United States Senate
WASHINGTON, DC 20510

November 15, 2019

Donald Deieso, Ph.D
Executive Chairman & Chief Executive Officer
WCG Clinical
212 Carnegie Center, Suite 301
Princeton, NJ 08540

Dear Dr. Deieso:

We write today to request information about the commercial Institutional Review Boards (IRBs) controlled by WCG Clinical. IRBs, which review and approve research proposals to ensure they are conducted ethically, are entrusted with protecting participants and vulnerable populations. Investor-owned for-profit IRBs, however, can be inherently vulnerable to conflicts of interest that could inhibit their ability to protect research subjects—and we are interested in better understanding the steps that WCG Clinical takes, if any, to ensure that its commercial IRBs protect participants from harm.

Commercial, for-profit IRBs are a large and growing force in clinical research. Commercial IRBs now oversee approximately 70% of all drug and medical device trials in the United States.[1] Market consolidation has left a handful of investor-owned IRB companies overseeing the lion's share of commercially reviewed clinical research. Your company, WCG Clinical, was formed in 2012 when a private equity firm, Arsenal Capital, acquired two of the largest commercial IRBs, Western IRB and Copernicus Group IRB, followed by a number of other competitor firms, including Aspire IRB, Midlands IRB, and New England IRB.[2] Similarly, Chesapeake IRB and Schulman IRB merged in 2017 to form Advarra, a company that has since acquired Quorum Review, bringing together three of the largest operators into a single company, also owned by a private equity firm.[3]

Academic and non-profit IRBs are not immune from conflicts of interest. However, the business model of commercial IRBs—particularly those owned by private equity firms—creates an inherent conflict of interest for for-profit review boards. As for-profit operators who depend on fees from their applicants, commercial IRBs have an incentive to provide quick approvals that minimize obstacles for the sponsor. The recent trend of private equity ownership is especially troubling, given the pressures to reduce costs and ramp up profits that often accompany private

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[1] Stat News, "In clinical trials, for-profit review boards are taking over for hospitals. Should they?" Sheila Kaplan, July 6, 2016, https://www.statnews.com/2016/07/06/institutional-review-boards-commercial-irbs/
[2] Center Watch Compilation Report Series, "IRB market consolidating rapidly," https://store.centerwatch.com/pdfs/samples/BRRCR17-IRBMarket.pdf
[3] Melissa Fassbender, "IRB Consolidation: Advarra acquires Quorum Review and Kinetiq," March 5, 2019, https://www.outsourcing-pharma.com/Article/2019/03/05/IRB-consolidation-Advarra-acquires-Quorum-Review-and-Kinetiq

equity's entry into a field.[4] If managers see their primary responsibility as generating returns for their investors, they may emphasize speed over thoroughness in the review process, creating risks for patients.

Furthermore, IRB reviewers may have industry ties. One survey of academic IRB members, for example, found that 32% had some form of industry financial ties, and 25% reported voting on a protocol with which they had a conflict of interest. 20% of respondents said that they did not always disclose relevant industry relationships.[5] No similar survey of commercial IRB members is available; we have no way to know if conflicts of interest among for-profit IRB reviewers are more or less common. Transparency of these financial conflicts is limited, and there is currently no way for the public to know whether those reviewing the research have a personal or financial stake in it or whether a clear conflict of interest policy has been consistently enforced.

We are also concerned by the seeming rise in "pay to participate" trials and recent reports that suggest researchers are taking advantage of patients eager for new treatments by requiring individuals to pay to participate in a clinical trial.[6] In one particularly egregious example, a Florida physician proposed fees as high as $285,000 for participants in a study of plasma infusions to prevent aging.[7] Another trial asked parents of autistic children to pay $7,200 to enroll in a trial of stem cell therapy, not including travel and other expenses, which could increase the total cost of participation to more than $20,000.[8] These practices, by definition, restrict access to clinical trials and risk taking advantage of vulnerable patients and their families. In addition, they create strong incentives for sponsors to oversell the potential benefits of the research, when—in reality—many early-stage trials fail.[9] Furthermore, these study designs often forego a control group, since participants are unlikely to be willing to pay if they are not actually receiving a treatment—potentially compromising their scientific validity.[10] IRB oversight should aim to prevent precisely these types of exploitative schemes.

