United States Senate

WASHINGTON, DC 20510

November 10, 2026

Robert F. Kennedy Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Secretary Kennedy,

We are concerned about a troubling development that prediction markets are now allowing individuals to bet on clinical trials and drug approvals. Clinical trials and approvals are critical processes that rely on scientific integrity to provide a new avenue of care for patients with targeted conditions and advance medical care for everyone. Allowing individuals to bet on the success of these trials and drugs undermines the scientific process, creates perverse incentives for researchers, harms trial participants, and could lead to dangerous medical outcomes for untold numbers of Americans.

Reports indicate that Kalshi and Polymarket have launched programs allowing users to trade event contracts on drug approvals and clinical trial outcomes.[1] Users have traded on whether the U.S. Department of Health and Human Services' (HHS or Department) Food and Drug Administration (FDA) will approve experimental medications from weight loss treatments, Alzheimer's disease, and different cancers, including lung, breast, pancreatic, and blood.[2] Many of the clinical trials implicated by these markets may be funded, in whole or in part, by the National Institutes of Health (NIH), one of the largest sources of clinical research funding in the country. Some trials subject to betting may also be conducted by NIH's own intramural research program, including at the NIH Clinical Center.

Researchers and medical professionals have expressed concern that offering bets on clinical trials threatens the integrity of the drug development process.[3] Specifically, experts expressed fears that study results may be compromised by participants dropping out of ongoing studies or

[1] Bobby Allyn, Kalshi and Polymarket bets on clinical trials criticized as 'ghastly', NPR (Aug. 7, 2026), https://www.npr.org/2026/08/07/nx-s1-5922530/patients-betting-kalshi-polymarket-clinical-trials.
[2] Rebecca Robbins, Should You Be Able to Bet on Drug Trials?, The N.Y Times (July 28, 2026), https://www.nytimes.com/2026/07/28/business/kalshi-polymarket-prediction-market-drugs.html; Reuters, Kalshi to allow bets on clinical trials, FDA decisions, Reuters (July 16, 2026) ,https://www.reuters.com/legal/litigation/kalshi-allow-bets-clinical-trials-fda-decisions-2026-07-16/.
[3] Robbins, supra note 2.

administrators altering their behavior due to the public prediction market.[4] Troublingly, there are also concerns that this expansion will tempt researchers to place bets on insider knowledge, creating incentives for researchers to tamper with trial data in hopes of a windfall that may have a consequential impact on patient safety and public health.[5] Kalshi has proposed safeguards to limit this concern, however the prediction market platforms do not have access to the long list of people involved in a clinical trial and therefore cannot adequately monitor for misconduct.[6] These concerns are well founded as in the past few years the U.S. Securities and Exchange Commission (SEC) has charged multiple people with insider trading connected to clinical trials.[7]

These integrity risks are not merely abstract - they fall most directly on patients, study participants, and volunteers hoping for answers and medical advancement, and whose participation makes these trials possible. Patients must receive informed consent, have their privacy protected, and have provisions put in place for monitoring of the data collected to ensure their safety.[8] Nowhere in the informed consent process, which requires disclosure of reasonably foreseeable risks and inconveniences to study participants, is it contemplated that a treatment outcome could become the subject of public wagering.[9] Allowing individuals to bet on the success of clinical trials allows people to bet on whether another individual is going to receive an available treatment or not. These platforms are allowing bettors to wager on the health, or even life and death, of complete strangers affected by these medical trials. The success of many late-stage cancer trials like those Kalshi is allowing users to trade event contracts is measured by how many participants survive which has raised concerns with patients and clinical trial participants.[10] It is disturbing to encourage a landscape where bettors are "rooting for experimental medicine to fail just to earn a buck."[11]

These risks to trial integrity and participant welfare fall squarely within your statutory responsibilities. As HHS Secretary, you are responsible for promoting public health through the prompt and efficient review of clinical research.[12] FDA must monitor the progress of clinical trials and ensure the safety of clinical testing and patients in the development of drugs to treat

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[4] Id.
[5] Allyn, supra note 1.
[6] Rebbecca Robbins, supra note 2; see also Rebecca Klar & Nyah Phengsitthy, Kalshi's Drug Trial Bets Raise Alarm Over Ethics, Insider Trades, Bloomberg (Sept. 16, 2026), https://news.bloomberglaw.com/securities-law/kalshis-drug-trial-bets-raise-alarm-over-ethics-insider-trades (explaining that insider trading concerns are heightened in the health and pharmaceutical world because of the number of people involved and questions whether the prohibitions that Kalshi outlines can be enforced at scale in this large network).
[7] SEC Charges Biopharmaceutical Company Consultant with Insider Trading (2026), https://www.sec.gov/enforcement-litigation/litigation-releases/lr-26460; Sec Charges Couple with Insider Trading on Confidential Clinical Trial Data (2021), https://www.sec.gov/newsroom/press-releases/2021-94.
[8] 45 CFR §46.111.
[9] FDA Guidance E6 (R3) Good clinical Practice §2.8.10 (f)-(g) https://www.fda.gov/media/169090/download.
[10] Rebbecca Robbins, supra note 2.
[11] Allyn, supra note 1.
[12] 21 U.S.C. §393(b)(1).

