



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, DC 20201

November 24 , 2021

Emory A. Rounds, III
Director
U.S. Office of Government Ethics
1201 New York Avenue, N.W., Suite 500
Washington, DC 20005-3917

Dear Mr. Rounds:

In accordance with 5 C.F.R. § 2634.605(c)(2), I am enclosing a supplement to the ethics agreement and to the nominee public financial disclosure report of Robert M. Califf, who has been nominated for the position of Commissioner of Food and Drugs, Food and Drug Administration, U.S. Department of Health and Human Services on November 15, 2021.

Following the signing of his ethics agreement on November 12, 2021, and certification of his nominee public financial disclosure report, the agency determined while reviewing Dr. Califf's Senate questionnaire that he had inadvertently omitted a position that he holds on the editorial board of the *Journal of the American College of Cardiology*, published by Elsevier.

Based on my review of the supplement to his nominee public financial disclosure report and his ethics agreement, I am of the opinion that both are complete and disclose no conflict of interest under applicable law and regulations.

Sincerely,

Randall J. Hall -
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Hall -S
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Randall J. Hall
Acting Associate General Counsel for Ethics
Alternate Designated Agency Ethics Official

Enclosures

November 23, 2021

Mr. Randall J. Hall
Acting Associate General Counsel for Ethics
Alternate Designated Agency Ethics Official
U.S. Department of Health and Human Services
Room 710-E, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Supplement to Ethics Agreement of Robert M. Califf

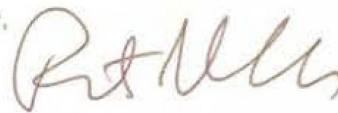
Dear Mr. Hall:

The purpose of this letter is to supplement my ethics agreement signed on November 12, 2021. In a separate document, I also am supplementing Part I of my financial disclosure report by reporting my position as a Member of the Editorial Board for the *Journal of the American College of Cardiology*, published by Elsevier, BV (Elsevier), which I inadvertently omitted from the report.

Upon my confirmation to the position of Commissioner of Food and Drugs of the Food and Drug Administration at the U.S. Department of Health and Human Services, I will resign from my position with *Journal of the American College of Cardiology* (Elsevier). Pursuant to the impartiality regulation at 5 C.F.R. § 2635.502, for a period of one year after my resignation, I will not participate personally and substantially in any particular matter involving specific parties in which I know that entity is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

I have been advised that this supplement to my ethics agreement will be posted publicly, consistent with the public information law at 5 U.S.C. § 552, on the website of the U.S. Office of Government Ethics with ethics agreements of other Presidential nominees who file public financial disclosure reports.

Sincerely,



Robert M. Califf

November 12, 2021

Mr. Randall J. Hall
Acting Associate General Counsel for Ethics
Alternate Designated Agency Ethics Official
U.S. Department of Health and Human Services
Room 710-E, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Hall:

The purpose of this letter is to describe the steps that I will take to avoid any actual or apparent conflict of interest in the event that I am confirmed for the position of Commissioner of Food and Drugs, Food and Drug Administration, at the Department of Health and Human Services. It is my responsibility to understand and comply with commitments outlined in this agreement.

SECTION 1 – GENERAL COMMITMENTS

As required by the criminal conflicts of interest law at 18 U.S.C. § 208(a), I will not participate personally and substantially in any particular matter in which I know that I have a financial interest directly and predictably affected by the matter, or in which I know that a person whose interests are imputed to me has a financial interest directly and predictably affected by the particular matter, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2). I understand that the interests of the following persons are imputed to me:

- Any spouse or minor child of mine;
- Any general partner of a partnership in which I am a limited or general partner;
- Any organization in which I serve as an officer, director, trustee, general partner, or employee; and
- Any person or organization with which I am negotiating or have an arrangement concerning prospective employment.

In the event that an actual or potential conflict of interest arises during my appointment, I will consult with an agency ethics official and take the measures necessary to resolve the conflict, such as recusal from the particular matter or divestiture of an asset.

If I have a managed account or otherwise use the services of an investment professional during my appointment, I will ensure that the account manager or investment professional obtains my prior approval on a case-by-case basis for the purchase of any assets other than cash, cash equivalents, investment funds that qualify for the regulatory exemption for diversified mutual funds and unit investment trusts at 5 C.F.R. § 2640.201(a), or obligations of the United States.

I will receive a live ethics briefing from a member of the ethics office after my confirmation but not later than 15 days after my appointment pursuant to the ethics program regulation at 5 C.F.R. § 2638.305. Within 90 days of my confirmation, I will submit my Certification of Ethics Agreement Compliance which documents my compliance with this ethics agreement.