Despite the crucial role that IRBs play in protecting research participants, almost no data is publicly available about their effectiveness.[11] IRBs must generally register with the Department

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[4] Center for Economic and Policy Research, "Private Equity Partners Get Rich at Taxpayer Expense," Eileen Applebaum and Rosemary Batt, July 2017, https://populardemocracy.org/pirateequity

[5] *JAMA Internal Medicine,* "Industry Relationships Among Academic Institutional Review Board Members: Changes from 2005 Through 2014," September 2015, E.G. Campbell, C. Vogeli, S.R. Rao, M. Abraham, R. Pierson, and S. Applebaum, https://www.ncbi.nlm.nih.gov/pubmed/26168043

[6] Stat News, "Amid rising concern, pay-to-play clinical trials are drawing federal scrutiny," Rebecca Robbins, August 6, 2019, https://www.statnews.com/2019/08/06/amid-rising-concern-pay-to-play-clinical-trials-are-drawing-federal-scrutiny/

[7] Stat News, "How a society gala was used to sell young-blood transfusions to baby boomers desperate to cheat death," Rebecca Robbins, March 2, 2018, https://www.statnews.com/2018/03/02/young-blood-anti-aging-study/

[8] Spectrum News, "Experts question rationale for stem cell trial for autism," Hannah Furfaro, July 25, 2019, https://www.spectrumnews.org/news/experts-question-rationale-for-stem-cell-trial-for-autism/

[9] *Medicine, Health Care, and Philosophy,* "Permitting patients to pay for participation in clinical trials: the advent of the P4 trial," David Shaw, Guido de Wert, Wybo Dondorp, David Townend, Gerard Bos, and Michel van Gelder, October 18, 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5487744/

[10] Wharton Public Policy Initiative, "Pay to Play: Should Patients Have to Pay to Be Part of Experimental Trials?" Danielle Martinez-McCormack, November 7, 2016, https://publicpolicy.wharton.upenn.edu/live/news/1514-pay-to-play-should-patients-have-to-pay-to-be-part#_edn2

[11] Stat News, "Assess institutional review boards by their quality of decisions, not ownership," Stephen Rosenfeld and Jim Gearhart, October 20, 2016, https://www.statnews.com/2016/10/20/institutional-review-boards-assessment/

of Health and Human Services (HHS) and provide a list of members, the number of employees, and the expected number of protocols to be reviewed.[12] Once registered, the IRB can be listed on an institution's application for Federalwide Assurance, which is needed to apply for federal funding.[13] HHS publishes a list of registered IRBs that includes contact information, but no other information about their policies, procedures, or outcomes.[14] Although this lack of transparency affects both institutional and commercial IRBs, it is especially troubling to lack information about the operations and outcomes of for-profit IRBs, in light of the profit incentive and pressure that they may feel from their investors.

Commercial IRB leaders have argued in the past that they should be evaluated based on the quality of their decisions.[15] We agree. To help us better understand the role of commercial IRBs and their vulnerabilities, we request the following data for each of the past five years by no later than December 13, 2019. For each of the questions below, please provide specific answers for Western IRB, Copernicus Group IRB, Aspire IRB, Midlands IRB, and New England IRB:

1. The number of research proposals received, the number of research proposals reviewed, and the number of research proposals approved without major substantive modifications, the number of research proposals approved with major substantive modifications, and the number of research proposals disapproved,
2. The number of research proposals approved under expedited review,
3. The number of reviews in which the IRB engaged a consultant to provide additional expertise not available on the regularly constituted panel,
4. The number of research proposals in which the IRB exercised its authority to observe, or have a third party observe, the consent process and/or the research itself,
5. The number of research proposals in which participant surveys or comprehension tests were used to evaluate participant satisfaction or understanding,
6. The number of proposals received that had initially been rejected by another IRB, and the number that were eventually approved,
7. The number of approved proposals in which the IRB received reports of serious and unexpected adverse events or unanticipated problems,
8. The number of proposals received from sponsors who have had at least one proposal denied by this IRB in the past five years,
9. The number of proposals that are reviewed on average during a single meeting of the IRB panel and the maximum number of proposals that may be reviewed per meeting,

