Public Comment PORTAL Program On Regulation, Therapeutics, And Law

Date:	July 27, 2026
To:	Stephen Andrews, Deputy General Counsel for Regulation Mark Fajfar, Senior Assistant General Counsel Commodity Futures Trading Commission Three Lafayette Centre, 1155 21st Street NW Washington, DC 20581
Re:	**Prediction Markets; Public Interest Determinations (RIN 3038-AF65)**

Dear Mr. Andrews and Mr. Fajfar:

On behalf of the Cancer Innovation and Regulation Initiative in the Program On Regulation, Therapeutics, And Law (PORTAL)[1] at Harvard Medical School and the Brigham and Women's Hospital, we appreciate the opportunity to submit comments to the Commodity Futures Trading Commission on the notice of proposed rulemaking on prediction markets and public interest determinations.

We wanted to alert the Commission to a new class of event contracts that was introduced after publication of the Advance Notice of Proposed Rulemaking and this Proposed Rule. In July 2026, a designated contract market (DCM) and its data partner announced a suite of event contracts that would settle on (i) outcomes and design of Phase 3 clinical trials and (ii) Food and Drug Administration (FDA) regulatory decisions on drugs. Example contracts include: *"Will AR1001's POLARIS-AD Phase 3 trial meet its primary endpoint in early Alzheimer's disease?"* and *"Will the FDA approve Gilead/Arcellx's anito-cel for relapsed/refractory multiple myeloma?"*.

The expansion of prediction markets into clinical trials and regulatory decisions for investigational therapies raises serious concerns. This class of event contracts settles on outcomes that a small group of insiders know about in advance and can influence, and where the underlying activity is federally regulated research on human subjects. Without appropriate guardrails, such contracts could disrupt the sensitive conduct of human clinical testing, incentivize leakage and exploitation of material non-public and protected health information, and endanger clinical trial participants. **We urge the Commission to act in this rulemaking to:**

- Exercise its authority under section 5c(c)(5)(C)(i)(VI) of the Commodity Exchange Act and proposed §40.11(a)(2)(vi) to **determine human subjects research as an activity similar to the Enumerated Activities and event contracts based on such research is contrary to the public interest**; and

[1] Based in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital and Harvard Medical School, PORTAL is one of the largest academic research centers in the United States dedicated to investigating the regulation, use, evidence, and cost of prescription drugs and other technologies. Our research program is independent of the pharmaceutical industry.

- **Adopt in Appendix F that event contracts based on human subjects research raise public interest and policy concerns applying proposed §40.11(a)(5)**.

Our comment on the Proposed Rule does not take a position on other types of event contracts or prediction markets in general.

We thank the Commodity Futures Trading Commission for the opportunity to provide comments on this Proposed Rule. Our team is available to discuss these issues at any time, and we welcome further engagement with CFTC on issues relating to event contracts and public health.

Sincerely,

Thomas Hwang, MD
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PORTAL Program On Regulation, Therapeutics, And Law

Risks of Harm from Event Contracts Involving Clinical Trials

The Special Rule covers contracts, transactions, agreements, and swaps in excluded commodities based on the "occurrence, extent of an occurrence, or contingency (other than a change in the price, rate, value, or levels of a commodity described in [CEA] section la(2)(i))." Whether a clinical trial meets its primary endpoint—or whether the FDA imposes (or lifts) a clinical hold suspending (or resuming) a clinical trial—is an occurrence beyond the control of any party to the contract and carries financial, commercial, or economic consequence.

Our research has shown that clinical trials commonly fail due to safety or efficacy issues. In our study of late-stage clinical trials, we found that roughly half of all Phase 3 clinical trials failed in clinical development, of which nearly 75% of trial failures were due to inadequate efficacy or safety concerns.[2] Event contracts involving human clinical trials raise serious safety and data integrity concerns that could disrupt trial conduct and potentially endanger trial participants:

[2] Hwang TJ, et al. *JAMA Intern Med* 2016;176(12):1826-1833.

1. **Outcomes of clinical trials of experimental therapies depend on sensitive and protected health information.** Longstanding federal regulations have carefully built a data firewall to guard interim data in clinical trials, recognizing the risks from mishandling, misinterpreting, or mistakenly disclosing evolving clinical trial data. Specifically, Phase 3 studies have independent Data and Safety Monitoring Boards, which can recommend that a trial be stopped early because of concerns about participant safety or because the trial is statistically unlikely to be successful based on early data (i.e., for 'futility'). These independent expert committees must be independent of the trial sponsors and institutions conducting the trial. Event contracts based on these outcomes could incentivize breach of participants' protected health information (protected under the Health Insurance Portability and Accountability Act) and derogate the ability of Data and Safety Monitoring Boards to operate in participant's best interests. For example, a serious adverse event or death of a participant in a clinical trial could result in imposition of a 'clinical hold' (or suspension) by the FDA or termination of the clinical trial. Improper and premature disclosure of this or similar even could undermine the integrity of the data generated by the trial and may jeopardize urgent investigations by the Data and Safety Monitoring Board, trial sponsors, and the FDA to adjudicate whether this safety event was causally linked to the experimental therapy and whether other trial participants might be at risk. Adjudication of these outcomes could drift to align with market expectations. Such contracts would create incentives for misuse of material non-public and protected health information by not only members of the Data and Safety Monitoring Board but also staff and other insiders with knowledge of its proceedings;