I understand that as an appointee I will be required to sign the Ethics Pledge (Exec. Order No. 13989) and that I will be bound by it. Among other obligations, I will be required to recuse from particular matters involving specific parties involving my former employer or former clients for a period of two years after I am appointed, with the exception of federal, state, and local governments.

I will not modify this ethics agreement without your approval and the approval of the U.S. Office of Government Ethics pursuant to the ethics agreement requirements contained in the financial disclosure regulation at 5 C.F.R. § 2634.803(a)(4).

SECTION 2 – VERILY LIFE SCIENCES, LLC, AND GOOGLE, LLC (ALPHABET, INC.)

Upon confirmation, I will resign from my positions with the following subsidiaries of Alphabet, Inc.: Google, LLC (Google Health) and Verily Life Sciences, LLC. I own unvested Verily Award Units. I also own Verily Employee Units, representing an equity ownership interest in the company. Under the Verily Life Sciences, LLC, Value Creation Award Plan, when the Verily Award Units vest, they are settled in Employee Units. I do not have equity interests in Google, LLC, and do not hold equity in the parent company, Alphabet, Inc.

Upon my resignation from Verily Life Sciences, LLC, I will forfeit all unvested Verily Award Units. As is consistent with the terms of the Verily Life Sciences, LLC, Value Creation Award Plan and the benefit provided to other similarly situated executives, I am permitted to cash out my vested Employee Units at any time. The value of the units is regularly set by the board. I will receive the most recent valuation. As soon as practicable but not later than 90 days after my confirmation, I will divest all of my Employee Units. Until I have divested all of my Employee Units through the cash out, I will not participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of Verily Life Sciences, LLC, Google, LLC, Alphabet, Inc., or any other subsidiary of Alphabet, Inc., unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2). I have verified that I will be able to carry out the divestitures within the timeframe described above. Pursuant to the impartiality regulation at 5 C.F.R. § 2635.502, for a period of one year after my resignations from Google, LLC, and Verily Life Sciences, LLC, I will not participate personally and substantially in any particular matter involving specific parties in which I know Verily Life Sciences, LLC, Google, LLC, Alphabet, Inc., or any other subsidiary of Alphabet, Inc., is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

SECTION 3 – AMYRIAD PHARMA, INC.

Upon confirmation, I will resign from my position as a member of the Advisory Team of AMYRIAD Pharma, Inc. Pursuant to the terms of my agreement with the company, if I participate in the advisory team meeting scheduled for December 2021, I am entitled to receive unvested stock options in the company. Upon my resignation from AMYRIAD Pharma, Inc., I will forfeit my unvested stock options. Pursuant to the impartiality regulation at 5 C.F.R. § 2635.502, for a period of one year after my resignation, I also will not participate personally and substantially in any particular matter involving specific parties in which I know AMYRIAD Pharma, Inc., is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

SECTION 4 – CENTESSA PHARMACEUTICALS, PLC

Upon confirmation, I will resign from my position on the Board of Directors of Centessa Pharmaceuticals, PLC. This resignation will also terminate my position on the Nominating and Corporate Governance Committee of the Board of Directors. Pursuant to my agreement with the company, I am entitled to receive any outstanding directors fees and committee fees pro-rated through the date of my resignation. The company will make these payments to me in the month following the end of the quarter. If any fee payments are outstanding at the time I assume the duties of the position of Commissioner of Food and Drugs, I will not participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the ability or willingness of Centessa Pharmaceuticals, PLC, to make those payments, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1).

I own unvested nonqualified stock options for American depositary shares of Centessa Pharmaceuticals, PLC. I do not own shares or American depositary shares of Centessa Pharmaceuticals, PLC, and I do not own vested stock options. Pursuant to the Centessa Pharmaceuticals, PLC, Amended and Restated 2021 Stock Option and Incentive Plan, upon my resignation from Centessa Pharmaceuticals, PLC, the Administrator of the company is authorized to and has agreed to accelerate the vesting of my unvested stock options that vest prior to February 19, 2022. After February 19, 2022, my unvested stock options vest on a monthly basis. Any remaining unvested stock options will be forfeited. Pursuant to the terms of the plan, I have 90 days to exercise my vested options.

