

Congress of the United States

House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371
www.science.house.gov

March 24, 2017

The Honorable Thomas E. Price
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Price:

The Committee on Science, Space, and Technology is conducting oversight of the National Institutes of Health's (NIH) National Institute of Environmental Health Sciences (NIEHS) contract and grant management. The Committee is investigating the scientific integrity of the work performed by NIEHS contract and grant recipients. According to public records, the Ramazzini Institute ("Ramazzini" or "the Institute"), an independent international science academy that conducts cancer related studies, benefited from at least seven sole source government contracts.¹ The Committee is concerned that contracts awarded to the Ramazzini Institute and its affiliates may not meet adequate scientific integrity standards. Additionally, these sole source contracts raise questions about the integrity of the acquisition process at NIH and NIEHS. We are writing to request documents and information to determine whether NIEHS is complying with all federal acquisition regulations and ensuring award recipients are adhering to the utmost standards of scientific integrity.

According to a March 17, 2017, media report, Italy's Ramazzini Institute has received at least thirteen different NIEHS contracts through four different third parties since 2009, totaling nearly \$2 million.² Of the thirteen contracts, seven appear to be sole source, representing over \$1 million taxpayer dollars. Further, media reports indicate that since 2009 NIEHS has directed as least \$92 million in *grant* funds to the Ramazzini Institute and its U.S. affiliate.³ If true, this raises serious questions about the integrity of the acquisition process at NIEHS.

¹ USA Spending.gov, *Ramazzini Results Summary*, available at <https://www.usaspending.gov/Pages/AdvancedSearch.aspx?sub=y&ST=C,G&FY=2017,2016,2015,2014,2013,2012,2011,2010,2009&A=0&SS=USA&k=ramazzini> (last visited Mar. 23, 2017) [hereinafter USA Spending.gov Results].

² E&E Legal, Press Release, *E&E Legal Again Forced to Sue NIH for Public Records Re: U.S. Taxpayer-Funded Payments to the International Agency for Research on Cancer, Italy's Ramazzini Institute* (Mar. 17, 2017) [hereinafter *E&E Legal Again Forced to Sue NIH*]; see also *Id.*

³ *E&E Legal Again Forced to Sue NIH*, *supra* note 1.

The NIEHS conducts and provides resources for environmental health sciences with a mission “to discover how the environment effects people in order to promote healthier lives.”⁴ NIEHS claims an impressive record of important scientific accomplishments achieved in part by contracts awarded to institutions conducting scientific work to support the NIEHS mission.⁵ According to public records and media reports, NIEHS contracted with Ramazzini and its affiliates through multiple third parties, yet it is unclear what services were rendered under these contracts.⁶ Reports indicate NIEHS director Linda Birnbaum, a Ramazzini fellow, funneled millions of dollars in NIEHS grant funds to other Ramazzini fellows and their affiliates.⁷ Further, since 1985, reports indicate that, in total, NIEHS has provided \$315 million in grant dollars to Ramazzini fellows.⁸

More recently, the NIEHS has refused to respond to FOIA requests seeking information related to contracts between your Department, including NIH and NIEHS, and Ramazzini.⁹ E&E Legal recently filed multiple lawsuits seeking materials NIEHS refused to produce through FOIA requests not only regarding contracts involving the Ramazzini Institute and grant money provided to the Institute’s fellows, but also information regarding Ramazzini’s U.S. affiliate’s President Phil Landrigan’s coordination with NIEHS.¹⁰ According to reports, Director Birnbaum coordinated with Dr. Landrigan to publish more than two dozen Ramazzini studies in the NIEHS run journal, *Environmental Health Perspectives* (EHP).¹¹

This is not the first instance in which this Committee raised questions regarding the scientific integrity of Ramazzini. In 2012, Committee members wrote the Environmental Protection Agency (EPA) regarding specific Ramazzini studies EPA relied on when conducting chemical risk assessments.¹² According to the EPA, agency scientists “identified discrepancies in the results of methanol studies conducted by the Ramazzini Institute.”¹³ As a result, EPA placed the four draft assessments that relied on the Ramazzini studies on hold, pending further review.¹⁴ This is concerning given the continued significant funding of Ramazzini studies and publication of Ramazzini studies in the EHP.

