OPENTHEBOOKS OVERSIGHT REPORT

CORRUPTION & CONFLICT

EXPOSING THE SECRET \$2 BILLION BIG PHARMA KICKBACK COMPLEX AT THE NATIONAL INSTITUTES OF HEALTH (NIH)



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This report is dedicated to Adam Andrzejewski OpenTheBooks Co-Founder & Former CEO

Adam unexpectedly passed away August 18, 2024 shortly after completing this report

"OpenTheBooks is doing the work I envisioned when the Coburn-Obama bill became law. Their innovative app and other tools are putting sunlight through a magnifying glass."

U.S. Senator Tom Coburn, MD Washington, D.C. | March 11, 2014

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Sen. Tom Coburn (R-OK) & Sen. Barack Obama (D-IL) (Public Law 109-282, 109th Congress)

"I know that restoring transparency is not only the surest way to achieve results, but also to earn back the trust in government..."

U.S. Sen. Barack Obama

PROLOGUE

For nearly three years OpenTheBooks.com has been locked into litigation with the National Institutes of Health as we attempt to uncover details surrounding the royalty payments received by NIH scientists for inventions created while they are employed by the agency.

As NIH scientists collaborate with private-sector researchers, and the agency itself gives over \$30 billion in research grants each year, every royalty payment represents a potential conflict of interest. Taxpayers deserve to understand the financial stakes in play as funding decisions and public health recommendations are made.

In 2022 OpenTheBooks.com and our litigation partner, Judicial Watch, won a lawsuit compelling the agency to disclose royalty payments made to scientists from October 2009-September 2021. The documents were heavily redacted, hiding the companies making the payments and how much each payment was worth. However, we were able to ascertain the number of discrete payments each scientist received, and the total dollar amount received by scientists within each subagency.

In 2023 we won another court battle–compelling the NIH to remove redactions on the companies paying royalties to the scientists. While we still don't know how much those scientists received individually, these new connections could be useful in untangling the web of government and industry at the NIH at home and abroad.

OpenTheBooks.com founder and former CEO Adam Andrzejewski discussed these and more of our findings with Sharyl Atkisson on her Full Measure program earlier this year,

including on-going mysteries surrounding four of the top five royalty recipients.

New data collected this year from OpenTheBooks.com's ongoing litigation shows more alarming trends: huge new increases in the amount of royalties received by NIH during the pandemicequal to more than the previous 12 years combined.



WHO WE ARE

American Transparency is a public charity. We do not accept government money. Our oversight reports present hard data so citizens, media, think tanks, politicians, and watchdogs can "follow the money." Hard facts are non-partisan and enhance the public discourse.

Ø OPENTHEBOOKS.COM

METHODOLOGY

Royalty payment data from FY2010-2022 was collected from documents obtained via the OpenTheBooks lawsuit against NIH. Documents from FY 2023 were obtained via usual Freedom of Information Act request processes and were not a part of the lawsuit.

Raw data files can be found here: FY2010-2021 | FY2022-2023

Computer programs were used to scrape data from the 3,477 pages produced by the NIH.

The data comprised of three primary categories:

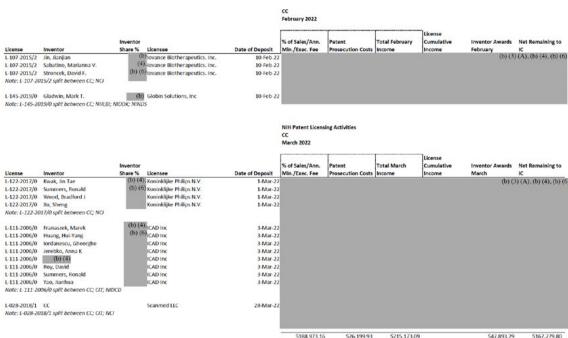
• Total payments in dollar amounts marked as "due to inventors by IC" in the NIH documents. IC stands for "Institutes and Centers," like the National Institute for Allergies and Infectious Diseases (NIAID) and National Cancer Institute (NCI). Payments were either made to scientists or, in some cases, to the ICs directly. All of these totals were checked by auditors by hand.

