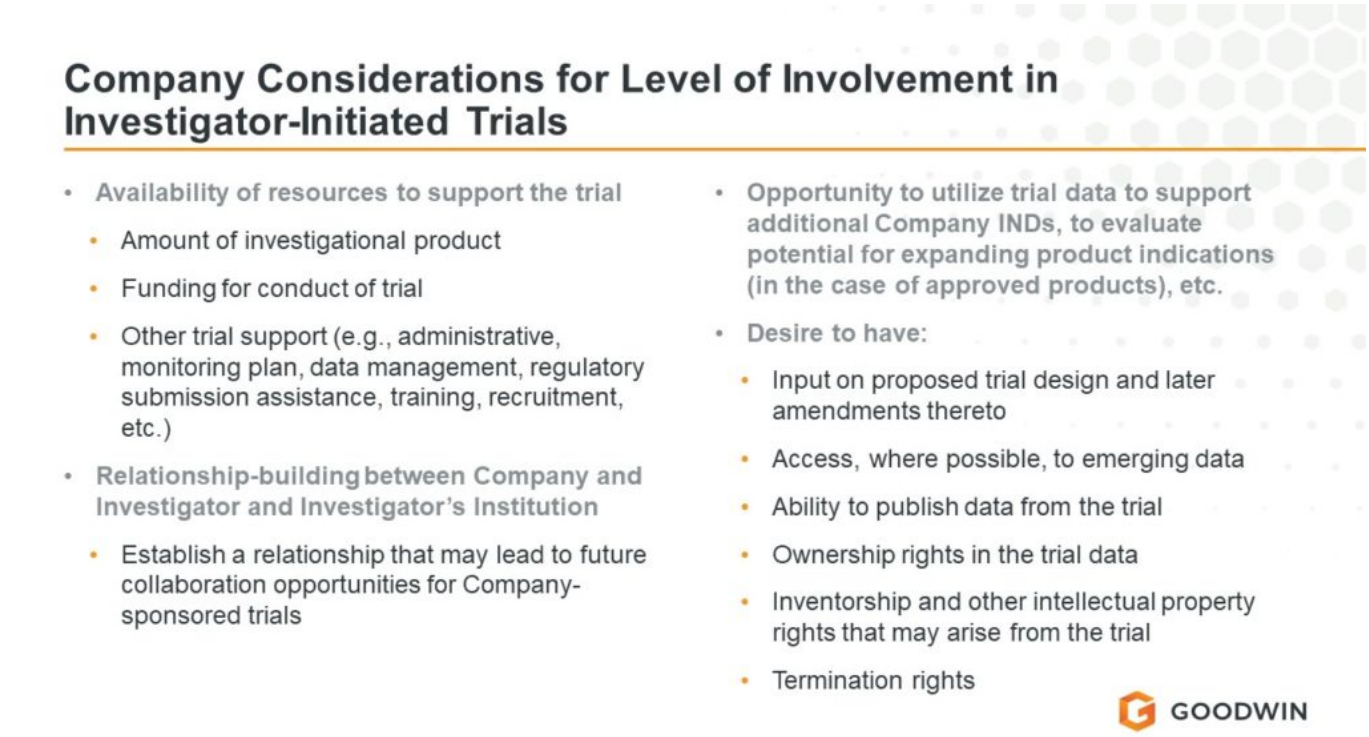
Antitrust & Competition Life Sciences 2022 Year In Review

 M&A activity in the life sciences space proceeded largely as usual in 2022, with most transactions receiving expected levels of agency scrutiny and closing in the normal course despite aggressive rhetoric from new leadership at both agencies. Notably, the government has thus far not applied more novel theories of antitrust harm outside of the tech space, and both agencies have met skeptical judges in other ongoing litigations. Antitrust + Competition lawyers **Arman Oruc**, **Andrew Lacy**, **Sarah Jordan**, **Elliot Silver**, and **Charlie Stewart** discuss transaction developments and predictions in the **Antitrust & Competition Life Sciences 2022 Year In Review**.