I will divest my interests in Centessa Pharmaceuticals, PLC, as soon as practicable but not later than 90 days after my confirmation. If I divest vested nonqualified stock options by exercising them, I will divest the resulting American depositary shares as soon as practicable but not later than 90 days after my confirmation. I will not participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of Centessa Pharmaceuticals, PLC, until I have divested it, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2). I have verified that I will be able to carry out the divestitures within the timeframe described above. Pursuant to the impartiality regulation at 5 C.F.R. § 2635.503, if Centessa Pharmaceuticals, PLC, accelerates the vesting of my unvested stock options, I also will not participate personally and substantially in any particular matter involving specific parties in

which Centessa Pharmaceuticals, PLC, or any of its subsidiaries is a party or represents a party for a period of two years from the date on which my stock options vested, unless I first receive a written waiver, pursuant to 5 C.F.R. § 2635.503(c). Pursuant to the impartiality regulation at 5 C.F.R. § 2635.502, if Centessa Pharmaceuticals, PLC, does not accelerate the vesting of my unvested stock options, I will not participate personally and substantially in any particular matter involving specific parties in which I know Centessa Pharmaceuticals, PLC, or any of its subsidiaries is a party or represents a party for a period of one year from the date of my resignation, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

SECTION 5 – CLINETIC, INC.

Upon confirmation, I will resign from my position on the Board of Directors of Clinetic, Inc. I own vested nonqualified stock options for shares of Clinetic, Inc. I do not own shares of Clinetic, Inc., or unvested stock options for shares of Clinetic, Inc. Upon my resignation from Clinetic, Inc., I will forfeit all my stock options. Pursuant to the impartiality regulation at 5 C.F.R. § 2635.502, for a period of one year after my resignation, I also will not participate personally and substantially in any particular matter involving specific parties in which I know Clinetic, Inc., is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

SECTION 6 – CYTOKINETICS, INC.

Upon confirmation, I will resign from my position on the Board of Directors of Cytokinetics, Inc. This resignation will also terminate my position on the Science and Technology Committee of the Board of Directors. I own stock and unvested restricted stock units. I also own unvested and vested nonqualified stock options for shares of Cytokinetics, Inc. I do not own vested restricted stock units. Upon my resignation from Cytokinetics, Inc., I will forfeit all unvested restricted stock units and all unvested nonqualified stock options for shares of Cytokinetics, Inc. As soon as practicable but not later than 90 days after my confirmation, I will divest all of my stock and all of my vested nonqualified stock options in Cytokinetics, Inc. If I divest the stock options by exercising them, I will divest the resulting stock as soon as practicable but not later than 90 days after my confirmation. Until I have divested all of these financial interests, I will not participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of Cytokinetics, Inc., unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2). I have verified that I will be able to carry out the divestitures within the timeframe described above. Pursuant to the impartiality regulation at 5 C.F.R. § 2635.502, for a period of one year after my resignation, I also will not participate personally and substantially in any particular matter involving specific parties in which I know Cytokinetics, Inc., is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

SECTION 7 – OTHER RESIGNATIONS

Upon confirmation, I will resign from my positions with the following entities:

- Basking Biosciences, Inc
- Bitterroot Bio, Inc.
- Clinical Research Forum, Inc.
- Critical Path Institute (C-PATH)
- Duke University
- *European Heart Journal* (Oxford University Press)
- Keystone Symposia on Molecular & Cellular Biology
- Mayo Foundation for Medical Education & Research
- Medical University of South Carolina
- Medicxi Ventures (UK), LLP
- OneFifteen
- Stanford University
- University of Colorado
- Vanderbilt University Medical Center

Pursuant to the impartiality regulation at 5 C.F.R. § 2635.502, for a period of one year after my resignation from each of these entities, I will not participate personally and substantially in any particular matter involving specific parties in which I know that entity is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

Upon confirmation, I also will resign from my position on the *All of Us* Research Program Advisory Panel at the National Institutes of Health, Department of Health & Human Services.

SECTION 8 – OTHER DIVESTITURES

I will divest my interests in the following entities as soon as practicable but not later than 90 days after my confirmation:

- Acme United Corporation (ACU)
- Agnico Eagle Mines Limited (AEM)
- Amgen, Inc. (AMGN)
- Anika Therapeutics, Inc. (ANIK)
- B&G Foods, Inc. (BGS)
- Bristol-Myers Squibb Company (BMY)
- Carrier Global Corporation (CARR)
- Dime Community Bancshares, Inc. (DCOM)
- Discovery, Inc. (DISCK)
- EnerSys (ENS)
- Exelixis, Inc. (EXEL)
- Fastenal Company (FAST)
- Franchise Group, Inc. (FRG)
- Gilead Sciences, Inc. (GILD)
- Goldman Sachs Group, Inc. (GS)

