBLISHED IN THE *JOURNAL OF CLINICAL PSYCHIATRY*, JUNE 2016.

Machine Learning Algorithms in Health Care Litigation

The health care industry has experienced exponential growth in the variety and richness of data, driven in part by the advent of electronic medical records and introduction of industry reporting requirements such as the Sunshine Act.

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It has been further fueled by technological innovations that provide both greater data storage and ever-increasing computing power. However, the growing volume and complexity of available data are testing the limits of familiar analytical tools such as spreadsheets and statistical software.

Enter machine learning. Machine learning uses algorithms to detect complex and unforeseen relationships in high-dimensional data (i.e., where there is an abundance of different types of variables, including numbers, text, and/or visual images). In a litigation context, in particular, the proliferation of health care data can be daunting. Here are a few examples of how attorneys can leverage machine learning to strengthen their cases while optimizing their efforts.

Crafting a legal strategy

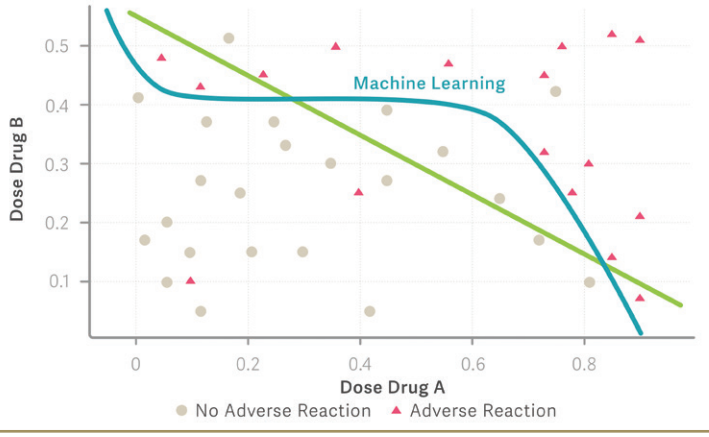
Machine learning can be applied during the discovery phase of litigation to quickly find relevant information in large quantities of data. Consider a dispute over alleged off-label promotion of prescription drugs. Conventional analyses might serve as a blunt instrument, grouping together all patients with a particular condition (e.g., lung cancer). Machine learning methods, on the other hand, can identify similarities among patients based on a wider and deeper range of variables or characteristics, leading to finer groupings. Such clustering could reveal clinical differences (e.g., advanced age, failure on other cancer therapies, genetic markers) among groups of patients that might explain use of the drug independent of any promotion. Uncovering these types of patterns at an early stage in the litigation can be beneficial to attorneys as they contemplate the theory of the case.

Assessing the value of a patent when its validity is challenged in court

In patent infringement cases, machine learning

Machine learning algorithms offer a flexible approach to modeling complex, non-linear relationships among data.

Classification Example: Adverse Event Drug-Drug Interactions



can be used to sort through reams of filings using natural language processing capabilities in order to reveal features common to desired outcomes. Unlike conventional statistical methods, machine learning algorithms can be "taught" to recognize the importance of particular word and phrase combinations or other characteristics within patent claims that are associated with a specified outcome, and then use these associations to improve predictions. This information can be combined with other data to approximate the process that leads to final judgments at the patent office. In a patent dispute, such predictions can help the parties decide whether to negotiate a settlement or engage in costly litigation.

Mining data efficiently to strengthen a case

Machine learning can make use of the vast amounts of data in a company's possession to conduct much more sophisticated analyses that support testimony or provide counterfactual scenarios. For example, attorneys defending a pharmaceutical manufacturer against allegations of kickbacks paid to physicians might use machine learning to identify doctors who did not receive any payments but had similar prescribing patterns to those who did. Deposing such physicians could shed light on factors that drive prescribing patterns in the absence of any possible inducements.

Conventional methods can be cumbersome, taking up valuable time and resources, and require analysts to specify selected parameters of interest. If the wrong parameters are selected, the most useful candidates may be overlooked. But with machine learning, there is no restriction on the number of—or interrelationships among—parameters the computer can account for, which increases the efficacy of the search while controlling time and effort. Information that might once have been discarded as impractical or irrelevant for expert modeling purposes, such as unstructured data like patient/physician perceptions, can be mined for use in discovery or economic analysis.

In the increasingly complex and technical world of litigation, the widespread adoption of machine learning will no doubt prove to be a significant advantage. These new techniques can be harnessed to help attorneys develop better legal strategies, conduct informed fact discovery, provide testifying experts with the most complete set of relevant information, and prepare analyses at a previously unseen level of granularity. ■

ADAPTED FROM "MACHINE-LEARNING ALGORITHMS CAN HELP HEALTH CARE LITIGATION," BY LISA B. PINHEIRO, JIMMY ROYER, NICK DADSON, AND PAUL E. GREENBERG, PUBLISHED ON LAW360.COM, JUNE 8, 2016; AND "PRACTICAL USES FOR MACHINE LEARNING IN HEALTH CARE CASES," BY MIHRAN YENIKOMSHIAN, LISA B. PINHEIRO, JIMMY ROYER, AND PAUL E. GREENBERG, PUBLISHED ON LAW360.COM, SEPTEMBER 22, 2016.