2. **Event contracts would invite manipulation of underlying clinical trial data.** Patient reporting of outcomes is an integral part of clinical trials, such as patients reporting symptoms, views on their quality of life, and other measures related to their disease or condition. Event contracts would incentivize manipulation of clinical trial data, particularly through participant-reported outcomes. For example, trial participants with a financial position in the event contract may selectively report or misreport information to study investigators, or they may selectively drop-out of the trial or discontinue treatment, which could bias the analysis. In some cases, patient outcomes are graded by trial investigators: for example, an investigator evaluates whether a tumor has shrunk or if the disease has progressed using imaging criteria, or an investigator examines psoriasis lesions and grades its severity based on lesion redness, thickness, and scaling. Investigators conducting this outcome grading may be improperly influenced by prediction markets, for example grading patient outcomes more favorably for the treatment arm (increasing probability of success of the trial) or more aggressively reporting side effects in the treated group (decreasing probability of trial success). Trial sponsors may be motivated to halt trials sooner based on market feedback from these contracts; and

3. **Event contracts could stymie patient enrollment and raise questions about trial equipoise.** Fewer patients may volunteer to participate in a clinical trial, if event contracts based on the trial's success are trading unfavorably at that point in time. Moreover, clinical trials rely on an ethical concept known as "equipoise," which means there must be a state of genuine uncertainty about which treatment or intervention is better. It would be unethical to enroll participants in a trial if a treatment is already known to work better than its comparator, or if participants are knowingly given an inferior option. Event contracts with market-implied odds of trial failure could violate equipoise.

Clinical trials may need to be halted prematurely if broken equipoise due to market odds contaminates investigator and participant expectations about benefit and safety.

Event Contracts Involving Clinical Trials are Not in Public Interest

Proposed §40.11(a)(2)(vi) implements section 5c(c)(5)(C)(i)(VI) of the Commodity Exchange Act, which permits the Commission to determine by rule or regulation an activity similar to the Enumerated Activities that is contrary to the public interest. **We urge the Commission to clarify event contracts based on human subjects research as contrary to the public interest.**

1. **Ongoing human subjects research is similar to the Enumerated Activities, and event contracts based on clinical trials could harm trial participants and incentivize trading on confidential and protected patient health information.**

   Similar to the Enumerated Activities, and described above, event contracts based on clinical trials create perverse financial incentives for actions that harm or hasten harm to trial participants. The Commission highlights the case of event contracts settling based on player injury as posing negative public interest factors, because such event contracts "could encourage or facilitate physical harm to athletes" and "raise public interest concerns about the confidentiality of medical information and the potential for such sensitive information to be leaked or exploited by insiders". This same reasoning applies for event contracts based on clinical trials. The individuals with the greatest capacity to influence or determine the settling occurrence are directly entrusted with the safety and welfare of human subjects. The risks from event contracts may be lower, though not fully extinguished, for clinical trials that have already been completed, or contracts settling on published trial results. These concerns are less applicable for event contracts based on aggregate or overall trends: for example, an event contract on whether a disease-modifying drug for an incurable condition will be approved by the FDA by 2030 would not raise the same issues as an event contract predicated on the outcome of a clinical trial of said investigational product.

2. **Event contracts based on human subjects research are contrary to the public interest based on the factors proposed by the Commission.**

   There are multiple structural reasons why event contracts based on clinical trials are not in the public interest. First, clinical trial outcomes depend on highly sensitive and protected health information, and event contracts based on clinical trials would create incentives for information leakage and misuse of this material non-public and protected health information. Meaningful insight into the underlying event is concentrated outside the broader market in a small number of individuals, for example the trial Data and Safety Monitoring Boards; clinical trial site investigators; and actual trial patients. The settlement-determining information for such event contracts is not dispersed among many participants; instead, this information is held by a closed and protected set of participants until its release. Unlike other events, any informational value from event contracts is clearly and greatly outweighed by the reflexive, perverse influence of price signal noise on clinical trial conduct and data integrity. Second,

the settling occurrence would be subject to manipulation, as detailed in the prior section. For example, trial participants may selectively report or misreport clinical study outcomes; investigators may grade patient symptoms or report disease state differently; and trial sponsors may undermine Data and Safety Monitoring Boards to halt trials sooner or later. Third, there is no effective surveillance mechanism that could reach the prediction market's population for these event contracts. Employment verification is inadequate to effectively police insiders at trial Data and Safety Monitoring Boards as well as clinical trial sites, contract research organizations, and central laboratories.

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Therefore, we urge the Commission to act in this rulemaking to:

- Exercise its authority under section 5c(c)(5)(C)(i)(VI) of the Commodity Exchange Act and proposed §40.11(a)(2)(vi) to **determine human subjects research as an activity similar to the Enumerated Activities and event contracts based on such research is contrary to the public interest**; and

- **Adopt in Appendix F that event contracts based on human subjects research raise public interest and policy concerns applying proposed §40.11(a)(5)**.

We thank the Commodity Futures Trading Commission for the opportunity to provide comments on this Proposed Rule, and we welcome further engagement with CFTC on issues relating to event contracts and public health. ■