

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

September 27, 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 continuing its oversight of the National Institutes of Health's, National Institute of Environmental Health Sciences (NIEHS) contracts with the Ramazzini Institute (RI), an Italian organization engaged in cancer-related research. On May 16, 2017, the Department of Health and Human Services (HHS or the Department) provided the Committee with a letter and a limited amount of the requested documents labeled "Enclosure 1" and "Enclosure 2" (in total referred to as "the production"). Unfortunately, the production, rather than answering the Committee's questions, only raised new questions. Specifically, the Committee is concerned about the informal nature of the agreements and contracts between NIEHS and RI, the lack of evidence of competition in contracting, and the unjustified continuation of the contracts for 17 years. The totality of these potential problems require that the Committee continue its oversight efforts. Today, I am writing to reiterate the Committee's March 24, 2017, request and ask for additional documents.

Enclosed please find six pages of documents from the production by HHS, which were part of Enclosure 1. These pages demonstrate that there has been some sort of relationship – perhaps contractual, but in any case a fiduciary one – between NIEHS and the RI dating back to July 2000. The informality of these pages raises significant concerns about whether NIEHS was operating within the rigorous confines of the Federal Acquisition Regulation (FAR) when awarding contracts to the RI. Enclosure 2 of the production contains various contracts and task orders, but the earliest date appears to be 2004 – four years after NIEHS and the RI began their relationship.

The record is also void of any evidence of competition or justification for sole source awards of the contracts. As you will recall, the March 24, 2017, letter from the Committee requested, among other documents:

Provide all contracting file documents, *including but not limited to any justification and approval documents*, for the following contract numbers:
HHSN291200555535C, HHSN27300152, HHSN27300212,

HHSN27300063, HHSN27300149, HHSN27300390, and
HHSN27300230.¹

The Committee has a responsibility to ensure that the federal government funds and engages in scientific research free from external pressures and opinions – competition in the marketplace encourages the best value for the taxpayers. Chief among the Committee’s concerns is the basis for renewing the contract successively for 17 years *even after* another federal government agency raised questions related to the integrity of scientific work performed by the RI.

In June 2010, the Environmental Protection Agency (EPA) questioned the RI’s studies related to chemicals undergoing review by the EPA’s IRIS Program.² In the case of certain chemicals and certain cancers, the EPA decided *not* to rely on the work of the RI at all. In fact, EPA made its decision “after receiving a report from the National Toxicology Program (NTP) that reviewed results of some research studies completed by the RI, a lab in Italy that conducts animal testing to evaluate the potential cancer-causing effects of chemicals. The report found differences of opinion between NTP and RI scientists in the diagnosis of certain cancers reported in a study on methanol.”³ To better understand the discrepancies, EPA worked with an independent group of scientists, “the Pathology Working Group (PWG), to review a larger group of animal studies performed in the RI lab.”⁴ The independent review by the PWG led the EPA to conclude:

Because of the differences of opinion between the RI and PWG scientists in diagnosing leukemias and lymphomas, EPA has decided not to rely on data from the RI on lymphomas and leukemias in these IRIS assessments. This decision will impact the IRIS assessments for methanol, MTBE and ETBE. The draft assessment for acrylonitrile was not affected, as EPA relied on data from sources other than RI to complete this IRI [integrated risk information] assessment.⁵

Although some data collected by the RI was used, the PWG deemed it appropriate and necessary to make “recommendations for changes in RI’s laboratory procedures and EPA hopes that RI will fully implement these recommendations to allow for the use of future RI data in IRIS assessments.”⁶ The Committee is concerned that NIEHS has not fully vetted these issues brought to light by the EPA. It appears that the annual extension of the contract between NIEHS and RI has become a perfunctory exercise without any evaluation of the merits. From the record

¹ Letter from Hon. Lamar Smith, Chairman, H. Science, Space, & Tech. Comm. to Hon. Thomas E. Price, Secretary, U.S. Dep’t of Health and Human Services, Mar. 24, 2017 (emphasis added).

