



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**

WASHINGTON, DC 20201



MAR 13 2017

Mr. Andrew Goldman  
Legal Counsel  
Knowledge Ecology International  
1622 Connecticut Avenue, NW, Suite 500  
Washington, DC 20009

Dear Mr. Goldman:

I am responding to your letter dated January 28, 2017, concerning potential violations of the Bayh-Dole Act by Isis Pharmaceuticals, now known as Ionis Pharmaceuticals, and Cold Spring Harbor Laboratory. You requested that the Inspector General investigate whether two inventions patented by Isis and Cold Spring Harbor are Federally-funded subject inventions that should have been disclosed to the National Institutes of Health (NIH) and, if so, recommend an appropriate remedy. We have consulted with our counsel and, as explained below, we believe your request is better handled by NIH.

Under the Inspector General Act of 1978 (IG Act), OIG may conduct investigations relating to fraud, waste, abuse or other misconduct in connection with programs and operations of HHS. However, OIG's authority is limited. To preserve OIG's independence and objectivity, OIG may not assume responsibility for the operation of a Departmental program. See §§ 4 and 9(a) of the IG Act. Here, the responsibility for administering and overseeing extramural research grants rests with NIH's Office of Policy for Extramural Research Administration (OPERA). This responsibility includes monitoring invention reporting and remedying noncompliance. For this reason, OIG must decline your request.

We did, however, contact representatives from NIH in connection with your letter. We provided NIH with a copy of your letter, and we were informed that NIH/OPERA is currently addressing your concerns. We recommend that you contact NIH/OPERA for further information about this matter.

We hope that this information is useful to you. If you have additional questions, please do not hesitate to contact me or Peter Taschenberger, Senior Counsel at [Peter.Taschenberger@oig.hhs.gov](mailto:Peter.Taschenberger@oig.hhs.gov) or (202) 205-8896.

Sincerely,

Matthew Charette  
Special Agent in Charge  
Investigations Branch

cc: James Love, Director  
Zack Struver, Research Associate  
Diane Singhroy, Scientific Advisor