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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

CHRISTOPHER R. HIXON, STAFF DIRECTOR
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May 2, 2018

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

The Committee on Homeland Security and Governmental Affairs is examining the process by which the Department of Health & Human Services (HHS) and its components finalize regulations. According to recent commentary, someone “without authority to do so” finalized nearly 200 regulations issued by the Food and Drug Administration (FDA).¹ I respectfully write to request your assistance in understanding HHS’s compliance with the requirements of the federal rulemaking process.

The Supreme Court has held that any individual exercising significant authority as an Officer of the United States—such as congressionally delegated rulemaking authority—must be appointed in the method prescribed by Article II of the U.S. Constitution.² Article II of the Constitution states, “[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint . . . all other officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.”³

Recent commentary by legal scholars suggests that the FDA may not be abiding by the Supreme Court’s holding.⁴ For example, scholars cite the FDA’s so-called “Deeming Rule,” which subjected vaping products and small businesses to the same regulations as cigarettes under

¹ Todd Gaziano & Tommy Berry, *Career Civil Servants Illegitimately Rule America*, WALL ST. J. (Feb. 28, 2018), <https://www.wsj.com/articles/career-civil-servants-illegitimately-rule-america-1519862395>.

² See *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (in *Buckley*, the Court stated that “Officers of the United States” as used in Art. II, was a term with substantive meaning and any appointee exercising “significant authority” pursuant to the laws of the United States must be appointed in the manner prescribed by Article II, § 2, cl. 2 of the U.S. Constitution). See also *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 76-77 (2007) (Officer of the United States, meaning “a position to which is delegated by legal authority a portion of the sovereign powers of the federal government. Such powers primarily involve binding the government or third parties for the benefit of the public, such as by administering, executing, or authoritatively interpreting the laws”).

³ See U.S. CONST. art. II, § 2, cl. 2.

⁴ See Gaziano & Berry, *supra* note 1.

the Tobacco Control Act of 2009.⁵ The Committee has conducted oversight of this costly and burdensome rule, which stifles innovation and growth of vaping products as alternatives to cigarettes.⁶ The authors allege that Leslie Kux, the FDA official who signed the Deeming Rule, is not an Officer as defined by the Constitution and Supreme Court.⁷ Ms. Kux has signed nearly 200 regulations as Associate Commissioner for Policy.⁸

To assist the Committee in determining the authorities and the policies of the FDA with respect to federal regulations, I respectfully request the following information:

1. Does HHS delegate or otherwise authorize employees other than the Secretary to sign regulations? If so, please provide the document(s) delegating this authority, all supporting legal justification, and a list of position titles to whom such authority has been delegated.
2. With respect to the FDA's Deeming Rule, have you, or any of your predecessors, delegated your rulemaking authority to Leslie Kux? If so, please provide all documents delegating this authority.
3. Please provide the number of regulations that have been signed by any federal employee who was not an Officer of the United States from 2008 to present. Please provide:
 - a. The title of the regulation;
 - b. The date it was signed;
 - c. The name and title of the federal employee who signed it;
 - d. The economic impact of the individual regulation; and
 - e. The economic impact of all regulations signed by a federal employee instead of an Officer.

Please provide this material as soon as possible but no later than 5:00 p.m. on May 16, 2018. When delivering production sets, please produce to Majority staff in room 340 of the Dirksen Senate Office Building and to Minority staff in room 442 of the Hart Senate Office Building.

⁵ *Id.*; see also Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28973 (May 10, 2016) (codified in 21 C.F.R. § 1100.1).

⁶ See Letter from Sen. Ron Johnson, Chairman, S. Comm. on Homeland Sec. & Governmental Aff., to Dr. Robert Califf, Commissioner, U.S. Food & Drug Admin. (May 17, 2016); see also Michael Siegel, *Senator Johnson Call on FDA to Halt Implementation of E-Cigarette Deeming Regulations Pending the New Administration*, TOBACCO ANALYSIS BLOGSPOT (Nov. 30, 2016), <http://tobaccoanalysis.blogspot.com/2016/11/senator-johnson-calls-on-fda-to-halt.html>.

⁷ Ilya Shapiro, *A Lawsuit to Make Rulemakers Follow the Rules*, WASHINGTON EXAMINER (Feb. 5, 2018), <http://www.washingtonexaminer.com/a-lawsuit-to-make-rulemakers-follow-the-rules/article/2648032>; see also U.S. FOOD & DRUG ADMIN., OC OFFICE OF POLICY, PLANNING, LEGISLATION AND ANALYSIS ORGANIZATIONAL CHART, <https://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/ucm381358.htm> (last updated Jan. 30, 2018).

⁸ Gaziano & Berry, *supra* note 1.

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The Committee on Homeland Security and Governmental Affairs is authorized by Rule XXV of the Standing Rules of the Senate to investigate “the efficiency, economy, and effectiveness of all agencies and departments of the Government.”⁹ Additionally, S. Res. 62 (115th Congress) authorizes the Committee to examine “the efficiency and economy of all branches of the Government including the possible existence of fraud, misfeasance, malfeasance, collusion, mismanagement, incompetence, corruption, or unethical practices”¹⁰

If you have any questions regarding this letter, please ask your staff to contact Scott Wittmann or Josh McLeod of the Committee staff at (202) 224-4751. Thank you for your attention to this matter.

Sincerely,



Ron Johnson
Chairman

cc: The Honorable Claire McCaskill
Ranking Member

Enclosure

⁹ S. Rule XXV(k); *see also* S. Res. 445, 108th Cong. (2004).

¹⁰ S. Res. 62, 115th Cong. § 12 (2017).