National Institutes of Health Office of Financial Management Royalties Semiannual Report -- Payments due to Inventors by IC -- Period ending: March 2022 \$47,893.29 (b) (3) (A), (b) (4) Franaszek, Marek Gladwin, Mark T. Huang, Hui-Yang Iordanescu, Gheorghe Jerebko, Anna K Jin, Jianjian Kwak, Jin Tae Lay, Nathan Stephan (b) (4) Reinhard Roth, Holger Roy, David Sabatino, Marianna V. Stroncek, David F. Summers, Ronald Tsehay, Yohannes Kebede Turkbey, Evrim Wood, Bradford J Xu. Sheng Yao, Jianhua CDC \$387,543.00 (b) (3) (A), (b) (4), (b) (6) Ades, Edwin W. Aloisio, Carol H. Anderson, Burt E. Anderson, Larry J. Bagarozzi, Dennis Anthony Barclay, Leslie Beck, Eric T. Bellini, William J. Berman, LaShondra

Example of data showing "Payments due to inventors by IC" from NIH royalty production. This example can be found <u>here</u> on page 1.

- Total payments in dollar amounts, marked as "Total Income" on the NIH documents. These include all non-redacted payment royalty totals being paid either to inventors or to the ICs directly; "Inventor Awards" (which are the same as the amounts marked "due to inventors by IC"); "Net Remaining to IC," which are payments sent directly to the IC.
- Number of payments to scientists from licensees. Our computer program scraped each time a scientist's name appeared in payment data, along with the date the payment was made, the licensee paying the royalty, and the IC the scientist belonged to. The amount of each individual payment is still redacted, but we hypothesize that the number of payments is correlated to the amount each scientist is being paid over the course of the year. These numbers were spot checked by auditors for accuracy. An estimated 14% of pages in the NIH productions are not machine readable, however, and data on the number of payments was not collected from those pages. Scientist and licensee names also frequently contained typos or alternate spellings, and while auditors attempted to correct these errors, with nearly 70,000 payments to over 2,600 scientists from about 1,700 companies, some errors may still be present. For these reasons the number of payments cannot be considered exact, but rather a close approximation to the true number.

Data used in our analysis is provided in excel format in the "Data" section of this report.



Example of data marked as "Total Income," "Inventor Awards," and "Net Remaining to IC" used in this analysis. This example would be from the first half of FY 2022 for the NIH Clinical Center (CC). This example also shows the scientist names, licensees, and date of deposit data also scraped for our analysis. This example can be found here on page 37.

DATA INCONSISTENCIES

The true amount awarded to inventors and awarded to the inventors' IC is unknown because of redactions that we continue to fight in court. Numbers are redacted in these cases because there are so few scientists receiving royalties in some ICs that the NIH argues it would be too easy to approximate the amount owed to individual scientists if they were unredacted. It is likely the missing totals are also relatively small and OpenTheBooks auditors do not believe the redacted totals would have a material impact on the billions of dollars already recorded.

NIAAA Cinar, Resat Iyer, Malliga R. Kunos, George I

Example of redacted total payments by IC due to inventors. In this case only three scientists would be owed funds from the National Institute of Alcohol Abuse and Alcoholism (NIAAA). The NIH argues that to protect the privacy of these scientists, the total amount must be redacted. This example can be found here on page 23.

The NIH was not always consistent in its own redacting practices, however, and the categories of "payments due to inventors by IC" and "inventor awards" do not equal the same amount. Sometimes NIH would redact data in one and not the other, we assume in error. The accidentally unredacted payments "due to inventors by IC" equaled \$1.24 million from FY 2020-2023 and were added by OpenTheBooks auditors to our total amount awarded to inventors.





Examples of totals being redacted in one area ("Inventor awards," graphic A.) but not the other ("Payments due to inventor by IC," graphic B. Auditors assumed this was a mistake on the part of the NIH redactors and added the number on the right to our total inventor awards. These examples are from here on page 259-260 and 183, respectively.