- Greenhill & Co., Inc. (GHL)
- InterDigital, Inc. (IDCC)
- Interpublic Group of Cos., Inc. (IPG)
- John B. Sanfilippo & Son, Inc. (JBSS)
- Kinder Morgan, Inc. (KMI)
- Mastech Digital, Inc. (MHH)
- Mastercard, Inc. (MA)
- Moelis & Company (MC)
- Newell Brands, Inc. (NWL)
- ONEOK, Inc. (OKE)
- People's United Financial, Inc. (PBCT)
- Pitney Bowes, Inc. (PBI)
- Pretium Resources, Inc. (PVG)
- Principal Financial Group, Inc. (PFG)
- Prudential Financial, Inc. (PRU)
- QUALCOMM, Inc. (QCOM)
- Service Properties Trust (SVC)
- Silvercrest Asset Management Group, Inc. (SAMG)
- TESSCO Technologies, Inc. (TESS)
- Toll Brothers, Inc. (TOL)
- Trecora Resources (TREC)
- United Parcel Service, Inc. (UPS)
- Visa, Inc. (V)
- Walgreens Boots Alliance, Inc. (WBA)
- WisdomTree Investments, Inc. (WETF)

With regard to each of these entities, I will not participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the financial interests of the entity until I have divested it, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2). I have verified that I will be able to carry out the divestitures within the timeframe described above.

I will divest my interests in the following bonds as soon as practicable but not later than 90 days after my confirmation:

- Avnet, Inc., bonds
- B&G Foods, Inc., bonds
- Barclays Bank, PLC, bonds
- BellSouth, LLC, bonds
- BlackRock TCP Capital Corporation, bonds
- Deutsche Bank, AG, bonds
- Freeport-McMoRan, Inc., bonds
- General Electric Company, bonds

- Goldman Sachs Group, Inc., bonds
- Host Hotels & Resorts, Inc., bonds
- JPMorgan Chase & Co., bonds
- Kinder Morgan, Inc., bonds
- Kraft Heinz Foods Co., bonds
- Lamar Media Corporation, bonds
- National Fuel Gas Company, bonds
- New York Community Bancorp, Inc., bonds
- ONEOK, Inc., bonds
- Owens & Minor, Inc., bonds
- Plains All American Pipeline, LP, bonds
- Service Properties Trust, bonds
- Starwood Hotel & Resorts, bonds
- Tanger Properties, LP, bonds
- Western Union Company, bonds
- Williams Companies, Inc., bonds

With regard to each of these bonds, I will not participate personally and substantially in any particular matter that to my knowledge has a direct and predictable effect on the marketability or market resale value of the bond or on the ability or willingness of the issuer to pay their debt obligations to me until I have divested it, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2). I have verified that I will be able to carry out the divestitures within the timeframe described above.

SECTION 9 – CERTIFICATE OF DIVESTITURE & ASSET REPURCHASES

I understand that I may be eligible to request a Certificate of Divestiture for qualifying assets and that a Certificate of Divestiture is effective only if obtained prior to divestiture. Regardless of whether I receive a Certificate of Divestiture, I will ensure that all divestitures discussed in this agreement occur within the agreed upon timeframes and that all proceeds are invested in non-conflicting assets. I understand that I must timely submit my request for a Certificate of Divestiture to allow for adequate time for OGE to process the Certificate of Divestiture and in order to divest assets within the agreed upon timeframe.

I (including my spouse and dependent children if applicable) will not repurchase any asset I was required to divest without consulting with my agency ethics official and the U.S. Office of Government Ethics.

SECTION 10 – OTHER COMMITMENTS

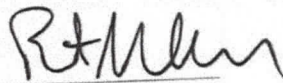
In order to avoid potential conflicts of interest during my appointment as Commissioner of Food and Drugs, I (including my spouse and dependent children, if applicable) will not acquire any direct financial interest in entities listed on the Food and Drug Administration's prohibited holdings list or in entities involved, directly or through subsidiaries, in the following

biotechnology, or medical devices, equipment, preparations, treatment, or products; (2) veterinary products; (3) healthcare management or delivery; (4) health, disability, or workers compensation insurance or related services; (5) food and/or beverage production, processing or distribution; (6) communications media; (7) computer hardware, computer software, and related internet technologies; (8) wireless communications; (9) social sciences and economic research organizations; (10) energy or utilities; (11) commercial airlines, railroads, shiplines, and cargo carriers; or (12) any sector mutual fund or sector exchange-traded fund that concentrates its portfolio in any single country other than the United States. In addition, I (including my spouse and dependent children, if applicable) will not acquire any interests in any sector mutual fund or sector exchange-traded fund that concentrates its portfolio in any of the aforementioned sectors.

SECTION 11 - PUBLIC POSTING

I have been advised that this ethics agreement and the Certification of Ethics Agreement Compliance will be posted publicly, consistent with the public information law at 5 U.S.C. § 552, on the website of the U.S. Office of Government Ethics with ethics agreements of other Presidential nominees who file public financial disclosure reports.

Sincerely,



Robert M. Califf

November 12th, 2021