When to Consider a Machine Learning Approach

There are many potential uses of machine learning algorithms in a litigation context. While they are not the solution to every analytical problem, they are poised to add significant value to the analyses, especially when three conditions are met:

1. The goal of the analysis is to *predict* an outcome;
2. Out-of-sample performance is the desired measure of success; and
3. A rich dataset is available to take advantage of interactions among many potential predictors with complex interrelationships (e.g., a nonlinear function of many factors for which it is difficult to specify its form in advance).

Of course, as was the case with other new technologies that have been introduced to the courtroom (e.g., fingerprints, DNA evidence), testifying experts' reliance on machine learning might invite initial skepticism. When using such a methodology, the expert will need to rigorously validate the chosen model and evaluate whether results are meaningful and sufficiently accurate (e.g., a model that accurately predicts an outcome 90 percent of the time but has a high false positive rate might not be appropriate). Testifying experts using machine learning methods will also need to educate and convince the court of the validity of these less familiar models. ■

The Myth of "Price Disconnects" in U.S. Pharma Markets

In pharmaceutical markets, the strategy of introducing a "new and improved" version of an existing brand product is sometimes alleged to be an antitrust violation.

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ADAPTED FROM "THE MYTH OF 'PRICE DISCONNECTS' IN US PHARMA MARKETS," BY STEPHEN FINK AND MARK J. LEWIS, PUBLISHED ON LAW360.COM, MAY 17, 2016.

Critics dispute the medical improvements of the new product, claiming that it merely interferes with competition from cheaper generic drugs which are not automatically substitutable.

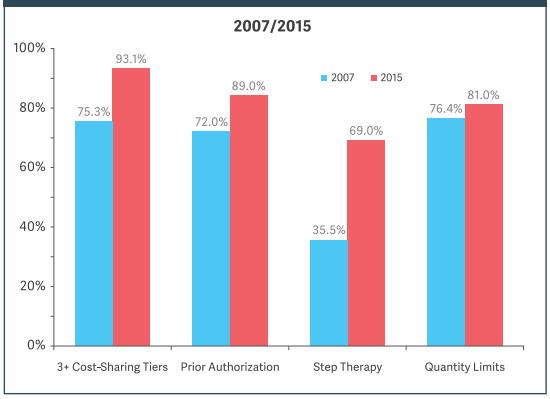
Some antitrust analysts argue that a "price disconnect" makes pharmaceutical markets particularly vulnerable to this allegedly anticompetitive behavior. They claim that prescribers, patients, insurers, and pharmaceutical benefit managers (PBMs) all fail to make the trade-off between price and quality that is routine in other markets. According to this argument, physicians prescribe drugs with little thought to cost, while patients only track their own costs (co-pays, deductibles, etc.) knowing their insurer will pay the rest.

This argument ignores the economic incentive insurance companies and PBMs have to monitor price/quality trade-offs. These stakeholders regularly employ drug formularies to direct coverage to cost-effective treatments. Pharmacy and therapeutic committees consisting of physicians, pharmacists, nurses, administrators, and quality assurance directors, among others, review and update these formularies, and can adjust the benefit design accordingly.

Research shows increasing use of formulary features for cost efficiencies **(see figure)**:

- **Cost-sharing "tiers"** steer doctors and patients to cheaper alternatives.
- **Prior authorization** prohibits reimbursement for a drug unless specified conditions are met.
- **Step therapy** requires that a patient first try and fail on an alternative, less expensive therapy before obtaining reimbursement for the drug in question.
- **Quantity limits** restrict reimbursement for a drug to specified amounts over a given period.

Use of Select Formulary Management Features



Sources: Pharmacy Benefit Management Institute, "Prescription Drug Benefit Cost and Plan Design Report," 2015-2016, pp. 18, 31; "Prescription Drug Benefit Cost and Plan Design Report," 2007, pp. 12, 29

The use of insurer mechanisms for shaping patients' and physicians' prescription drug choices does not guarantee that the connection between prices and quality is perfect and that adjustments to new pharmaceutical developments are instantaneous. But these imperfections are not unique to pharmaceuticals; introducing "new and improved" products is common to many markets.

