

SETTLEMENT AGREEMENT

This Settlement Agreement (the “Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”) (collectively, the “United States”) and Van Andel Research Institute (“VARI”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. VARI is an independent research institute in Grand Rapids, Michigan that receives grant funding from the National Institutes of Health (“NIH”).

B. The United States contends that it has civil claims against VARI arising from (1) claims that VARI submitted in connection with NIH Grant No. R01GM127710 between June 5, 2017 and December 31, 2020; and (2) claims that VARI submitted in connection with NIH Grant No. R01GM129436 between July 13, 2018 and December 31, 2020. The United States contends that these claims were false because as set forth below and based on the alleged conduct set forth in **Attachment 1**:

- Foreign Component. VARI failed to disclose, to NIH, a Foreign Component of NIH Grant No. R01GM127710 that was being performed under a partially-executed Research Collaboration Agreement between VARI and the Harbin Institute of Technology (“HIT”) in Harbin, Heilongjiang, China;
- Senior/Key Personnel. VARI failed to disclose, to NIH, that an HIT professor, [REDACTED], worked on NIH Grant No. R01GM127710. VARI further failed to identify Dr. [REDACTED], who contributed in a substantive, meaningful way to the scientific development and execution of NIH Grant No. R01GM127710, as Senior/Key Personnel; and
- Other Support. VARI failed to disclose, to NIH, Other Support for former VARI researchers, [REDACTED], and [REDACTED], who served as a Principal Investigator for NIH Grant Nos. R01GM127710 and R01GM129436.

This Other Support included biological research samples that Dr. [REDACTED] and HIT provided to Dr. [REDACTED] and Dr. [REDACTED] laboratories, Dr. [REDACTED] selection to a Chinese talent recruitment program, and Dr. [REDACTED] cooperative agreement with Nanjing Agricultural University (“NAU”) in Nanjing, Jiangsu, China.

The conduct described in this Paragraph C and in **Attachment 1** is referred to below as the Covered Conduct.

D. This Settlement Agreement is neither an admission of liability by VARI nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. VARI shall pay to the United States ONE MILLION ONE HUNDRED THOUSAND DOLLARS (\$1,100,000.00) (the “Settlement Amount”), of which \$357,512.48 is restitution, by electronic funds transfer pursuant to written instructions to be provided by the U.S. Attorney’s Office for the Western District of Michigan no later than 15 days after the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and conditioned upon the United States’ receipt of the Settlement Amount, the United States releases VARI from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Civil Monetary Penalties Law, 42 U.S.C. §1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including the suspension and debarment rights of any federal agency, or actions pursuant to, or otherwise consistent with, 42 C.F.R. § 52.9, 45 C.F.R. §§ 75.207–75.208, or 45 C.F.R. §§ 75.371–75.375;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. VARI waives and shall not assert any defenses VARI may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

5. VARI fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that VARI has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. a. Unallowable Costs Defined. All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of VARI, and its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audits and civil and criminal investigations of the matters covered by this Agreement;
- (3) VARI's investigation, defense, and corrective actions undertaken in response to the United States' audits and civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment VARI makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs. Unallowable Costs will be separately determined and accounted for by VARI, and VARI shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment.

Within 90 days of the Effective Date of this Agreement, VARI shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by VARI or any of its subsidiaries or affiliates from the United States. VARI agrees that the United States, at a minimum, shall be entitled to recoup from VARI any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine VARI's books and records and to disagree with any calculations submitted by VARI or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by VARI, or the effect of any such Unallowable Costs on the amount of such payments.

