

March 28, 2017

Elizabeth J. Fischmann, Esq.
Associate General Counsel for Ethics
Designated Agency Ethics Official
U.S. Department of Health and Human Services
Room 710-E, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. Fischmann:

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, Food and Drug Administration, U.S. Department of Health and Human Services.

SECTION 1 – GLOBAL RECUSAL REQUIREMENT

As required by 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 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 officer, director, trustee, general partner or employee; and any person or organization with which I am negotiating or have an arrangement concerning prospective employment.

SECTION 2 – NEW ENTERPRISE ASSOCIATES

I have a position with New Enterprise Associates. Through that position, I provided services to other entities as clients and have positions with American Pathology Partners and Collective Health. Upon confirmation, I will resign from my positions with these three entities. 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). In addition, I will not participate personally and substantially in any particular matter involving specific parties in which I know a former client of mine is a party or represents

Elizabeth J. Fischmann, Esq.
Associate General Counsel for Ethics
Designated Agency Ethics Official
March 28, 2017
Page 2

a party, for a period of one year after I last provided service to that client, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

I do not hold any financial interest in New Enterprise Associates, but I hold financial interests in the following client companies:

- American Pathology Partners
- Bright Health
- Collective Health
- Golden State Medical
- Radiology Partners
- U.S. Renal Care

Within 90 days of my confirmation, I will divest my interests in these entities. 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).

SECTION 3 – T.R. WINSTON & COMPANY

I have a position with T.R. Winston & Company. Through that position, I provided services to other entities as clients and have a position with Cell BioTherapy, Inc. Upon confirmation, I will resign from my positions with these two entities. I previously held a position with Tivorsan Pharmaceuticals from which I resigned in March 2017 and a position with Kure from which I resigned in May 2016. 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). In addition, I will not participate personally and substantially in any particular matter involving specific parties in which I know a former client of mine is a party or represents a party, for a period of one year after I last provided service to that client, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

I do not hold any financial interest in T.R. Winston & Company, but I hold financial interests in the following client companies:

- Angion Pharmaceuticals
- Cell Biotherapy, Inc.
- Chanticleer Holdings

Elizabeth J. Fischmann, Esq.
Associate General Counsel for Ethics
Designated Agency Ethics Official
March 28, 2017
Page 3

- Emmaus Life Sciences
- Inspyr Therapeutics, Inc.
- Kure
- Lillis Energy, Inc.
- Neuralstem, Inc.
- Pharma-Bio Serv Inc.
- Prosetta Biosciences;
- Social Reality
- Synthesis Energy Systems, Inc.
- Tivorsan Pharmaceuticals

Within 90 days of my confirmation, I will divest my interests in these entities. With regard to each of these entities in which I have an interest, 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).

SECTION 4 – SOLE PROPRIETORSHIP

I have performed consulting work as a sole proprietor, doing business under the name Scott Gottlieb, MD. I have not formed a legal entity for this purpose. During my appointment to the position of Commissioner, I will not perform consulting work. Any amounts owed to me by any of my clients will be fixed before I assume the duties of the position of Commissioner, and 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 any of these clients to pay these amounts. In addition, I will not participate personally and substantially in any particular matter involving specific parties in which I know a former client of mine is a party or represents a party, for a period of one year after I last provided service to that client, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

SECTION 5 – MEDAVANTE

Upon confirmation, I will resign from my position with MedAvante. I hold vested stock options in MedAvante. I do not hold unvested stock options. I hold an interest in the MedAvante Co-Invest Fund, which holds MedAvante preferred stock. Within 90 days of my confirmation, I will divest all stock, stock options, and interests in the MedAvante Co-Invest Fund. 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 MedAvante until I have divested all of these interests in MedAvante, unless I

Elizabeth J. Fischmann, Esq.
Associate General Counsel for Ethics
Designated Agency Ethics Official
March 28, 2017
Page 4

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 a contingent arrangement for a payment as compensation for services that I provided to MedAvante. I will forfeit this payment, unless I receive it prior to assuming the duties of the position of Commissioner. If I receive this payment, I will not, for a period of two years after my receipt of the payment, participate personally and substantially in any particular matter in which I know MedAvante, is a party or represents a party, unless I first receive a written waiver pursuant to 5 C.F.R. § 2635.503(c).

SECTION 6 – GLAXOSMITHKLINE PLC

Upon confirmation, I will resign from my position with GlaxoSmithKline plc. Pursuant to the company's compensation plan for members of the Product Investment Board (PIB), I will receive a payment for my service as a member of the PIB through the date of my withdrawal. I hold no other interests in GlaxoSmithKline plc. Until I have received all amounts owed, 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 GlaxoSmithKline plc, to pay amounts owed to me, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1). 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 GlaxoSmithKline plc 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 CURRENT POSITIONS

Upon confirmation, I will resign from my positions with Glytec. I previously held a position with Gradalis and Strike Bio from which I resigned in March 2017. 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). I hold the following interests in these entities:

- Glytec: I hold restricted stock and vested stock options. I do not hold stock or unvested stock options.
- Gradalis: I hold vested stock options. I do not hold stock, restricted stock, or unvested stock options.
- Strike Bio: I hold vested stock options. I do not hold stock, restricted stock, or unvested stock options.

