Confirmation Hearing of Dr. Stephen Hahn to Serve as FDA Commissioner

Introduction

Today, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing to consider the nomination of Stephen Hahn, M.D., to serve as the next Commissioner of the Food and Drug Administration (FDA). On November 5, President Donald Trump announced his intent to nominate Dr. Hahn. Though members of the Committee asked Dr. Hahn about a variety of topics vaping and e-cigarettes were a particular concern. Senators also asked Dr. Hahn about how he would approach other important issues facing the FDA, including opioids, drug pricing, importation of unapproved drugs, cannabis and cannabis compounds, regenerative medicine, and other topics.

Dr. Hahn currently serves as Chief Medical Executive of MD Anderson Cancer Center in Houston, Texas. Prior to working at MD Anderson, Dr. Hahn was Professor and Chair of Radiation Oncology at the University of Pennsylvania School of Medicine and was Chief of the National Cancer Institute’s Prostate Cancer Clinic. He holds a B.A. in Biology from Rice University and an M.D. from Temple University. Dr. Hahn is board certified in oncology and radiation oncology.

Analysis

The theme of Dr. Hahn’s opening statement and his responses to questions from the Committee members was his commitment to data, science, and the law as well as preservation of FDA’s “gold standard” of evidence approvals for medical products. When pressed on contentious issues such as vaping and flavored nicotine products, Dr. Hahn reiterated that data will guide his actions and policy were he to be confirmed as FDA Commissioner. Dr. Hahn also emphasized the importance of transparency in FDA policy development, a commitment to following and implementing the laws Congress has enacted, and to a bipartisan, science-based approach to the protection of public health.

Flavored nicotine products proved especially contentious at the hearing as the Committee members had assumed FDA would act to ban these products due to their appeal to children and teenagers. News reports have recently indicated that the President opposes this action and that a ban may not be forthcoming. Democratic and Republican members of the Committee repeatedly pressed Dr. Hahn to commit to FDA exercising its authorities to ban these products and take other actions to curb vaping-related illnesses, use of flavored products by children and teens, and nicotine addiction.
Opening Remarks

Chairman Lamar Alexander (R-TN) opened the hearing. He believes that Dr. Hahn is qualified to lead the FDA. This is a critical time for the FDA, with the agency facing demanding issues such as e-cigarettes and vaping, implementation of the 21st Century Cures Act, food safety, and opioid abuse and misuse.

Chairman Alexander emphasized that Dr. Hahn is well qualified to lead FDA by virtue of his experience as a clinical oncologist providing patient care and as the Chief Medical Officer of MD Anderson, with oversight of 21,000 employees positions him well to lead the FDA. Chairman Alexander introduced seven letters of support into the record, which included the support of professional organizations and five previous, bipartisan FDA Commissioners.

Ranking Member Patty Murray (D-WA) then delivered her prepared remarks. Ranking Member Murray cited to the need for a strong FDA and a Commissioner who is committed to science and the public health and who is inured to political and industry pressure. She cited the failure of FDA to act on vaping and e-cigarettes and is deeply concerned with the President’s possible decision to not remove flavored e-cigarettes from the market. Ranking Member Murray expects assurance from Dr. Hahn of a commitment to upholding the “gold standard” of FDA review of medical products. She expressed some reservations about Dr. Hahn’s lack of federal agency experience and lacks a public record on policy issues.

Chairman Alexander also announced that the Committee will consider Dr. Hahn’s nomination when they return on December 3; Chairman Alexander hopes to provide bipartisan support for a vote for his confirmation by the full Senate before Christmas.

Dr. Hahn’s Opening Statement

Dr. Hahn’s opening statement is available here. In his opening statement, Dr. Hahn emphasized that he has relied upon and trusted the integrity of FDA for his entire career. He promised to put the health of the American people first and affirmed his commitment to FDA’s “gold standard” for assuring the safety and effectiveness of medical products and the safety of the food supply. He pledged to continue to support the data, science, and laws that govern FDA. He also stated that he believes strongly in collaborating with the legislative branch to protect the public health.