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- OpenTheBooks.com has been locked in a years-long litigation battle with the NIH over royalty transparency. So far, our organization has unlocked 3,477 pages of royalty data, including scientists receiving royalties and companies paying royalties. Individual royalty amounts are still redacted.
- Auditors have found \$2.685 billion paid to NIH scientists and sub-agencies (like the National Institute of Allergy and Infectious Diseases, NIAID) by licensees from FY 2010-2023.
- About 1,650 companies were named as licensees, and over 2,600 scientists were named as inventors receiving payments.
- In over 2,000 instances, inventors' names were redacted from the payment information, raising questions about the nature of the relationship between those inventors, the NIH, and the licensees.
- Non-U.S. licensees outnumbered U.S.-based licensees in 2023, the first time since records begin in 2006.

- Some licensees have raised serious concerns of foreign influence over NIH. Auditors identified nearly 40 Chinese companies that have licensed NIH patents since 2010, including former Vaccine Research Center director John Mascola, and former deputy director Barney Graham.
- Scientists receiving royalties hold positions of power and influence at NIH, such as three-time National Cancer Institute Acting Director Douglas Lowy, whose patents were used in HPV vaccines.
- The top royalty recipient in our thirteen years of data, with over 1,000 payments, is Melinda Hollingshead, former Chief of Biological Testing Branch, Developmental Therapeutics Program at the National Cancer Institute. Before retiring this year Hollingshead worked at the NCI campus in Frederick, Maryland—the same location as Fort Detrick, a U.S. Army installation involved in the U.S. biological defense program.
- 44 NIH scientists received between one and nine payments from Moderna, including Vaccine Research Center director John Mascola, and deputy director Barney Graham.
- **Royalty Transparency Act**, which passed unanimously out of the Senate Homeland Security and Government Affairs Committee this year, would require scientists to disclose royalty payments, providing needed sunshine on the intersection between corporate and government funding, and influence at the NIH.



OpenTheBooks auditors recorded \$1,036,284,504 in funds marked as "inventor awards" between FY 2010 and 2023.

These funds were designated for 2,613 named scientists. Auditors additionally found 2,193 instances where a scientist's name was redacted in the payment records.

It is unknown why any names would be redacted, and it is something we continue to fight in our lawsuit with the agency.

Auditors recorded 1,655 companies paying these royalties in our 13-year timeframe.

Royalties paid directly to NIH "institutes or centers" (ICs) during this period equal \$1,649,534,342.

In all, over \$2.685 billion was paid to NIH institutes or scientists, nearly half, \$1.266 billion, paid out during the pandemic years of FY 2022-23.

The following sections will analyze this data in more detail.

EXTRAORDINARY AWARD INCREASES

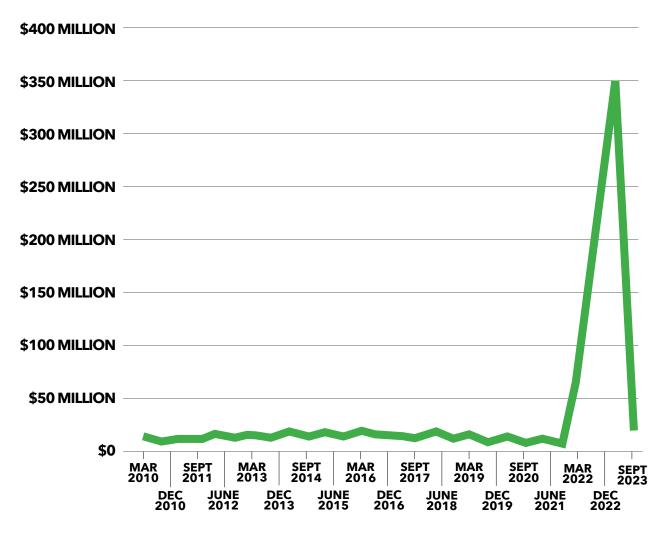
Over a billion dollars were marked as "inventor awards" during the thirteen-year period covered by our data. Most of those funds were paid by licensees in just two fiscal years, FY 2022-23.

From October 2021-September 2023 the number of inventor awards was \$710,467,147, over twice the amount of royalties paid during the previous ten years.