² Update on Ramazzini Institute Data in IRIS Assessments, available at <https://www.epa.gov/iris/update-ramazzini-institute-data-iris-assessments> (last visited Sept. 20, 2017) (IRIS stands for Integrated Risk Information System).

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

before the Committee, it is unclear what, if any, evaluations NIEHS has conducted of RI's procedures.

To assist the Committee in filling the gaps in the record, the Committee reiterates its prior request for documents and adds two new requests. Please provide all documents requested as soon as possible, but no later than noon on October 11, 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.
7. All documents and communications referring or relating to competition in contracting with the Ramazzini Institute, including but not limited to any justification and approval documents for contracts with the Ramazzini Institute.
8. All documents and communications referring or relating to any of the following:
 - A. An evaluation of the merits of continuing to contract with the Ramazzini Institute, or
 - B. An evaluation of the concerns articulated by EPA in 2010 related to the IRIS program.

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.

The Honorable Thomas E. Price.

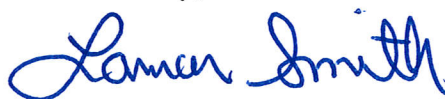
September 27, 2017

Page 4

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.

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

Sincerely,



Lamar Smith
Chairman

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

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Director

Telephone: 919-541-3201
Fax: 919-541-2260

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

July 17, 2000

Professor Cesare Maltoni
Scientific Director, Cancer Research Center
B. Ramazzini Foundation
Castello di Bentivoglio
40010 Bentivoglio
Bologna
ITALY

Dear Professor Maltoni:

The proposal is just fine with NIEHS! I propose that we create the joint scientific commission to identify the collaborative research to be performed.

I have asked Dr. Chris Portier, Director of the Environmental Toxicology Program, to take the lead for us. He will be in touch to work out the details of the composition of the Commission and a proposed work plan.

I look forward to a productive collaboration.

Sincerely yours,

A handwritten signature in black ink that reads "Ken".

Kenneth Olden, Ph.D.
Director

Enclosure

cc:
Dr. Portier



22nd June 2000

PROPOSAL OF AGREEMENT

for Institutional Scientific Collaboration between the National Institute of Environmental Health Sciences (NIEHS) and the European Foundation of Oncology and Environmental Sciences "B. Ramazzini" (Ramazzini Foundation)

Following:

- 1) scientific meetings between Dr. Kenneth Olden, Director of NIEHS and Professor Cesare Maltoni, Scientific Director of the Ramazzini Foundation, in occasion of Dr. Olden's visit to the Cancer Research Centre of the Ramazzini Foundation in Bentivoglio (Bologna);
- 2) an overview of the Ramazzini Foundation's scientific activity and the future programmes of the NIEHS and Ramazzini Foundation, during Dr. Olden's visit;

Considered that:

- 1) NIEHS and Ramazzini Foundation have many scientific interests and finalities in common;
- 2) more specifically, like the NIEHS, the Ramazzini Foundation is active and interested in:
 - identification of carcinogenic agents and quantification of oncogenic risks by long-term bioassays (to date the Ramazzini Foundation, in more than 30 years of activity, has tested nearly 190 industrial chemical and physical agents);
 - interaction and synergisms between genetic susceptibility and exogenous carcinogenic agents/factors;
 - basic mechanisms of carcinogenesis;
 - statistical evaluation of the significance of the data;
- 3) there are several interesting possibilities of integrating studies, results and materials, made available by NIEHS and the Ramazzini Foundation;

Recognized:

- 1) the expected positive potentialities of a collaboration between NIEHS and the Ramazzini Foundation in the fields of common interest;

all the oversaid taken into account

Dr. Kenneth Olden and Professor Cesare Maltoni agree on the following:

