Pricing, Litigation, Enforcement: The 2022 Law & Economics Symposium in Review

8 MIN READ

Which problem should be tackled first to lower drug prices? What's changing in False Claims Act (FCA) drug-pricing litigation, and how is data mining shifting the ways in which FCA allegations arise? What role does drug value play in evaluating loss arguments in pharmaceutical class actions?

Four webinars in Analysis Group's **Law & Economics Symposium** tackled these topics in 2022, generating lively discussions among a variety of academic and industry experts, legal counsel, and Analysis Group consultants.

What Happens Next? Value Assessment, Drug Pricing Policy, and the R&D Pipeline

Wednesday, June 8, 2022

Noam Kirson (moderator), Analysis Group

Joshua Cohen, Center for the Evaluation of Value and Risk in Health at Tufts Medical Center

Jeffrey L. Handwerker, Arnold & Porter

Anna Kaltenboeck, formerly Senior Health Advisor, US Senate Committee on Finance

Drug prices regularly command public attention, and proposals to lower them are a regular feature of the US public policy landscape. But the US pharmaceutical pricing ecosystem is complex, with a large number of participants, regulations, and market incentives. Within this vast pipeline, it can be difficult to achieve agreement on what's causing the problem, let alone how to solve it.

This panel's experts examined the workings of the US pharmaceutical market and discussed the ongoing debate over value versus price when pursuing solutions for lowering consumer prices.[1]

What Price Is Right? The panelists agreed that drug pricing in the US depends on an extremely complex system of interactions between drug manufacturers, wholesalers, pharmacies, pharmacy benefit managers (PBMs), insurance companies, and regulators. With all these different forces at play, "price" means different things to the different participants, depending on their role in the system – including the ultimate consumer, the patient.

Jeffrey Handwerker

Show Me the Value. When asking whether a drug price is too high or not, the value of the drug or treatment also comes into play. In many countries outside of the US, independent organizations such as the Institute for Clinical and Economic Review (ICER) provide health technology assessments (HTAs) that measure value in terms of benefit received, such as in quality-adjusted life years (QALYs) or the incremental cost per cured individual.

Joshua Cohen

A Delicate Balance. A critical component of the ongoing debate over drug pricing is understanding what level of revenue is needed to incentivize drug manufacturers' investment in risky innovation. Would lowering prices mean sacrificing the kind of innovation that has led to more-effective treatments based on cutting-edge technologies such as CAR T-cell therapy?

Joshua Cohen **Anna Kaltenboeck**

How Big Is Too Big? The panel also discussed how the increasing vertical integration in health care markets, such as PBMs being absorbed into large insurance companies and national pharmacy chains, could have a potential impact on the role that competition and market power play in influencing drug pricing and, ultimately, out-of-pocket costs for the consumer.

Anna Kaltenboeck

False Claims Act and Drug Pricing-Related Cases

Wednesday, September 14, 2022

Crystal Pike (moderator), Analysis Group

Anupam B. Jena, Harvard Medical School and Massachusetts General Hospital

Andrew O'Connor, Ropes & Gray

Christopher Ody, Analysis Group

Jesse Siegel, Ipsen Biopharmaceuticals

In recent years, FCA enforcement seemingly increased its focus on drug pricing, and in particular matters involving higher-priced drugs. While cases involving more traditional areas of scrutiny, such as physician participation in speaking programs and consulting arrangements, continue to be pursued, recently there have been increases in cases where the questions center around the impact of companies' actions on drug prices and on government policies and programs originally intended to help control the costs of pharmaceuticals.

This panel of industry, legal, and economic experts explored some of the key compliance priorities that are facing pharmaceutical and biotech companies with respect to the FCA and the Anti-Kickback Statute (AKS), as well as the economic and pricing issues that are often at the crux of these matters.

Not Over Yet? The panelists noted that patient support programs (PSPs) – especially those that offer copay assistance to Medicare patients for drugs, including through charitable organizations – are drawing increased attention due to a perceived risk that pharmaceutical manufacturers could use them to steer patients toward their own products, potentially violating the AKS and the FCA.

Andrew O'Connor

Beware of Unintended Consequences. Enforcement agencies seem increasingly concerned with the question of whether cost-sharing programs can lead to potential excess use of a drug. However, an overly simplistic approach to this issue will not account for the broader impact on patient health and total health care costs. For example, a reduction in copay assistance due to increased FCA enforcement could also lead to under-utilization of drugs certain patients need, which in turn could lead to worse outcomes and higher hospitalization costs. It also may oversimplify the reality and need in highly specialized or rare treatments.