Elizabeth J. Fischmann, Esq.
Associate General Counsel for Ethics
Designated Agency Ethics Official
March 28, 2017
Page 5

Within 90 days of my confirmation, I will divest my interests in Glytec, Gradalis, and Strike Bio. 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).

In addition, upon confirmation, I will resign from my positions with the following entities: American Enterprise Institute, the New York University School of Medicine, the Society of Hospital Medicine, the BDO Center for Healthcare Excellence and Innovation, and Daichii Sankyo U.S. 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).

SECTION 8 – OTHER PRIOR POSITIONS AND SERVICES

I previously served on the Board of Directors of Tolero Pharmaceuticals. I resigned from this position in December 2016. I hold contingent value rights in Tolero Pharmaceuticals. I do not hold any other interests in Tolero Pharmaceuticals. I will divest my interests in Tolero Pharmaceuticals within 90 days of 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 Tolero Pharmaceuticals 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). 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 Tolero Pharmaceuticals is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

I previously served on the Board of Directors of CombiMatrix. I resigned from this position in December 2016. I hold no interests in CombiMatrix. 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 CombiMatrix is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

I previously provided consulting services through Innovating Healthcare LLC, an entity which I established for the purposes of a single consulting project with Bristol-Myers Squibb. Innovating Healthcare LLC ceased active operations in December 2016. During my appointment to the position of Commissioner, Innovating Healthcare LLC will remain dormant and will not advertise. I will not perform any services for this entity, except that I will comply with any requirements involving legal filings, taxes and fees

Elizabeth J. Fischmann, Esq.
Associate General Counsel for Ethics
Designated Agency Ethics Official
March 28, 2017
Page 6

that are necessary to maintain the entity while it is in an inactive status. As Commissioner, 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 Innovating Healthcare LLC. I will not participate personally and substantially in any particular matter involving specific parties in which I know Bristol-Myers Squibb is a party or represents a party, for a period of one year after I last provided service, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

I previously provided consulting services through YourEncore, an entity used by Vertex Pharmaceuticals for its consultants. I ceased my involvement with YourEncore in August 2016. I will not participate personally and substantially in any particular matter involving specific parties in which I know YourEncore or Vertex Pharmaceuticals is a party or represents a party, for a period of one year after I last provided service, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

I previously provided services to Forbes Magazine LLC as a contributing writer. I ceased contributing to Forbes in November 2016. 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 Forbes Magazine LLC is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d).

SECTION 9 – ADDITIONAL ASSETS TO BE DIVESTED

Within 90 days of my confirmation, I will divest my interests in the entities identified in Attachment A. 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).

In order to avoid potential conflicts of interest during my appointment as Commissioner, I, my spouse, or any minor children of mine will not acquire any direct financial interest in entities listed on the FDA prohibited holdings list or in entities involved, directly or through subsidiaries, in the following industries: (1) research, development, manufacture, distribution, or sale of pharmaceutical, 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, ship lines, and cargo carriers; or (12) sector mutual funds that concentrate their

Elizabeth J. Fischmann, Esq.
Associate General Counsel for Ethics
Designated Agency Ethics Official
March 28, 2017
Page 7

portfolios on one country other than the United States. In addition, we will not acquire any interests in sector mutual funds that concentrate in any of these sectors.

SECTION 10 – ADDITIONAL ACTIONS

I will meet in person with you during the first week of my service in the position of Commissioner in order to complete the initial ethics briefing required under 5 C.F.R. § 2638.305. Within 90 days of my confirmation, I will also document my compliance with this ethics agreement by notifying you in writing when I have completed the steps described in this ethics agreement.

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.

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 exemption at 5 C.F.R. § 2640.201(a), obligations of the United States, or municipal bonds.

I understand that as an appointee I will be required to sign the Ethics Pledge (Exec. Order no. 13770) and that I will be bound by the requirements and restrictions therein in addition to the commitments I have made in this ethics agreement.

I have been advised that this ethics agreement will be posted publicly, consistent with 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,

A handwritten signature in black ink, appearing to read "Scott Gottlieb", with a horizontal line extending to the right.

Scott Gottlieb, M.D.

Elizabeth J. Fischmann, Esq.
Associate General Counsel for Ethics
Designated Agency Ethics Official
March 28, 2017
Page 8

ATTACHMENT A

Fidelity Japan Smaller Companies Fund
iShares U.S. Energy ETF
Powershares DB Commodity Index ETF
Sector SPDR Energy ETF
Sector SPDR Utilities ETF
Van Eck Vectors Agribusiness ETF