- 1) the establishment of a scientific collaboration between NIEHS and the Ramazzini Foundation in fields of common interest;
- 2) the priorities of such collaboration have been identified as:
 - carcinogenicity bioassays on agents jointly identified;
 - research on the interactions between genetic susceptibility and exogenous carcinogens;
 - biostatistical analysis of results ..
 - molecular biology studies on the basic mechanisms of carcinogenesis;
- 3) a joint scientific commission with representatives of both institutions will specifically identify the research to be performed in the oversaid scientific areas, considering also the know-how and the material made available by both institutions;
- 4) Dr. Olden and Professor Maltoni, as Directors, will appoint their representatives in the scientific commission and will also identify the responsible scientists involved in the various scientific projects;
- 5) the organization, performance and calendar, and the administrative and economical aspects of each project may be specifically agreed in ad hoc documents;
- 6) the results of the above research will be published as a joint NIEHS-Ramazzini Foundation research programme, as a first option in current issues or Supplements of Environmental Health Perspectives, or in a mutually agreed journal. The sequence of the Authors will be established on the basis of their scientific input to the specific studies;
- 7) the present agreement will last 2 years and, based upon the results of this experience, may be renewed for the future.

Approved
Ken Olden



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health
National Institute of
Environmental Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709

at
Collezione Ramazzini
file
ES 5/2

090187 MAY-28

NIEHS

April 29, 2002

Olden / Airy

CONTINUATION OF AGREEMENT

For Institutional Scientific Collaboration between the National Institute of Environmental Health Sciences (NIEHS) and the European Foundation of Oncology and Environmental Sciences "B. Ramazzini" (Ramazzini Foundation)

Following:

- 1) scientific meetings between Dr. Kenneth Olden, Director of NIEHS and Professor Cesare Maltoni, Scientific Director of the Ramazzini Foundation, in occasion of Dr. Olden's visit to the Cancer Research Centre of the Ramazzini Foundation in Bentivoglio (Bologna);
- 2) and the successful establishment of a series of contacts and scientific collaborations between staff of the Ramazzini Foundation and the NIEHS during the 2-year duration of the initial agreement

Considered that:

- 1) NIEHS and the Ramazzini Foundation continue to have many scientific interests and finalities in common;
- 2) more specifically, like the NIEHS, the Ramazzini Foundation is active and interested in:
 - identification of carcinogenic agents and quantification of oncogenic risks by long-term bioassays (to date the Ramazzini Foundation, in more than 30 years of activity, has tested nearly 190 industrial chemical and physical agents);
 - interaction and synergisms between genetic susceptibility and exogenous carcinogenic agents/factors;
 - basic mechanisms of carcinogenesis;
 - statistical evaluation of the significance of the data;

- 3) and that the first steps have been taken toward integrating studies, results and materials, made available by NIEHS and the Ramazzini Foundation;

Recognized:

- 1) the expected positive potentialities of a continued collaboration between NIEHS and the Ramazzini Foundation in the fields of common interest;

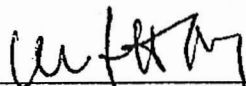
all the oversaid taken into account

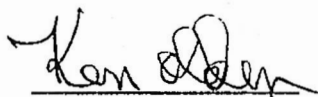
Dr. Kenneth Olden and Dr. Morando Soffritti agree on the following:

- 1) the continuation of the scientific collaboration between NIEHS and the Ramazzini Foundation in fields of common interest;
- 2) the priorities of such collaboration have been identified as:
 - carcinogenicity bioassays on agents jointly identified;
 - research on the interactions between genetic susceptibility and exogenous carcinogens;
 - biostatistical analysis of results and the establishment of common data management tools
 - molecular biology studies on the basic mechanisms of carcinogenesis;
- 3) a joint scientific commission with representatives of both institutions will specifically identify the research to be performed in the oversaid scientific areas, considering also the know-how and the material made available by both institutions;
- 4) Dr. Olden and Dr. Soffritti, as Directors, will appoint their representatives in the scientific commission and will also identify the responsible scientists involved in the various scientific projects;
- 5) the organization, performance and calendar, and the administrative and economical aspects of each project may be specifically agreed in ad hoc documents;

- 6) the results of the above research will be published as a joint NEIHS-Ramazzini Foundation research programme, as a first option in current issues or Supplements of Environmental Health Perspectives, or in a mutually agreed journal. The sequence of the Authors will be established on the basis of their scientific input to the specific studies;

the present agreement will last 2 years and, based upon the results of this experience, may be renewed for the future.


Dr. Morando Soffritti


Dr. Kenneth Olden