From October 2009-September 2021 all total payments equaled \$325,817,357.

In the last six months of fiscal year 2023, inventor awards plummeted to \$25 million, which is still higher than most of the preceding years.

INVENTOR AWARDS



Inventor awards at six-month intervals, October 2009 - September 2023.

Most of this increase is accounted for through the National Institute of Allergies and Infectious Diseases, which alone distributed \$690,218,610 from FY 2022-2023.

Previous years saw the collective NIAID inventor awards at around \$1 million or less.

Top Five NIAID Payment Recipients And Top Ten Licensees

Because we do not know the amounts being paid out, we do not know which scientists received the most royalty payments total. We assume that there is a correlation between the number of payments and the total amount received but cannot know for certain until payment totals are unredacted.

The number of payments from licensees could also reflect both the number of licenses a company holds and the number of inventors paid out through each license.

The top five NIAID scientists by the number of times they received an inventor award are:

SCIENTIST	POSITION	INVENTOR AWARD COUNT
DEAN METCALFE	Chief of the Mast Cell Biology Section, NIAID	79
ARNOLD KIRSHENBAUM	Position unknown	79
CAM AKIN	Former fellow at NIAID, current clinician-scientist and a Professor of Medicine at the University of Michigan Division of Allergy and Immunology	78
PETER KWONG	Former Chief of the Structural Biology Section, Vaccine Research Center, NIAID. In 2023 Kwong transitioned to an NIH Special Volunteer and is co-director of the Aaron Diamond AIDS Research Center at Columbia University	53
TONGQING ZHOU	Current Chief of the Structural Biology Section, Vaccine Research Center, NIAID	46

The top ten licensees in terms of total payments to named NIAID scientists are:

LICENSEE	COUNT
GlaxoSmithKline	154
Icosavax	136
Merck, Sharp & Dohme	122
Meso Scale Diagnostics, LLC	92
Changchun BCHT Biotechnology	86
BioLegend	77
Ceva Sante Animale S.A.	72
BlueWillow Biologics	69
Medigen Vaccine Biologics Corp	56
ADMA Biologics, Inc.	53

A few of these companies, like Merck and GlaxoSmithKline, are recognizable as some of the largest pharmaceutical companies in the world. Other notable top fifteen companies include:

- Intranasal vaccine developer BlueWillow Biologics
- Taiwan-based Medigen Vaccine Biologics Corp, which developed the MVC COVIC-19 vaccine
- State-owned Chinese vaccine developer Changchun BCHT.

Pfizer and Moderna are not among the top royalty payers during this time: Moderna made 29 payments and Pfizer made nine. In early 2023 Moderna settled a patent dispute with the NIH over royalty payments for technologies related to the company's COVID-19 vaccine. Moderna <u>agreed</u> to pay out \$400 million to NIH and to pay a small percentage of royalties on future vaccine sales. It is unknown if that payment is included in the data.

It is unclear which companies are licensing patents related to COVID-19 treatments.

FOREIGN LICENSEES

Foreign companies linked to adversarial states are among the hundreds of institutions paying royalties to NIH scientists and institutes, raising questions about foreign influence on government scientists.

A survey of the data revealed at least 31 countries represented including China, Russia, Belarus, Cayman Islands and Hong Kong, in addition to United Kingdom, Switzerland, Japan, Germany, France, Canada, India, Ireland, Singapore, Israel and many others.

In Russia, we found Pokrov Biologics Plant (20 payments) paid NIH royalties to license technologies paid for by U.S. taxpayers. Pokrov is a <u>vaccine company for farm animals that was an alleged front for bioweapons/ dangerous pathogens.</u>

In Belarus, we found BelVituniPharm (12 payments) paid NIH royalties to license technologies paid for by U.S. taxpayers. This is an <u>unstable veterinary company</u> in a country with a reputation of rabid corruption.

In China, there are at least 39 Chinese companies that have licensed NIH technologies since 2010 including:

China National Biotec Group Company (107) - A <u>subsidiary</u> of the state-owned pharmaceutical company Sinopharm, the company was formerly under direct management of the Chinese Ministry of Health.

