

QUESTIONS FOR DR. STEPHEN HAHN, NOMINEE FOR FDA COMMISSIONER

Question One: Reference Pricing

Are you willing to support referential pricing as a means to reduce the astronomical cost of prescription drugs in this country?

Background: In 2014, Hahn [wrote a paper calling for reference pricing](#). Reference pricing (defined) involves selling a product just below the price of a competitor's product. When it comes to pharmaceuticals, the patient/consumer would likely pay their insurance company difference between the drug's list price and the price of the "reference" product. So for example, a reference product might be a generic version of a product. And in this example, the patient/consumer might pay their insurance company the difference between the drug's list price and the generic. Trump has signaled support for international reference pricing on drugs, but the pharmaceutical industry is wildly opposed to reference pricing.

Hahn Suggested A "Middle Ground" Pricing Model That Used Reference Pricing To Build Evidence And Then Allowed Drugmakers More Discretion Once Evidence Was Collected. "Hahn and Bekelman seem to suggest a middle ground: use reference pricing to build evidence, but allow drugmakers to "reset" the price based on the evidence." [Politico Pro Prescription Pulse, [10/8/19](#)]

- **Hahn Wrote That Prices For A New And More Expensive But Promising Therapy Should Be Tied To Products Already On The Market.** "In his paper with Justin Bekelman, Hahn suggests that prices for an expensive but promising newer therapy (in his example, proton therapy for cancers) can be tied to prices for treatments already on the market while evidence builds for the new product." [Politico Pro Prescription Pulse, [10/8/19](#)]

September 2019: House Democrats Included Trump's "Controversial International Referencing Pricing Idea" In Their Sweeping Drug Pricing Bill. "House Speaker Nancy Pelosi on Thursday revealed a sweeping plan aimed at lowering drug prices, harnessing aspects of President Donald Trump's controversial international reference pricing idea to cap the price the government could negotiate for up to 250 expensive brand drugs." [Modern Healthcare, [9/19/19](#)]

Reference Pricing Was Referred To As The Drug Industry's "Biggest Nightmare." "The drug industry's 'biggest nightmare is that the Obama administration decides to do something like reference pricing,' said Paul Heldman, an analyst with Heldman Simpson Partners. "Then the government would be making a decision that two products are similar and Medicare should reimburse at the rate of the lower-cost one." [Kaiser Health News, [5/25/16](#)]

Question Two: Recent Controversy

This past spring, your employer MD Anderson came under fire for dismissing ethnically Chinese researchers over academic espionage concerns. Can you explain what happened?

Background:

2019: Hahn "Came Under Fire From MD Anderson Employees Who Saw The Dismissals Of Ethnically Chinese Researchers [...] As Racially Motivated." "[T]his spring, Hahn came under fire from MD Anderson employees who saw the dismissals of ethnically Chinese researchers under investigation for unduly influencing U.S. research as racially motivated [...] While the dismissals came in response to an FBI investigation, they still sparked fears of racial profiling." [STAT, [9/10/19](#)]

- **MD Anderson Had Moved To Oust Three Sciences Over Academic Espionage Concerns Raised By NIH, FBI.** "MD Anderson Cancer Center is ousting three scientists in connection with concerns China is trying to steal U.S. scientific research, the first such publicly disclosed punishments since federal officials directed some institutions to investigate specific professors in violation of granting agency policies. MD Anderson took the actions after receiving e-mails last year from the National Institutes of Health, the nation's largest public funder of biomedical research, describing conflicts of interest or unreported foreign income by five faculty members. The agency, which has been assisted by the FBI, gave the cancer center 30 days to respond." [Houston Chronicle, [4/19/19](#)]

Question Three: Lack Of Oversight

In 2012, your employer MD Anderson was the recipient of a controversial cancer-drug development grant that had not undergone any scientific peer review and caused large scandal in the medical community. Given this history, how can you be sure you would be able to prevent something similar from happening on a larger scale?