For these reasons, the pharmaceutical market should not be singled out for failing to make price/quality trade-offs. At a minimum, the insurers' ability to make tangible connections between prices and quality needs to be considered when evaluating allegations that a product introduction is anticompetitive. ■

Payments to Doctors: Causal Inferences Require a Closer Look

An Analysis Group team responded to a ProPublica report's provocative suggestion that doctors prescribe more drugs when paid by manufacturers (e.g., with speaking/consulting fees, business travel, meals, royalties, or gifts).

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ADAPTED FROM "CORRELATION OR CAUSE: BRAND-NAME DRUG PRESCRIPTION RATES," BY PAUL E. GREENBERG, TAMAR SISITSKY, AND RICHARD A. MORTIMER, PUBLISHED ON LAW360.COM, MARCH 23, 2016.

Noting the age-old wisdom that correlation does not establish causation, our team articulated four overarching points of caution.

1. A strong correlation between speaking payments and prescribing may be explained by reasons other than those implied by ProPublica. For example, doctors who have the greatest familiarity with a manufacturer's product are likely the best spokespeople to impart firsthand experiences with prescribing the drug.
2. The ProPublica investigation focused on the relationship between overall payments and overall prescribing. It did not consider disaggregated data or any counterexamples. For instance, increased prescribing by some doctors may have started prior to any speaking engagements. Other doctors might have received high speaking fees but had low levels of prescribing. Still others might have continued to prescribe even after payments stopped. Aggregate analyses might miss insights from granular counterexamples such as these.
3. Payments to physicians from competing firms dilute the potential impact of those from any one manufacturer. Data from ProPublica as well as the Open Payments federal program provide information on payments to specific doctors from particular drug companies. These rich data sources reveal, for example, that many doctors have received payments from multiple manufacturers in the same therapeutic space.
4. The ProPublica study failed to control for the many factors that affect prescribing decisions. These include: drug attributes and publicly available information concerning efficacy, safety, and side effects; disease practice guidelines and compendial listings; reimbursement coverage; physician-specific characteristics (e.g., age, specialty, region, or past experience with the drug); and patient-specific medical circumstances. Without controlling for these and other potential influences on prescribing choices, it is not possible to draw much insight from aggregate correlations.

Consequently, ProPublica's findings do not validate prevailing legal theories that payments from manufacturers drive physician prescribing. From an analytical perspective, the enormous amounts of data that ProPublica has made available can provide real insights into important questions in the pharmaceutical industry, and may even shed light on problematic financial relationships between individual physicians and manufacturers. But substantial caution is in order when it comes to interpreting correlation results from these aggregated data. ■

The ProPublica study failed to control for the many factors that affect prescribing decisions. … Without controlling for these … it is not possible to draw much insight from aggregate correlations.

In 2016, Analysis Group's Health Care practice was recognized as an industry leader at prominent international conferences in the U.S., Asia, and Europe

ISPOR Annual International Meeting

Analysis Group presented a workshop, moderated an issue panel, and exhibited 18 posters at the 21st Annual International Meeting of the International Society for Pharmoeconomics and Outcomes Research (ISPOR). During the workshop "The Health Economics and Outcomes Research Applications and Valuation of Digital Health Technologies and Machine Learning," Managing Principal Mei Sheng Duh presented on the statistical properties of machine learning algorithms and highlighted the advantages of such techniques over traditional regression models when applied to HEOR research. Vice President Noam Kirson moderated the panel "Are Alternative Financing Approaches Needed for Innovative Therapies?" in which the panelists discussed the reimbursement challenges for transformative therapies in the face of patient switching across payer types over time. The posters were focused on cost-of-illness, comparative effectiveness, and health care resource utilization studies targeting ischemic stroke, prostate cancer, metastatic breast cancer, uterine fibroids, schizophrenia, diabetes, and obesity, among others. Research contributors included Managing Principals Mei Sheng Duh, Patrick Lefebvre, Edward Tuttle, Alan White, and Eric Wu; Vice Presidents James Signorovitch, Francis Vekeman, Jipan Xie, and Mihran Yenikomshian; Managers Wendy Cheng, Lynn Huynh, Nick Li, Elyse Swallow, and Hongbo Yang; and Senior Economists François Laliberté and Marie-Hélène Lafeuille.

Visit analysisgroup.com for more information about our presence at ISPOR's Asia-Pacific and European events.

International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE)

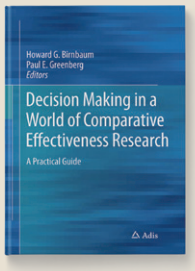
Senior researchers gave three podium and four poster presentations at ICPE, which brought together epidemiologists in the pharmaceutical, legal, and health insurance industries, as well as from academia. The presentations examined the impact of paliperidone palmitate versus oral atypical antipsychotics, the comparative hepatotoxicity of echinocandins, and the epidemiology of advanced pancreatic neuroendocrine tumors in the era of targeted therapy. The posters explored aspects of thalassemia intermedia in the United States, adult patients with sporadic angiomyolipoma in the Netherlands, and the impact of long-acting reversible contraceptive use in a commercially insured population, as well as patient characteristics and overall survival in the metastatic castration-resistant prostate cancer community setting. Research contributors included Managing Principals Mei Sheng Duh and Patrick Lefebvre; Vice President Francis Vekeman; Managers Wendy Cheng and Lynn Huynh; and Senior Economist François Laliberté.