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[12] Office for Human Research Protections, "IRB Registration Process FAQs," accessed October 10, 2019, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/irb-registration-process/index.html

[13] Office for Human Research Protections, "IRBs and Assurances," accessed October 10, 2019, https://www.hhs.gov/ohrp/irbs-and-assurances.html. https://www.gao.gov/new.items/d09448t.pdf

[14] Office for Human Research Protections, "OHRP Database for Registered IORGs & IRBs, Approved FWAs, and Documents Received In the Last 60 Days," Accessed October 10, 2019, https://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc

[15] Stat News, "Assess institutional review boards by their quality of decisions, not ownership," Stephen Rosenfeld and Jim Gearhart, October 20, 2016, https://www.statnews.com/2016/10/20/institutional-review-boards-assessment/

10. The number of pay-to-participate clinical trial proposals received, the number of pay-to-participate clinical trials reviewed, and the number of pay-to-participate clinical trials approved,
11. The distribution of proposed cost to participants in approved pay-to-participate clinical trial proposals,
12. The proportion of approved pay-to-participate proposals that included a control group, and
13. The proportion of proposals involving participant fees that were either disapproved, or were approved only after the sponsor agreed to eliminate participant fees.

Please also provide written answers to the following questions by no later than December 13, 2019:

1. What procedures does your IRB have in place to ensure high-quality, efficient, and effective review?
2. What metrics does your IRB use to evaluate the quality, efficiency, and effectiveness of its review process?
3. What criteria are used to evaluate risks and benefits when reviewing a proposal?
4. Please describe the background and expertise of the non-affiliated member(s) of the IRB panel.
5. Please describe the background and expertise of the non-scientist member(s) of the IRB panel, including how they may be representative of patients or vulnerable populations.
6. In your organizational structure, does anyone besides members of the IRB panel attend IRB discussions or sign off on IRB decisions? If so, please describe their title, role, and involvement in the review process.
7. What is the process for IRB members to review proposals ahead of full IRB meetings? How far in advance do members receive proposals, and how many members are expected to review the full details of the proposal before discussing it?
8. What processes does your IRB have in place to work with researchers to improve a proposal before it is submitted for review?
9. How is information about adverse events memorialized and reported to the relevant federal agencies?
10. Please describe the IRB's process for disclosure of member conflicts of interest, and how the IRB responds to these disclosures.
    a. How are these financial conflicts disclosed to other IRB members and the public?
    b. What policies does the IRB have in place for member recusals? How are these policies enforced?
    c. To illustrate how this policy has been implemented in practice, please describe any cases in the past five years in which IRB members recused themselves due to conflicts of interest.
    d. What percentage of IRB members have financial ties to the pharmaceutical or medical device industry (excluding stock ownership through widely held vehicles such as index or mutual funds)?

e. How are conflict of interest policies applied and enforced with regard to consultants who are engaged on specific reviews?

11. How does the IRB review process evaluate equitable access to clinical trial participation and the diversity, including race, ethnicity, age, gender identity, and sexual orientation, of potential participants?
12. What procedures are in place to determine if the investigator plans to charge participants a fee, and if so, what the amount of that fee is?
13. What criteria are used to evaluate "pay to participate" proposals? Please describe how those criteria differ from standards for clinical trials that do not involve participant fees.
14. What factors does the IRB consider when reviewing a proposal that lacks a control group and/or a double-blind study design?

Sincerely,

Elizabeth Warren
United States Senator

Bernard Sanders
United States Senator

Sherrod Brown
United States Senator