PG Briefing
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Private Equity Investment in Institutional Review Boards

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Private equity (PE) investment in health care has its detractors, skeptics, believers, and proponents with strongly held beliefs as to why their positions are the "right" positions. The debate about PE's role in health care has intensified over the past several years, particularly as PE investment in the global health care sector hit an all-time high in 2021 with a reported $200 billion in buyouts.[1] Although this global figure includes investments in the health care sector broadly (e.g., biotech, pharma, health care information technology), the largest portion of that investment has been in health care services in the United States including hospitals, nursing homes, and increasingly, physician practices.[2]

The number of journal articles and policy papers has also risen with this level of increased investment. A recent research paper reviewed 55 empirical studies conducted between 2010 and 2023 of PE ownership in U.S. health care operations including nursing homes, hospitals, and physician practices, to determine the impact on health care outcomes, costs to patients and payers, and quality of care.[3] Researchers concluded that PE investment was most closely associated with increased costs but had inconclusive effects on health outcomes. However, there are studies that reached the opposite conclusion.[4]

PE firms' targeting of commercial institutional review boards (IRBs) has not received the same level of scrutiny as PE firms' investment in hospitals, nursing homes, and physician offices. This is understandable. IRBs are notoriously difficult to evaluate for "quality."[5] Although accreditation by the Association for the Accreditation of Human Research Protections Programs is one indicia of a "good" IRB, accreditation alone does not tell the whole story. Moreover, PE firm investment in the commercial IRB space does not have the same longevity as the broader health care sector. This Briefing highlights the concerns raised by PE-backed IRBs as well as the positive impact of such investment.

Why Now?

In November 2019, Senators Elizabeth Warren (D-MA), Bernie Sanders (I-VT), and Sherrod Brown (D-OH) (Senators) requested information from the two largest commercial IRBs (WCG Clinical and Advarra), which also happen to be PE-owned.[6] The Senators noted that "[i]nvestor-owned for-profit IRBs . . . can be inherently vulnerable to conflicts of interest that could inhibit their ability to protect research subjects . . . ."[7] The Senators went on to express concern that "a handful of investor-owned IRB companies oversee[] the lion's share of commercially reviewed clinical research," thus sparking their interest in understanding the steps these two IRBs take, "if any, to ensure that [these] commercial IRBs protect participants from harm."[8]

Although WCG Clinical and Advarra submitted responses and documentation pursuant to the request, the Senators were not satisfied. In June 2020, the Senators asked the U.S. Government Accountability Office (GAO) to investigate commercial IRBs, including WCG Clinical and Advarra. The GAO took up that charge and in January

2023, issued a report titled *Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness.*[9]

Although independent IRBs have been around for decades, their share of protocol reviews in the market vastly increased between 2012 and 2021 regarding new drug studies that require approval by the U.S. Food and Drug Administration (FDA). By 2021, independent IRBs reviewed 48% of FDA-regulated research, bypassing university IRBs, which reviewed 42% of such research studies during the same time period.[10] The GAO Report also concluded, based on FDA data analysis, that in 2012 only 28% of FDA applications were associated with independent IRBs, and this proportion grew to 53% of FDA applications in 2021.[11]

The GAO's findings are discussed below.

Who Are the Players?

An IRB is an independent committee that evaluates the ethical aspects of research involving human participants. Depending on the nature of the clinical study, an IRB may be governed by the Common Rule (as codified),[12] which governs research that is conducted, supported, or otherwise subject to regulation by a federal department, e.g., the National Institutes of Health (NIH). Commercially sponsored drug and device trials require IRB approval pursuant to specific FDA regulations.[13]

Although historically most IRBs were housed within academic medical centers and other institutions conducting research, the late 1990s heralded the rise of independent or commercial IRBs. As privately funded clinical trials have become more commonplace, pharmaceutical, biomedical, and device manufacturers are looking for a "one stop shop" for their multi-site trials. There have also been changes in federal regulations that have normalized (and indeed required) the reliance on a single IRB, which tend to be commercial IRBs.[14] But the increase in PE-backed funding for commercial IRBs is the focus of this Briefing.

PE firms commonly raise capital from institutional investors, e.g., pension funds, and increasingly from high-net-worth investors to buy and sell target businesses. Although PE firms deploy a variety of strategies to identify a target, typically, PE firms look for historically profitable companies that are currently underperforming, or companies that are not currently productive but could change with strategic performance improvement measures. PE firms look to sell their investments for a profit within a fairly short timeline, e.g., three to five years, with some going as long as seven years.