⁴ Nat’l Institute of Environmental Health Sciences, *About NIEHS*, available at <https://www.niehs.nih.gov/about/index.cfm> (last visited Mar. 23, 2017).

⁵ *Id.*

⁶ *E&E Legal Again Forced to Sue NIH*, *supra* note 1; *USASpending.gov Results*, *supra* note 1.

⁷ *E&E Legal Again Forced to Sue NIH*, *supra* note 1

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² Letter from Hon. Paul Broun & Hon. Andy Harris, H. Comm. on Science, Space, & Tech. & Hon. David Vitter & Hon. James Inhofe, U.S. Senate, to Dr. Linda Birnbaum, Director, Nat’l Toxicology Program & Dr. Paul Anastas, Asst. Admin., Office of Research and Dev. (Jan. 31, 2012).

¹³ Letter from Lek Kadeli, Acting Asst. Admin., U.S. Environmental Protection Agency, to Hon. Paul Broun, H. Comm. on Science, Space, & Tech. (Mar. 13, 2012).

¹⁴ *Id.*

The Committee has a responsibility to ensure that the federal government funds and engages in scientific research free from external pressures and opinions. To assist the Committee's oversight of NIEHS, please contact Committee staff by March 31, 2017, to arrange a briefing on this matter. The Committee requests communications and materials related to the scientific integrity of the work performed by NIEHS contractors and grant recipients to ensure proper stewardship of taxpayer dollars and sound science. To understand the relationship between NIEHS and Ramazzini, please provide the following documents and information as soon as possible, but no later than noon on April 7, 2017 for the time period January 1, 2009 to the present:

1. All documents and communications referring or relating to any grant issued by NIEHS to the Ramazzini Institute or any Ramazzini affiliate.
2. All documents and communications referring or relating to any contract issued by NIEHS to the Ramazzini Institute or Ramazzini affiliate.
3. All documents and communications between and among NIEHS employees and any fellow of the Ramazzini Institute or affiliated entity referring or relating to any grant or contract award.
4. All documents and communications between and among NIEHS employees referring or relating to Ramazzini or its affiliates' business practices.
5. A list of all Ramazzini fellows employed by NIH, including but not limited to, NIEHS employees.
6. Provide all contracting file documents, including but not limited to any justification and approval documents, for the following contract numbers: HHSN29120055535C, HHSN27300152, HHSN27300212, HHSN27300063, HHSN27300149, HHSN27300390, and HHSN27300230.

The Committee has jurisdiction over environmental and scientific research and development programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X. This request and any documents created as a result of this request will be deemed congressional documents and property of the House Science Committee.

When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2321 of the Rayburn House Office Building and the Minority Staff in Room 394 of the Ford House Office Building. The Committee prefers, if possible, to receive all documents in electronic format. An attachment to this letter provides additional information regarding producing documents to the Committee.

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If you have any questions about this request, please contact Drew Colliatie or Caroline Ingram of the Science, Space, and Technology Committee staff at 202-225-6371. Thank you for your attention to this matter.