Leveraging Investigator-Initiated Trials in Rare Disease Drug Development

Investigators interested in rare disease treatment development have the opportunity to approach drug and biologic developers to obtain investigational drug supply for trials in which the investigators, typically at academic institutions, act as sponsor-investigators. Similarly, companies open to extending their product development pipelines can look to investigator-initiated trials as a mechanism to better understand the overall safety profile for their product candidates while exploring the potential therapeutic utility of their product candidates in diseases where unmet medical needs remain. So often, those needs exist in rare diseases where populations are small and investment returns are difficult to project. Drug developers deciding whether to supply investigational products to sponsor-investigators looking to explore therapeutic potential in areas of their research interests should evaluate what level of involvement to exercise over the investigator-initiated trial. We highlight some of these considerations below.



Ultimately, drug developers hold the decision-making power over whether to allow investigator-initiated research for their product candidates. Thereafter, the contracting process around the setup of an investigator-initiated trial and clinical supply agreement provides drug developers the opportunity to negotiate their level of involvement in the research of their candidates. In negotiating the setup of investigator-initiated research supply, drug developers often balance their support of research into what are often unmet needs with limited company resources, limited supply that may be available and any potential risks that may flow from trial learnings in the proposed disease space. As an upside, investigator-initiated trials afford developers the opportunity to extend their research reach and product development pipelines, so any interest by investigators to conduct research with industry candidates warrants consideration.

Goodwin Invites You to a Conversation with Rare Disease Community Leaders

In global observance of Rare Disease Day, Goodwin invites you to join us for a special awareness event on March 1, 2023 in our Boston office or virtually for those attending remotely to spotlight the critical work being done to address over 7,000 rare diseases that impact more than 300 million people globally.

Goodwin's Life Sciences Regulatory & Compliance team is bringing together global leaders in the rare disease community for a series of three fireside chats to discuss what inspires them, what challenges continue to face the rare disease community and rare disease patients, the work ahead in

the global effort against rare disease, and what we can do to help. Our registration links and full agenda are below, and a networking reception will follow the in-person event in Boston.

A Conversation with Rare Disease Leaders (March 1, 2023) Agenda:

12:00 PM – 12:30 PM EDT | Welcome & Networking Lunch

12:30 PM – 1:00 PM EDT | Fireside Chat – The CEO View

- Justin Klee and Josh Cohen, Co-CEOs & Co-Founders Amylyx (via Zoom)
- Julie Tibbets, Moderator

1:00 PM – 1:30 PM EDT | Fireside Chat – The Patient View

- Bob Coughlin, Managing Director, JLL and Cystic Fibrosis Patient Advocate
- Julie Tibbets, Moderator
- Matt Wetzel, Moderator

1:30 PM – 2:00 PM EDT | Fireside Chat – The Policy View

- Tom DiLenge, Senior Partner, Global Public Policy, Regulatory & Governmental Strategy, Flagship Pioneering (formerly of BIO)
- Matt Wetzel, Moderator

2:00 PM – 2:30 PM EDT | Networking Reception

Click **here** to register for the in-person event in our Boston offices.

Click **here** to register for the virtual event.

340B Drug Pricing Program Reform Considerations

The 340B Drug Pricing Program is a government program, administered by the Health Resources and Services Administration (HRSA), that allows qualifying hospitals and clinics that treat low-income and uninsured patients to buy certain prescription drugs at a steep discount from drug manufacturers. Drug manufacturers participate in the 340B Program as a condition of obtaining Medicaid coverage of their drugs. For the many drug manufacturers who want their products to reach the broadest patient population, participation in the 340B Program is essentially mandatory.

The program is intended to help safety-net health care providers' financial resources reach more

financially vulnerable patients and deliver comprehensive services.[1] At the same time, drug manufacturers have concerns about the program:

- Manufacturers are concerned that deeply discounted prescription drugs should only go to covered entity patients and not diverted to individuals who are not covered entity patients, i.e., a practice commonly known as drug diversion.
- Manufacturers are concerned that the covered entities do not get both a deep Section 340B discount and any additional discounts and rebates under Medicaid, i.e., duplicate discounts.