7. This Agreement is intended to be for the benefit of the Parties only.

8. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

9. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

10. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the Western District of Michigan. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

11. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

12. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

13. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

14. This Agreement is binding on VARI's successors, transferees, heirs, and assigns.

15. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

16. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

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THE UNITED STATES OF AMERICA

ANDREW BYERLY BIRGE
United States Attorney

DATED: 8/27/21 BY: Adam B. Townshend

ADAM B. TOWNSHEND
Assistant U.S. Attorney
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Grand Rapids, MI, 49501

DATED:

BY:

GREGORY DEMSKE

Digitally signed by GREGORY
DEMSKE
Date: 2021.08.27 10:45:26 -04'00'

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

VAN ANDEL RESEARCH INSTITUTE

DATED:

BY:

TIMOTHY MYERS
Chief Financial Officer

DATED:

BY:

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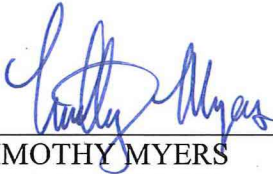
THE UNITED STATES OF AMERICA


ANDREW BYERLY BIRGE
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DATED: BY: _____
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Counsel for Van Andel Research Institute

ATTACHMENT 1

UNITED STATES' STATEMENT OF COVERED CONDUCT

The United States contends that VARI violated the False Claims Act, 31 U.S.C. § 3729, *et seq.*, based on the following alleged conduct:¹

Introduction

1. On December 17, 2019, VARI and the United States entered into a settlement agreement to resolve allegations that VARI violated the False Claims Act, 31 U.S.C. § 3729, *et seq.*, by, among other things, failing to disclose, to NIH, foreign research support of two VARI researchers.

2. On January 19, 2020, U.S. Customs and Border Protection (“CBP”) stopped [REDACTED], at Detroit Metro Airport following an inbound flight that originated from Shanghai, China. Dr. [REDACTED] a former VARI employee, was carrying, in his luggage, undeclared biological research samples: nine blotter papers and one vial of clear liquid. Dr. [REDACTED], a professor at HIT in China, acknowledged, to CBP, that he synthesized the biological research samples in his laboratory at HIT. Dr. [REDACTED] also admitted that the biological research samples were destined for the laboratory of [REDACTED], a VARI faculty member who was the principal investigator on NIH grants.

3. The January 19, 2020 CBP border stop prompted a second investigation of VARI that revealed the alleged conduct described below.

Allegations Regarding An Undisclosed And Unapproved Foreign Component And Undisclosed Senior/Key Personnel For NIH Grant R01GM127710

4. On or about June 5, 2017, VARI submitted a grant application to NIH, on behalf of [REDACTED], for a project entitled, “Structural and Functional Studies of Rhodopsin and G-Protein Coupled Receptors.” NIH awarded the grant to VARI on or about March 21, 2018 (R01GM127710, the “NIH Award”).

5. On or about December 21, 2017—after VARI submitted the application for the NIH Award, but before NIH awarded funding on March 21, 2018—Dr. [REDACTED] at VARI began negotiating a Research Collaboration Agreement with HIT (the “VARI-HIT RCA”) for a research collaboration between Dr. [REDACTED] laboratory at VARI and Dr. [REDACTED] laboratory at HIT in China.

6. The VARI-HIT RCA overlapped with the NIH Award in research subject matter, research methods, and research objectives. VARI knew about this overlap because, among other things, certain members of VARI leadership knew about the proposed VARI-

¹ Capitalized terms and acronyms shall have the meanings ascribed to them in the Settlement Agreement.

HIT collaboration and understood that Dr. [REDACTED] work would be restricted to performing research and providing biological research samples in connection with the NIH Award.

7. While HIT signed the VARI-HIT RCA in March 2018, VARI did not countersign the agreement. VARI did not inform HIT, or the collaborating faculty at VARI or HIT, that the VARI-HIT RCA was not fully executed.

8. The VARI-HIT research collaboration thus continued, post-award, consistent with the terms of the partially-executed VARI-HIT RCA. Dr. [REDACTED] worked on-site at VARI on several occasions, including in or around January 2018, September 2018, January 2019, February 2019, May 2019, June 2019, and November 2019.

9. Dr. [REDACTED] provided research data to Dr. [REDACTED] laboratory, including findings that VARI subsequently reported to NIH in a December 2018 Research Performance Progress Report (“RPPR”) under the NIH Award (the “December 2018 RPPR”).