Sincerely,


Lamar Smith
Chairman


Darin LaHood
Chairman
Subcommittee on Oversight

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space and Technology

The Honorable Don Beyer, Ranking Minority Member, Subcommittee on Oversight

The Honorable Suzanne Bonamici, Ranking Minority Member, Subcommittee on Environment

Enclosure

Responding to Committee Document Requests

1. In complying with this request, you are required to produce all responsive documents, in unredacted form, that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. You should also produce documents that you have a legal right to obtain, that you have a right to copy or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party. Requested records, documents, data or information should not be destroyed, modified, removed, transferred or otherwise made inaccessible to the Committees.
2. In the event that any entity, organization or individual denoted in this request has been, or is also known by any other name than that herein denoted, the request shall be read also to include that alternative identification.
3. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, or thumb drive) in lieu of paper productions.
4. Documents produced in electronic format should also be organized, identified, and indexed electronically.
5. Electronic document productions should be prepared according to the following standards:
 - (a) The production should consist of single page Tagged Image File ("TIF"), or PDF files.
 - (b) Document numbers in the load file should match document Bates numbers and TIF or PDF file names.
 - (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
6. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.
7. Documents produced in response to this request shall be produced together with copies of file labels, dividers or identifying markers with which they were associated when the request was served.
8. When you produce documents, you should identify the paragraph in the Committee's schedule to which the documents respond.
9. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.

10. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), you should consult with the Committee staff to determine the appropriate format in which to produce the information.
11. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production. Failure to provide an explanation constitutes a waiver of any objections to the subpoena.
12. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) the basis for withholding the documents; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other; and (f) any other description necessary to identify the document and to explain the basis for not producing the document. If a claimed privilege applies to only a portion of any document, that portion only should be withheld and the remainder of the document should be produced. As used herein, "claim of privilege" includes, but is not limited to, any claim that a document either may or must be withheld from production pursuant to the constitution or any statute, rule, or regulation.
13. In complying with this request, be apprised that the U.S. House of Representatives and the Committee on Science, Space, and Technology do not recognize: any of the purported non-disclosure privileges associated with the common law including, but not limited to, the deliberative process privilege, the attorney-client privilege, and attorney work product protections; any purported privileges such as privileges over law-enforcement sensitive disclosures or protections from disclosure under the Freedom of Information Act; or any purported contractual privileges, such as non-disclosure agreements. Any assertion by a request recipient of any such non-constitutional legal bases for withholding documents or other materials shall be of no legal force and effect and shall not provide a justification for such withholding or refusal, unless and only to the extent that the Chair of the Committee has consented to recognize the assertion as valid.
14. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control.
15. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you are required to produce all documents which would be responsive as if the date or other descriptive detail were correct.
16. Unless otherwise specified, the time period covered by this request is from January 1, 2009 to the present.
17. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data or information, not produced because it has not been

located or discovered by the return date, shall be produced immediately upon subsequent location or discovery.

18. All documents shall be Bates-stamped sequentially and produced sequentially.
19. Two sets of documents shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee on Science, Space, and Technology, production sets shall be delivered to the Majority Staff in Room 2321 of the Rayburn House Office Building and the Minority Staff in Room 324 of the Ford House Office Building.
20. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committees.
21. When representing a witness or entity before the Committee in response to a document request, request for transcribed interview, or subpoena from the Committee, or in connection with testimony before the Committee at a hearing, counsel for the witness or entity must promptly submit to the Committee a notice of appearance specifying the following: (a) counsel's name, firm or organization, and contact information; and (b) each client represented by the counsel in connection with the proceeding. Submission of a notice of appearance constitutes acknowledgement that counsel is authorized to accept service of process by the Committee on behalf of such client(s), and that counsel is bound by and agrees to comply with all applicable House and Committee rules and regulations.

Schedule Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office and intra-office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether

preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, email (desktop or mobile device), text message, instant message, MMS or SMS message, regular mail, telexes, releases, or otherwise.
3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.
4. The terms "person" or "persons" mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.
5. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; and (b) the individual's business address and phone number.
6. The term "referring or relating," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is pertinent to that subject in any manner whatsoever.
7. The term "affiliate" or "affiliates" means associated business concerns, organizations, or individuals if, directly or indirectly (a) either one controls or can control the other; or (b) a third party controls or can control both, and including but not limited to "Collegium Ramazzini."