Next Steps

After two hours of questioning, Dr. Hahn was thanked for his time and service. Chairman Alexander stated that the Committee will now consider the testimony and any further written submissions. Questions for the Record are due in ten days, and the Committee will consider his nomination on December 3rd. While there are few working days left in the Senate calendar, and
much uncertainty, Chairman Alexander stated that he hoped to see a vote for confirmation by the full Senate before Christmas.

Questions and Answers of Note

Vaping

The most discussed topic in the hearing was on the current status of e-cigarettes and other vape products, particularly given both safeguarding children and the recently documented illnesses and deaths linked to these products. No fewer than eight senators, including Chairman Alexander, Ranking Member Murray, Senators Mitt Romney (R-UT), Lisa Murkowski (R-AK), Tammy Baldwin (D-WI), Susan Collins (R-ME), Maggie Hassan (D-NH), and Doug Jones (D-AL), commented or asked questions on the issue. In general, the senators’ questions and comments concentrated on general support for bans on flavored products and vaping, and concerns with the Administration’s reported, recent decision to reverse a proposed ban. Several senators asked Dr. Hahn to commit to moving forward on the ban or to give his personal opinion on the matter. In general, this line of questioning became a surrogate for the broader question of Dr. Hahn’s ability to stand up to powerful interest groups and political pressure, adhere to science-based decision-making, and protect patients and public health.

Dr. Hahn responded to this line of questioning by stating that, if confirmed, he would seek to address concerns around vaping and, as an oncologist treating lung cancer patients, understands the issue and is deeply concerned by the existing data. That said, he also would not commit to an explanation of what he would do as FDA Commissioner because he was not privy to the Administration’s reasoning or to an FDA guidance that he understood was under development. Dr. Hahn stated his reasoning and judgement, if confirmed, would be guided by the science, data, the law, and protection of public health.

Senator Alexander noted, with regard to e-cigarettes and vaping, there is unanimity in the Committee of concern with lung injuries and the rise in youth use. Measures such as tamper-proof cartridges, age verification, improving labeling, regulating flavors, lowering the level of nicotine are already within the authority of FDA. Senator Alexander hoped that there will be urgency at FDA to use the authority it already has to regulate these products.

Senator Jones criticized Dr. Hahn’s failure to take a strong position on flavored nicotine products and vaping and asked that he supplement the record.

Opioids

As was expected, there were a number of questions regarding opioid use and abuse. Several Committee members including Chairman Alexander, Ranking Member Murray, Senator Tim Kaine (D-VA), and Senator Bob Casey (D-PA), asked Dr. Hahn how he would accelerate the development of non-addictive pain medicines and drugs with abuse-deterrent formulations to relieve the opioid crisis. There was, conversely, also recognition of the importance of meeting
legitimate patient need and palliative care, points raised by Chairman Alexander and Senator Jacky Rosen (D-NV). Dr. Hahn responded to these questions in personal terms, reflecting upon the importance of pain management as multifaceted and often requiring an interdisciplinary approach. He supports the efforts already underway to address opioid abuse, such as increased physician education, promotion of opioid alternatives, and changes to packaging and labeling. He is personally committed to palliative care.

**Drug Pricing**

Committee members asked Dr. Hahn numerous questions related to drug pricing, including Senator Mike Braun (R-IN), Senator Tim Scott (R-SC), Senator Baldwin, Senator Collins, and Senator Tina Smith (D-MN). While acknowledging that he is not familiar with drug pricing specifically, Dr. Hahn expressed sympathy for the impact of high prescription drug prices on patients. Among other things, he committed to working with Senators on Section 205 of the *Lower Health Care Costs Act (S. 1895)* and its potential impacts upon incentives to develop generic drugs, lowering the barriers to the introduction of biosimilars, and concerns with FDA’s classification of insulin as a biologic rather than a pharmaceutical might delay pending applications.

Senator Smith noted that efforts to lower prices and costs has resulted in more overseas manufacturing which has resulted, in some cases, in products that were unsafe. Dr. Hahn believed this issue might be addressed through enforcement, greater support for manufacturers, and advocacy for more advanced manufacturing techniques.