10. The collaboration between VARI and HIT was anticipated to, and did, result in co-authorship, including an article—A Complex Structure of Arrestin-2 Bound to a G Protein Coupled Receptor, Cell Research 29; 971–83 (2019)—that listed Dr. [REDACTED] and members of Dr. [REDACTED] laboratory as co-authors and acknowledged the NIH Award and foreign funding as support.

11. The government alleges that, based on the conduct described in Paragraphs 4 through 10, above, VARI added an unapproved foreign component to the NIH Award. VARI did not disclose the foreign component of the NIH Award or seek the required approvals from NIH. In the December 2018 RPPR, which incorporated certain of Dr. [REDACTED] research findings, VARI stated that there was “[n]o foreign component” to the NIH Award. VARI also stated that there was “[n]o foreign component” in a December 2019 RPPR under the NIH Award (the “December 2019 RPPR”).

12. Dr. [REDACTED] contributed in a substantive, meaningful way to the scientific development and execution of the NIH Award. VARI, however, did not identify Dr. [REDACTED] as Senior/Key Personnel in the December 2018 RPPR or December 2019 RPPR, nor did VARI identify Dr. [REDACTED] as having worked on the NIH Award.

Allegations Regarding Undisclosed Other Support: Biological Research Samples

13. Dr. [REDACTED] personally brought undeclared biological research samples into the United States for use at VARI. Dr. [REDACTED] also mailed biological research samples, for use at VARI, from China to his home address in Grand Rapids, Michigan. In mailing biological research samples, Dr. [REDACTED] falsely described the package contents as “documents” in order to circumvent institutional material transfer agreement requirements and foreign and domestic import/export restrictions.

14. These foreign-sourced research samples were required to be disclosed to NIH as “Other Support” for Drs. [REDACTED] and [REDACTED]. VARI knew or should have known

about shipments of foreign-sourced biological research samples from Dr. [REDACTED]. On or about May 24, 2018, for example, VARI identified, rejected, and returned a Federal Express shipment of biological research samples intended for Dr. [REDACTED] laboratory at VARI—a shipment falsely labeled as “documents”—from Dr. [REDACTED] at HIT.

15. The government contends that VARI did not adequately investigate Dr. [REDACTED] provision of biological research samples following the May 2018 rejected shipment.

16. The government contends that on several occasions in 2019, Dr. [REDACTED] (1) carried biological research samples into the United States, for use at VARI, on his person; and (2) mailed biological research samples, for use at VARI, from China to his home address in Grand Rapids, Michigan.

17. The government contends that VARI knowingly submitted false claims to NIH after rejecting the May 2018 shipment, including a December 2018 RPPR in which VARI claimed no changes in “Other Support” for Drs. [REDACTED] and [REDACTED]. The government contends that VARI acted with deliberate ignorance or reckless disregard as to whether that statement was true. The government further contends that in connection with the December 2019 RPPR, VARI submitted an updated “Other Support” document for Dr. [REDACTED] with deliberate ignorance or reckless disregard as to whether that document was complete and accurate.

Allegations Regarding Undisclosed Other Support: China’s 111 Program

18. On or about July 23, 2018, Dr. [REDACTED] received an e-mail from [REDACTED], a former post-doctoral student at VARI who is a professor at NAU in Nanjing, Jiangsu, China. In the e-mail, Dr. [REDACTED] invited Dr. [REDACTED] to join an application with another NAU professor, [REDACTED], to the Chinese 111 Program. Dr. [REDACTED] also provided Dr. [REDACTED] with information about the 111 Program through a Wikipedia link and a Chinese press release. The Chinese press release described the 111 Program as a program, funded by the Chinese government, to recruit foreign researchers to work at “innovation centers” at Chinese universities. Dr. [REDACTED] told Dr. [REDACTED] that he “definitely will benefit from this cooperation.”