The Fundamental Concern—Organizational Conflicts of Interests

The primary criticism of commercial IRBs (whether PE-backed or not) is that they are indebted to the sponsors that pay them to review protocols. The concern is that this conflict could lead to increased pressures for fast approval, approval without requests for modifications that should be requested, or approval with deficient informed consents.

But these organizational or "institutional" conflicts concerns are not unique to commercial or PE-backed IRBs. Institutional IRBs have the same, or at least similar, pressures. Their institutions want to attract research funding, prestigious studies, and enter into licensing and commercialization deals with industry sponsors, all of which may put pressure on IRBs when reviewing studies from these sponsors. Potential pressures within the IRB's own institution, such as not ruffling the feathers of a principal investigator with a robust portfolio of NIH grant funded studies, could also present conflicts of interest.

In 2009, the National Academy of Medicine (NAM) (formerly referred to as the Institute of Medicine) published a study on the risks of institutional conflicts of interest on the protections of human subjects (NAM Study).[15] The NAM Study stated:

> The question for institutions as well as individuals is whether a relationship with industry can be maintained in a way that achieves the desired benefits but avoids the risks of undue influence on decision making and the loss of public trust . . . . The risks to core missions posed by institutional conflicts of interest can be as serious as those created by individual conflicts.[16]

The NAM Study discussed at some length the 1999 death of Jesse Gelsinger in a gene transfer study conducted at the University of Pennsylvania's research institute. The NAM Study (citing numerous other studies) noted that the university's research institute received $25 million in donations annually from the sponsor of the study and the sponsor had exclusive rights to develop products arising from the study. The NAM Study also referenced that several past and then-current university officials had financial interests in the sponsor of the study, including the lead investigator who also was the director of the University of Pennsylvania's research institute.[17]

In the wake of the Gelsinger case, and sadly others, the institutional research community came under great scrutiny. Institutions made great strides in acknowledging weaknesses and developing conflicts mitigation strategies at the institutional level. In much the same way that institutions examined, learned from, and enhanced strategies for managing conflicts of interest, so too can the commercial IRB industry—provided that the protection of human subjects over profits remains the core driver.

Typical PE Firm Incentives, Culture, and Strategies Are at Odds with IRBs

The PE playbook has a several core chapters that investment firms follow to drive profitability, such as (i) charging the target management/consulting fees and taking on debt, (ii) pulling revenue out of the core business, (iii) cutting costs, (iv) becoming members of the target's board of directors, and (v) in some cases, serving in key management roles. A PE firm enters a market with a clear exit strategy and remains steadfast on that path. That does not make PE firms "bad." It does, however, create tensions with the typical IRB culture.

Commercial IRBs have been around for decades. These IRBs were formed by professionals in the research world who were steeped not just in the governing regulations, but best practices in research. Many of these founders sought to apply their experience and commercial funding to improve research oversight. "When [IRBs] are owned and closely held by those familiar with the history and challenges of research ethics, they may have greater flexibility and willingness to sacrifice some profit in the interest of participant protection, ethical leadership, and reputation management."[18]

These same IRBs recognize that their role in research goes well beyond compliance with the Common Rule or FDA regulations, which set the minimum requirements for protecting human subjects. For example, if a protocol before an IRB is approvable under the applicable regulations, but enhancements could be made to mitigate a potential risk, well-functioning IRBs may request protocol modifications to enhance a study design. But, once the PE firm invests, are those dedicated research professionals able to retain the autonomy to act in the best interests of the human subjects even at the risk of driving up sponsors' costs or slowing down approvals?

One hopes the answer is yes. PE firms are investing in a highly regulated business with the core mission of protecting those who voluntarily participate as human subjects in clinical and biomedical research. They are sophisticated entities that, one expects, understand the dire consequences of mismanaging that investment. Moreover, PE firms recognize the value of their investment, which can only be enhanced by maintaining the reputation of a well-regarded commercial IRB, which goes hand-in-hand with the IRB's commitment to quality IRB review and research ethics.

Lack of Transparency and Regulation of PE Firms

As PE firms buy private companies, there is commonly a lack of transparency in the details of the firms' investments and how PE ownership impacts the target's operations. There are not the same disclosure requirements as (and visibility into) publicly traded companies.