Balancing the interests of covered entities and drug manufacturers has been a challenge, and one that has come under scrutiny in recent years. Drug manufacturers have no way of tracking how covered entities use the discounts paid under the Section 340B program, and there is no legal requirement for covered entities to pass the savings they received from manufacturers to patients.

There are four emerging areas of tension between the interests of covered entities and drug manufacturers related to the 340B program :

- Section 340B telemedicine standards and patient eligibility;
- Contract pharmacy utilization;
- Section 340B covered entity child sites; and
- Drug manufacturer audit limitations.

Until these four key areas are addressed, the Section 340B program will not serve its true goals; and drug manufacturers and covered entities will face increasing conflict over ambiguous and outdated regulations.

For more information regarding these controversies in the 340B Program, please see our recent Health Law360 and Life Sciences Law360 article, "**4 Key Issues Driving Drug Discount Abuse Must Be Addressed**" (Jan. 9, 2023) as well as our recent Goodwin Procter LLP client alert, **Federal Court of Appeals Rejects HHS Stance on Section 340B Contract Pharmacies** (Feb. 1, 2023).

[1] Health Resources & Servs. Admin., 340B Drug Pricing Program (Dec. 30, 2022).

Understanding Data Monitoring Committee Conflict of Interest Limitations

For sponsors utilizing a data monitoring committee in their trial designs to monitor for emerging safety signals, lack of effect, and/or futility of treatment, understanding data monitoring committee conflict of interest limitations is important to ensuring an

objective view of the data from a trial. Where we see these conflict of interest considerations put to the test most often is in rare disease trials where the available pool of informed experts can be just as small as the patient populations under study. As explained in FDA's final **guidance** for industry on this topic, core considerations for avoiding potential conflicts of interest in data monitoring committee member selection include:

- **Financial interests.** Here, careful consideration must be given to whether any prospective committee member holds ownership interests in the sponsor entity or stands in a position to benefit financially from the outcome of the trial. This can include equity or stock interests, employee or temporary employee status, paid consulting or advisory board relationships with the sponsor, prior research funding from an institution involved in the study, whose product is being evaluated in the study or competes with a product being evaluated in the study, among other things. FDA generally recommends against appointing any committee members with *ongoing* financial relationships to the trial's sponsor.

- **Other roles in the trial.** Those individuals entering subjects into and conducting a trial stand in a considerable conflict position given their knowledge of interim data emerging from subjects at their trial site which could influence the recruitment or monitoring trends of those individuals for the trial. As such, FDA generally recommends against appointing any committee member who is serving as an investigator in the trial the data monitoring committee would oversee. Additionally, FDA disfavors appointment of any members that have had input into the design of the trial or are involved in the conduct of the trial in any other role for similar reasons.

- **Intellectual conflicts.** Perhaps most challenging to evaluate and navigate in rare disease trials is the risk to objectivity that strongly held views of prospective data monitoring committee members could play in their ability to review the data in a fully objective manner. This could include prospective committee members with strong views on the relative merits of the intervention under study vs. others under development. Additionally, FDA recommends against appointing committee members with strong relationships to or personal differences with trial investigators or to sponsor employees which are likely to cloud their objectivity.

FDA recognizes the tension that sponsors must navigate between placing a high value on independence and avoidance of conflicts of interest in the composition of its data monitoring committees, on the one hand, and understanding the importance of a well-informed data monitoring committee to the effective oversight of emerging data from a trial, on the other. While there is no one-size-fits all approach, data monitoring committee charters and sponsor conflict of interest policies can be helpful in this regard to establish and document the sponsor's limitations on engagement and interaction with the committee and vice versa. The more interconnected the sponsor-developer and investigator communities become, the more challenging it may become for sponsors, particularly those in the rare disease space, to ensure the objectivity of its data monitoring committees.