19. As of September 2019, a member of VARI’s staff was in possession of an unclassified FBI release from September 2015 that described “Project 111” as a program designed to “recruit[] the world’s top researchers and scholars regardless of nationality or ethnic origin to work with Chinese universities[.]”

20. On or about August 7, 2018, Dr. [REDACTED] sent a letter to an NAU professor, on VARI letterhead, accepting “your invitation to join your project application to the China Ministry of Education and the State Administration of Foreign Affairs entitled ‘111 project.’” Dr. [REDACTED] wrote, “It will be my pleasure to visit your university in Nanjing for different periods in the next few years and contribute to cooperative research and education for PhD students. I believe that the program will be of benefit to all parties involved. Scientific research and training will be advanced and this will benefit the future

of academic research in our mutual area of interest.” Dr. [REDACTED] also provided his passport photo, curriculum vitae, and date of birth in support of the 111 Program application.

21. Dr. [REDACTED] traveled to NAU in November 2018 for several days and gave an academic presentation. Dr. [REDACTED] a member of his laboratory staff, and certain other VARI employees knew about this trip. Dr. [REDACTED] laboratory received a formal invitation from Dr. [REDACTED] and NAU regarding sponsoring Dr. [REDACTED] travel to “explore the possibility of further academic cooperation with” NAU. VARI received this invitation after NIH published and circulated an August 20, 2018 “Dear Colleagues” letter regarding foreign influence in federally-sponsored research that emphasized the need for grant applications and progress reports to “include all sources of research support, financial interests, and relevant affiliations.”

22. Dr. [REDACTED] claims that he declined to participate in the 111 Program as of November 2018. The government contends that Dr. [REDACTED] does not know, however, whether Dr. [REDACTED] 111 Program application was accepted, whether the NAU faculty with whom Dr. [REDACTED] continued to actively collaborate were funded by the 111 Program, or whether the NAU graduate students that VARI continued to host in the United States through were funded by the 111 Program.

23. In November 2018, Dr. [REDACTED] separately e-mailed Dr. [REDACTED] about his plans to “apply for a grand [sic] which will be supported by China Ministry of Science[.]” Dr. [REDACTED] noted that the program required proof of collaboration with a scientist that is “funded by America government or will be funded.” In response, Dr. [REDACTED] sent Dr. [REDACTED] a copy of his NIH award letter. The government alleges that Dr. [REDACTED] did not inform VARI or NIH about this exchange.

24. In October 2019, VARI’s third-party compliance consultant sent Dr. [REDACTED] a questionnaire asking if, at any point during his employment at VARI, Dr. [REDACTED] “participate[d] in or accept[ed] any promise of benefit relating to any foreign (non-U.S.) talent recruitment program.” Dr. [REDACTED] checked, “No.” In response to a question about sponsored travel during his employment at VARI, Dr. [REDACTED] did not disclose his trip to NAU described in Paragraph 21, above.

25. On or about October 30, 2019, Dr. [REDACTED] e-mailed Dr. [REDACTED]. Dr. [REDACTED] thanked Dr. [REDACTED] for supervising three NAU students at VARI and advised Dr. [REDACTED] that “[w]e have the budget for inviting foreign scientists now. If you can spend 2-4 weeks in Nanjing and China before next March, I want to give you a formal invitation and pay all your expenses.” On or about November 4, 2019, Dr. [REDACTED] agreed and suggested “any time from September [2020] on.”

26. In November 2020, Dr. [REDACTED] told VARI that he received an invitation to join “an application for a 111 collaborative research project.” Dr. [REDACTED] told VARI that he expressed an interest in contributing to the project, but later declined to participate. VARI did not ask Dr. [REDACTED] further questions about this matter.

27. The government contends that VARI failed to disclose Dr. [REDACTED] selection to China's 111 Program, and his corresponding agreement to participate in cooperative research with NAU, as "Other Support" in the December 2018 RPPR and December 2019 RPPR.