life threatening illnesses, which necessitates frequent oversight to ensure that clinical trial data integrity and patient safety is not compromised due to the trading of event contracts.[13] FDA's Center for Biologics Evaluation and Research (CBER) has also issued guidance directing that trial sponsors - those responsible for initiating, managing, and financing a clinical trial - must: (1) ensure the integrity and confidentiality of data generated and managed to produce reliable results; (2) establish committees whose members have managed conflicts of interest and follow documented decision-making and operating procedures; (3) assess all trial–related decisions for their impact on participant rights; and (4) maintain an appropriate system for managing research quality.[14] NIH imposes parallel obligations on its extramural grantees: investigators receiving NIH funding must disclose significant financial interests related to their research, and their institutions must manage, reduce, or eliminate conflicts that could bias study design, conduct, or reporting.[15] These existing frameworks were not designed with prediction markets in mind, and it is unclear whether they are adequate to address the novel financial incentives these platforms create.

This obligation to safeguard trial integrity extends to your Department's own workforce. HHS employees cannot have a financial interest in a significantly regulated organization.[16] However, the Department's ethics policies do not yet include any reference outlining that HHS employees are also barred from trading related event contracts on prediction markets.[17] This gap applies with equal force to NIH's intramural investigators and staff who serve on Data and Safety Monitoring Boards, both of whom may have access to nonpublic, outcome-relevant trial data. It is essential that the Department take the necessary steps to ensure that employees are not seeking financial gain based on nonpublic information on these markets, and time is of the essence given that predication markets that focus exclusively on clinical trials have begun to emerge.[18]

Because it is clear that these markets create perverse incentives, undermine public confidence in trial outcomes, and perpetuate the commodification of human suffering, we are requesting that you provide answers to the following questions by **December 1, 2026**:

1. Please provide all documents and communications, including but not limited to policies, regulations, guidance, ethics opinions, and internal correspondence, concerning the

[13] 21 CFR §§ 312.87 & 312.88.
[14] FDA Guidance E6 (R3) Good Clinical Practice §§ 3.16.1(a), 3.9.1, 3.9.4, 3.9.9, & 3.10, https://www.fda.gov/media/169090/download (Sept. 2025).
[15] 42 CFR Part 50, Subpart F.
[16] 5 CFR §§ 5501.104, 5501.110.
[17] U.S. Department of Health and Human Services, HHS OGC Ethics Q&As, https://www.hhs.gov/about/agencies/ogc/ethics-questions-and-answers/index.html.
[18] Sy Mukherjee, Prediction markets are putting a price on pharma's secrets. Here's what companies need to know, PharmaVoice (Sept. 8, 2026), https://www.pharmavoice.com/news/prediction-markets-pharma-secrets-compliance/829766/ (explaining that immediate tasks include ensuring existing compliance systems explicitly accounts for prediction markets, employee training on these obligations, and reviewing audit clauses); Endpoint Arena, https://endpointarena.com/.

participation of FDA reviewers, advisory committee members, or contracted personnel in prediction markets or other financial instruments tied to matters pending before the agency. If no such policy currently exists, please provide all documents reflecting any Department consideration of adopting one, including a timeline for doing so.

2. Please provide all documents and communications between HHS and any of its subcomponents and Kalshi, Polymarket, or any other operator of event-contract markets concerning drug approval or clinical trial outcomes, including but not limited to correspondence regarding data access, market structure, or agency concerns, from January 1, 2026 to the present.
3. Please provide all documents and communications reflecting FDA policy, guidance, or requirements imposed on clinical trial sponsors, investigators, or contract research organizations regarding the prevention of trading on nonpublic trial data, and all documents reflecting FDA's assessment of whether such trading violates existing data integrity or good clinical practice requirements.
4. Please provide all documents, communications, memoranda, or internal analyses reflecting any FDA evaluation of the risk that these markets could incentivize premature unblinding of trial data, participant attrition, or investigator conduct inconsistent with protocol.
5. Please provide all documents and communications between HHS, FDA, and the Commodity Futures Trading Commission concerning the approval, self-certification, or ongoing oversight of event contracts tied to FDA regulatory actions or clinical trial outcomes.
6. Please provide all documents and communications reflecting any position taken by you or the Acting Commissioner, internally or externally, on whether these markets are compatible with the Department's statutory mission and the integrity of the drug approval process.
7. Please identify any NIH-funded or NIH-conducted clinical trials that are, or have been, the subject of event contracts on prediction markets, and provide all documents and communications between NIH and any such market operator concerning these contracts.
8. Please provide all documents and communications reflecting whether NIH's existing financial conflict-of-interest regulations for extramural investigators are understood to apply to, require updating, or are currently being updated in light of, trading on prediction markets tied to the outcome of NIH-funded research.
9. Please provide all documents reflecting whether NIH intramural investigators, Data and Safety Monitoring Board members, or other NIH staff with access to nonpublic trial data are subject to any policy restricting participation in prediction markets tied to trials in which they are involved.

Clinical trials are essential to the advancement of the medical field and provide hopeful treatment routes for many people struggling with difficult medical conditions. HHS, FDA, and NIH must uphold the integrity of the drug development process and maintain public trust in the public

health by putting essential guardrails in place to prevent individuals profiting on the success and approval of drugs that the American people depend on. We look forward to your response.

Sincerely,

Angela D. Alsobrooks
United States Senator

Ron Wyden
United States Senator