Opportunities Offered by PE Investment

That said, PE investment in health care does have the potential to bring some beneficial opportunities and outcomes. For instance, the GAO Report notes that "most experts, some stakeholders, and officials from two IRBs . . . noted private investment in IRBs has led to several positive changes to the IRB industry."[19] For example, the GAO found that institutional IRBs (i) meet less regularly than commercial IRBs; (ii) are mostly composed of volunteer, uncompensated members who have competing priorities; and (iii) may have less financial, technological, and personnel support facilitating IRB reviews.[20]

With PE backing, there are more resources available to (i) hire trained IRB administrators and support staff, (ii) provide education and training, and (iii) compensate IRB members allowing for them to carve out dedicated time to participate in more regularly scheduled reviews.[21]

Conclusion

PE investment in IRBs in and of itself is not necessarily a bad thing. PE-backed IRB studies do carry some benefits as noted in the GAO Report. That said, as discussed throughout this Briefing, there are numerous studies on the adverse impact of PE investment in health care, which give rise to concerns in commercial IRB investment, which is far less studied.

PE investment in health care is on a steady rise and there is no reason to believe this will cease, absent some significant change, such as legislation that drastically alters the landscape. As such, it is imperative that guardrails be in place to ensure, to the extent practicable, that research integrity, proper motives, and the protection of human subjects are not compromised for profits.

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[1] *Healthcare Private Equity Market 2022: The Year in Review and Outlook*, Bain & Company (2023), https://www.bain.com/globalassets/noindex/2023/bain_report_global-private-equity-report-2023.pdf.
[2] Robert Scheffler et al., *Monetizing Medicine: Private Equity and Competition in Physician Practice Markets*, American Antitrust Institute, Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, University of California, Berkely, and the Washington Center for Equitable Growth (Jul. 10, 2023), https://www.antitrustinstitute.org/wp-content/uploads/2023/07/AAI-UCB-EG_Private-Equity-I-Physician-Practice-Report_FINAL.pdf.
[3] Alexander Borsa, et al., *Evaluating Trends in Private Equity Ownership and Impacts on Health Outcomes, Costs, and Quality: Systematic Review*, 382 THE BMJ 1136 (July 19, 2023), https://www.bmj.com/content/382/bmj-2023-075244.
[4] Sneha Kannan et al., *Changes in Hospital Adverse Events and Patient Outcomes Associated With Private Equity Acquisition*, 330 JAMA 2365 (Dec. 26, 2023), https://jamanetwork.com/journals/jama/article-abstract/2813379.
[5] Stephen Rosenfeld, *Institutional Review Board Assessment-Balancing Efficiency and Quality*, 20 OCHSNER J. 50 (Spring 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7122259/; *see also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-104721, INSTITUTIONAL REVIEW BOARDS: ACTIONS NEEDED TO IMPROVE FEDERAL OVERSIGHT AND EXAMINE EFFECTIVENESS 59 (2023) (hereinafter, GAO Report).

[6] Letters from Sens. Brown, Sanders, and Warren to Donald Deieso, Ph.D (Executive Chairman and CEO of WCG Clinical) and Pat Donnelly, MBA (CEO of Advarra) (Nov. 15, 2019), https://www.warren.senate.gov/oversight/letters/senators-warren-brown-and-sanders-investigate-inherent-conflicts-of-interest-of-private-equity-owned-institutional-review-boards.
[7] *Id.*
[8] *Id.*
[9] GAO Report, *supra* note 5.
[10] *Id.* at 19.
[11] *Id.* at 20. The GAO Report provides in-depth analysis of drivers behind the sharp increase in independent IRBs' share of the FDA-regulated research market. That is beyond the scope of the Briefing, and as such we are not exploring that issue here.
[12] 45 C.F.R. pt. 46.
[13] 21 C.F.R. pts. 50 and 56.
[14] In 2016, the NIH issued policy guidance on the "Use of a Single [IRB] for Multi-Site Research." 81 Fed. Reg. 40325 (June 21, 2016). It was there that the NIH first clarified that federal grant funding could be properly utilized to engage a single IRB; *see also* U.S. DEPT. OF HEALTH & HUMAN SERVS., FDA, 2005D.0103, USING A CENTRALIZED IRB REVIEW PROCESS IN MULTICENTER CLINICAL TRIALS GUIDANCE FOR THE INDUSTRY (Mar. 2006).
[15] CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 216 (Bernard Lo and Marilyn Field eds., 2009).
[16] *Id.*
[17] *Id.* at 217.
[18] Holly Fernandez Lynch and Stephen Rosenfeld, *Institutional Review Board Quality, Private Equity, and Promoting Ethical Human Subjects Research*,173 J. ANN. INTERN. MED. 558 (Oct. 6, 2020), https://pubmed.ncbi.nlm.nih.gov/32687743/.
[19] GAO Report, *supra* note 5, at 28.
[20] *Id.* at 23.
[21] *Id.* at 29.