Jesse Siegel

It's Never Simple. A plethora of clinical practice and market considerations go into developing pricing strategies, and these must be factored into any examination of causation and utilization in FCA or AKS cases.

Christopher Ody **Anupam B. Jena**

Data Mining and the False Claims Act: Key Takeaways

Wednesday, October 12, 2022

Mihran Yenikomshian (moderator), Analysis Group

Paul Kalb, Sidley Austin

Amol Navathe, Perelman School of Medicine and The Wharton School, University of Pennsylvania

Paul Starrett, PrivacyLabs

Historically, the DOJ has relied almost entirely on whistleblowers to bring forward FCA allegations, as they can often provide firsthand accounts of the conduct in question. Increasingly, however, the DOJ is using sophisticated algorithms that screen data in order to root out FCA violations. How is the government using these data analytics? And what can companies do in-house to proactively assess their own risk?

The Rise of Data Analytics. While the number of *qui tam* cases, in which a private individual makes an allegation on behalf of the government, rose in the 2010s, cases without a whistleblower became much more prevalent in 2020 and 2021. The DOJ has noted that this is at least partially due to its increased use of data analytics – including machine learning – to move forward on its own, with less reliance on insiders.

Paul Kalb

Retaining the Human Touch. Even amid the vast expanse of health care data available, human intervention remains critical to determining whether fraud is present, as some courts have noted in their deliberations.

Amol Navathe

Paul Starrett

Going Beyond the Numbers. For instance, raw data without the appropriate context might flag disruptions to health care delivery from the COVID-19 pandemic, such as increased prescribing during telehealth appointments, as potential fraud. In actuality, such disruptions may simply come from real-world, practical solutions – in this case, telehealth as, at times, the only care delivery available during a viral pandemic.

Amol Navathe

What Can We Do? Because none of the models being developed for detecting fraud is perfect, companies should examine their own practices proactively to stay ahead of others who have access to the same data.

Paul Kalb

Economic Loss Arguments in Pharmaceutical Product Liability Class Actions

Wednesday, December 14, 2022

Brian Ellman (moderator), Analysis Group

David C. Chan, Jr., Stanford University; Center for Health Care Evaluation, US Department of Veterans Affairs Palo Alto; US Department of Veterans Affairs QUERI Center for Policy Evaluation

Punam Anand Keller, Center for Business, Government, & Society, Tuck School of Business at Dartmouth

Timothy E. Kosty, Pharmacy Healthcare Solutions

Gregory E. Ostfeld, Greenberg Traurig

Product liability litigation matters are nothing new for the pharmaceutical and medical device industries. What is new is the number of follow-on litigation cases in which plaintiffs allege that they have suffered economic losses – as opposed to health-related injury – as a result of their payment for the medical product involved in product liability matters.

This panel's experts explored the legal framework of such litigation and the intricate network of economic, clinical, industry, and consumer behavior dynamics that inform the determination of economic damages.

Where's the Harm? Economic loss cases in this industry often involve classes of plaintiffs that may not have suffered adverse treatment outcomes themselves, or may not even have been exposed to the medical products at all – for example, insurance providers that paid for the product on behalf of their beneficiaries.

Gregory Ostfeld

It's Complicated. Certain aspects of health care markets complicate the assessment of potential economic loss from product liability allegations – in particular, the number of parties other than the patient (including prescribers, PBMs, insurers, and even dispensing pharmacies) – that influence the ultimate purchase.

David Chan **Punam Anand Keller**

Worth Less or Worthless? The panelists discussed at length two primary allegations of economic loss in these cases: claims that the drug in question becomes "worth less" than the product plaintiffs thought they were purchasing, or, alternatively, claims that the alleged defect renders the drug entirely "worthless." The experts agreed that the "all or nothing" approach to economic value was a difficult one to rationalize.

David Chan **Gregory Ostfeld**

Timothy Kosty **Punam Anand Keller**

A Question of Value. Ultimately, panelists said, the true economic value of a drug can only be established through a nuanced understanding of how treatment and purchase decisions are contextualized in the real world.

Timothy Kosty **David Chan**

Timothy Kosty

Endnote

1. The webinar touched on proposed health care provisions included in the Build Back Better Act passed by the US House of Representatives in November 2021. Some elements of Build Back Better, such as a program for lowering prescription drug costs for Medicare beneficiaries, were later adopted in the Inflation Reduction Act, which was signed into law in August 2022.