Background:

March 2012: The Cancer Prevention And Research Institute Of Texas (CPRIT) Awarded An MD Anderson Team \$18 Million To Develop New Cancer Drugs. "In March, the taxpayer-funded Cancer Prevention and Research Institute of Texas (CPRIT) awarded a team of researchers at the Institute for Applied Cancer Science (IACS) at MD Anderson Cancer Center in Houston \$18 million to develop new cancer drugs." [The Scientist, [6/1/12](#)]

- **The Grant Was The Largest CPRIT Had Ever Awarded.** "Last month, the institute's chief scientific officer, Nobel laureate Alfred Gilman resigned, noting concerns about how the proposal for the large grant—the largest ever awarded by the institute, according to Nature—never underwent scientific review." [The Scientist, [6/1/12](#)]

May 2012: CPRIT's Chief Scientific Officer Resigned, Citing Concerns That The MD Anderson Grant Never Went Through Scientific Review. "Last month, the institute's chief scientific officer, Nobel laureate Alfred Gilman resigned, noting concerns about how the proposal for the large grant—the largest ever awarded by the institute, according to Nature—never underwent scientific review." [The Scientist, [6/1/12](#)]

- **Scientific Reviewers Also Resigned, Saying The MD Anderson Grant "Dishonored" The Peer Review System.** "The entire eight-member scientific review council of the Cancer Prevention and Research Institute of Texas (CPRIT) is stepping down, with most citing concerns about the integrity of the agency's peer review process. Many members of CPRIT's 100-strong roster of peer reviewers have begun to follow. [...] Now CPRIT's scientific reviewers are following Gilman out the door. (He steps down today). Sharp writes in a letter to CPRIT that he is resigning for the same reasons as Gilman. The peer review system 'was dishonored' because of how the MD Anderson incubator grant was reviewed and because grant awards were postponed over a 'suspicion of favoritism,' he writes. MIT's Tyler Jacks, also a member of the scientific review council, emphasizes the charges of bias in his letter: 'These accusations [of favoritism], as well as the failure to mandate scientific review of so-called incubator grants during this period, served to undermine the careful work of my committee and the sanctity of the larger CPRIT scientific review process,' he writes." [Science Magazine, [10/12/12](#)]

December 2013: A "Key Player" In The MD Anderson Award Was Later Indicted On Different Charges Of Bypassing Peer Review. "A grand jury in Travis County, Texas, indicted a former official of the Cancer Prevention and Research Institute of Texas for bypassing peer review in awarding an \$11 million grant to a Dallas-based company. Jerald Cobbs, the former CPRIT chief commercialization officer, was indicted on a felony charge of deceiving two of his CPRIT colleagues in 2010 by failing to disclose that the grant to Peloton Therapeutics Inc. was not subjected to review of either its science or its commercial potential. The indictment was dated Dec. 3. Cobbs, 62, is charged with securing execution of a document by deception, a first degree felony punishable by imprisonment of five to 99 years and a \$10,000 fine. Cobbs was also a key player in awarding an \$18 million grant to a Houston-area biotechnology incubator led by Lynda Chin, scientific director of the MD Anderson Cancer Center Institute for Applied Cancer Science and wife of the center's president, Ronald DePinho (The Cancer Letter, May 25, 2012)." [Cancer Letter, [12/13/13](#)]

Researchers And Legislatures Doubted CPRIT Would Ever Recover From The Scandal. "Since awarding an \$18 million research grant without any scientific peer review last March—among other shocking events revealed last year—investigations and dramatic resignations have mired the \$3 billion, state-funded Cancer Prevention and Research Institute of Texas (CPRIT). Now, amid results of a state audit, draft legislation for new regulations, and a band of fresh executives, CPRIT looks to reinstate its suspended grant application process, and—more importantly—rebuild its lofty reputation. But some researchers and legislatures have their doubts that the institute will recover from this high-profile scandal." [The Scientist, [2/12/13](#)]

Cancer Letter: The MD Anderson Grant Fallout Was "A Massive Scandal Closely Watched By Everyone In Cancer Science." "Efforts to award money to the MD Anderson incubator proposal were thwarted after CPRIT's chief scientific officer, Alfred Gilman, turned whistleblower, triggering a massive scandal closely watched by everyone in cancer science." [Cancer Letter, [12/13/13](#)]