AMCP's Nexus 2016

Three of the posters supported by Analysis Group research were awarded medals at this Academy of Managed Care Pharmacy (AMCP) conference. The research, covering cardiac resynchronization therapy, Type 2 diabetes, and multiple sclerosis, was led by Managing Principals Mei Sheng Duh, Patrick Lefebvre, and Eric Wu, and Vice President James Signorovitch. ■

Exclusive web content at www.analysisgroup.com/health-care-bulletins/fall-2016/

"Recent Trends in Affordable Care Act Insurance," by Managing Principal Anita Chawla and Associate Keziah Cook
"Evaluating Real-World Effectiveness in Prescription Coverages," Q&A with affiliate Robert Navarro



New Book Edited by Analysis Group: *Decision Making in a World of Comparative Effectiveness Research*

Evidence-based medicine now draws routinely on comparative effectiveness research (CER) to assess the impact of alternative treatments in real-world settings. Considerable research on CER has focused on methods and findings. In contrast, *Decision Making in a World of Comparative Effectiveness Research*, a new book edited by Principal Howard G. Birnbaum and Managing Principal Paul E. Greenberg, provides a practical guide to decision-makers that focuses on the impact of CER studies.

The book's chapters are authored by senior industry executives, key opinion leaders, accomplished researchers, and leading attorneys involved in resolving disputes in the life sciences industry. *Decision Making in a World of Comparative Effectiveness Research*, to be published by Springer in Spring 2017, is written for readers who commission CER within the life sciences industry, including pharmaceutical, biologic, and device manufacturers, as well as payers (both public and private). ■

Analysis Group Review Contributes to ICER Report Findings

The Institute for Clinical and Economic Review (ICER), an independent nonprofit research organization, recently commissioned a report on the cost-effectiveness of treatments for moderate-to-severe plaque psoriasis. An Analysis Group team including Managing Principal Eric Wu, Manager Keith Betts, and Associate Junlong Li reviewed the preliminary results of ICER's analysis, and identified and recommended a number of areas to improve. Corresponding changes were made by ICER in its final report, in which ICER noted that "Feedback from these companies resulted in the identification of an error in drug cost, and revisions to the model including addition of drug-specific discontinuation rates, modification of average patient weight, and inclusion of a switching cost for second line targeted drug treatment." These changes ultimately led to significant improvement in the accuracy of the incremental cost-effectiveness ratio estimates of the psoriasis treatments analyzed for comparative clinical effectiveness. ■

Video: The Economic Consequences of Obesity

In a video roundtable discussion, President Pierre Cremieux, Managing Principals Anita Chawla and Edward Tuttle, and Vice President Christian Frois discussed the worldwide obesity epidemic and future treatments. The discussion, based on Analysis Group's role editing an issue of the peer-reviewed journal *Pharmacoeconomics* on the economic impact of obesity, touched on the access and reimbursement challenges of introducing effective but potentially costly treatments such as bariatric surgery, and the investment and policy changes needed to address the societal burden. ■

To view the entire video, please visit **www.analysisgroup.com/obesity-video**. Or, to see the video come to life from this article, download the free Layar app for iOS, Android, or Blackberry and scan this (entire) page.

New Academic Affiliate: Dr. John E. Ware, Jr., Renowned PRO Expert

Analysis Group is pleased to announce that Dr. John E. Ware, Jr., an internationally recognized leader in measuring Patient Reported Outcomes (PRO), has become an academic affiliate.

Dr. Ware's substantial contributions to the outcomes research field have focused on developing, standardizing, and applying health metrics to assess patient reported outcomes. His work has led to the development of a set of standardized, generic PRO measures, including the SF-36® Health Survey, as well as disease-specific measures such as the Headache Impact Test (HIT-6™) survey. Dr. Ware frequently provides guidance on evidence support for PRO labeling, and he has been the invited expert for testimony on PRO topics at hearings held by the U.S. Food and Drug Administration. His current research interests also include applying modern psychometric methods to construct more actionable measures, including the first disease-specific quality-of-life (QOL) impact scale standardized across conditions and normed in representative chronically-ill populations.

Dr. Ware is Professor and Chief, Outcomes Measurement Science in the Department of Quantitative Health Sciences at the University of Massachusetts Medical School (UMMS), as well as a member of the National Academy of Medicine (formerly Institute of Medicine). ■