**Drug Importation**

Senators Braun and Baldwin were interested in how Dr. Hahn would implement FDA’s proposed pathways for the importation of unapproved drugs into the United States. Dr. Hahn emphasized that the FDA’s role would be to maintain the safety and security of the supply chain and that he would evaluate the science and data and then make any recommendations to the Secretary on the certification under section 804 of the Federal Food, Drug and Cosmetic Act that could potentially support importation. Chairman Alexander posed whether prescription drug costs and prices might be lowered if FDA could leverage the work done in other countries to expedite the review and approval of products already approved and marketed in those countries. Dr. Hahn agreed that measures to lower drug costs were important, while still maintaining FDA’s gold standard for approval of medical products.

**Cannabis**

Several Senators asked Dr. Hahn about cannabis and cannabis compounds. Senator Rosen noted the barriers to clinical research of marijuana. Senator Pat Roberts (R-KS) expressed concerns about how cannabidiol (CBD) products were being marketed and manufactured. Dr. Hahn emphasized the importance of developing clinical data for cannabis-based products and committed to a clear and transparent process.
Importance of Therapeutic Innovation, Rare Diseases
Senators Braun, Murkowski, and Scott all asked Dr. Hahn about development of therapeutic options for rare diseases and how barriers to innovation might be eased. Dr. Hahn committed to working with Congress to maintain a nimble, innovative and transparent FDA while still assuring that patient safety is protected and that the gold standard for approval of medical products is preserved. He also committed to listening to the patient voice if confirmed as a part of the process.

Senator Murkowski appreciated Dr. Hahn’s commitment to including the “patient voice” in clinical trials and decision-making.

Drug Shortages
Senator Collins and Baldwin both discussed the challenges posed by shortages of critical medical products, including vincristine, radiological medical isotopes, and other products. Dr. Hahn shared the concern and noted instances where, in his own experience, patient care has had to be delayed due to the unavailability of certain vital, life-saving products. Dr. Hahn committed to working with Congress to mitigate drug shortages.

Support for FDA
Chairman Alexander noted that one important component of the 21st Century Cures Act was improvement in FDA hiring to attract top talent. Dr. Hahn stated that he believes his experience in hiring at MD Anderson will be helpful to implementing this important part of the 21st Century Cures Act.

Regenerative Medicine
Chairman Alexander, Senator Romney and Senator Collins all expressed interest in encouraging development of regenerative medicine. Dr. Hahn agreed that these techniques present enormous therapeutic potential but also emphasized the importance of continuing to develop high quality data.

Food, Animals and Other Issues
Senator Christopher Murphy (D-CT) asked regarding a proposed rule to ban electrical stimulation devices and FDA work on adding sesame to allergen labeling.

Senator Bob Casey (D-PA) discussed legislation on over-the-counter (OTC) monograph reform. The effort has been ongoing for many years, with a desire to balance both patient protections and encourage innovation in the OTC space. Dr. Hahn expressed a commitment to modernization of the OTC process. When Senator Casey noted a concern with whether user fees would be included to support the OTC monograph reform. Dr. Hahn expressed his support for user fees generally and that, if confirmed, he would have to examine resources within the FDA to implement any monograph reform Congress enacted.
Senator Murkowski expressed concerns over genetically engineered salmon reviewed through the New Animal Drug Application process. The Senator also drew attention to the FDA’s seafood advisory for pregnant women, stating that FDA should use its own scientific and peer-reviewed data on the benefits of seafood for pregnant women rather than the Environmental Protection Agency’s mercury standards. Dr. Hahn committed to examining the data on this issue (including FDA’s own data) and reviewing the agency’s current advisory.

Both Senators Baldwin and Roberts expressed concerns about the lack of FDA action on “imitation” products, specifically dairy products and meats.

Senator Roberts asked Dr. Hahn whether he would take a risk-based or hazard-based approach with regard to antimicrobial resistance. Dr. Hahn committed to working with Senator Roberts on implementing the proper approach to address antimicrobial resistance. Dr. Hahn also committed to giving timely and accurate information about new biotechnology products such as animal gene editing. Senator Roberts also highlighted the support Dr. Hahn received from many organizations including the American Feed Industry Association.

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We hope that you find this information useful. Please contact us if you have any questions or need further assistance.