Wuhan Institute of Biological Products (70 payments) - This company is a <u>subsidiary</u> of the state-owned pharmaceutical company Sinopharm. In 2016, the company moved next to the Wuhan Institute of Virology to collaborate with them.

Yisheng Biopharma Holding (42 payments) - First based in Beijing, and then Hong Kong, and now has a U.S. subsidiary in Gaithersburg, Maryland and works with the U.S. Army on infectious disease research like Ebola.

WalVax BioTech (35 payments) - The company is <u>engaged</u> in research and development, manufacturing and distribution of, they claim, "safe and efficacious quality vaccines" in China with major investments from the Bill and Melinda Gates Foundation.

Guangzhou HeAn Biological (24 payments) - In 2017, the company made the FDA's "top grossing license agreements" on their list of "technology transfer success stories."

WuXi AppTec (97 payments) and its subsidiary WuXi Biologics (21 payments) are licensees that have recently come under intense scrutiny by Congress this year.

As the New York Times reported, WuXi AppTec produces materials for a vast array of pharmaceuticals used by Americans. Lawmakers are concerned about the company because of its supposed affiliation with the Chinese military and its access to American genetic information and intellectual property.

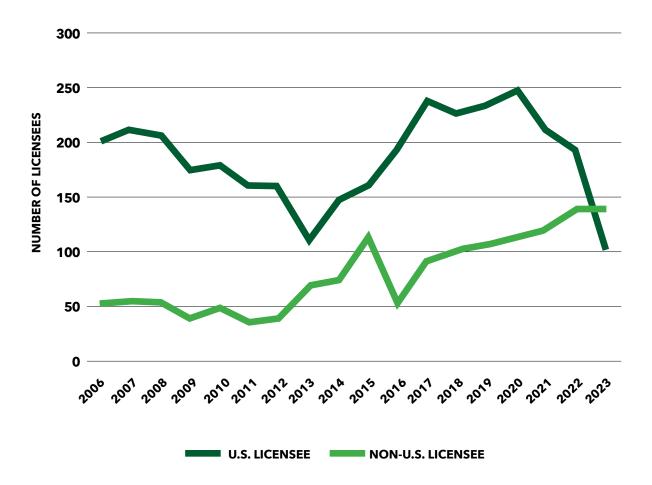
A bipartisan, bicameral group of lawmakers released a <u>letter</u> in February demanding Department of Commerce Secretary Gina Raimondo and Department of Defense Secretary Lloyd Austin investigate WuXi AppTec and WuXi Biologics for connections to the Chinese Communist Party.

In May Representatives Brad Wenstrup (R-Ohio) and Raja Krishnamoorthi (D-III.) <u>introduced</u> the BIOSECURE Act, which would prevent WuXi AppTec and another company, Beijing Genomics Institute, from accessing American patient data and tax dollars. In July House Speaker Mike Johnson (R-La.) <u>announced</u> that he would bring the bill to a vote on the House floor in the fall.

Other Chinese companies licensing NIH technologies developed with taxpayer funds and paying royalties include:

COMPANY	COUNT
China National Biotec Group Company Limited	107
WuXiAppTec, Inc.	97
Changchun BCHT Biotechnology Co.	86
Ping An Technology (Shenzhen) Company It	78
Sinovac Biotech, Ltd.	76
Wuhan Inst. of Biological Products	70
Yuhan R&D Institute	42
Yisheng Biopharma Holdings Ltd.	42
Walvax Biotech	35
Changchun Hongda Bio. Pharm. Co., Ltd.	30
Beijing Luzhu Biopharm Co., Ltd.	30
Beijing Advaccine Biotechnology Co, Ltd.	29
Shanghai ChemPartner Co., Ltd.	29
Shandong Yidu Biotechnology Co., Ltd.	28
Chengdu Boao Bio-tech Co.	27

Congress would be wise to watch for foreign influence on the NIH via its royalty schemes as well. In 2023 licenses to non-U.S. institutions surpassed American ones for the first time, according to an NIH <u>website</u>.



PAYMENT LIMITS

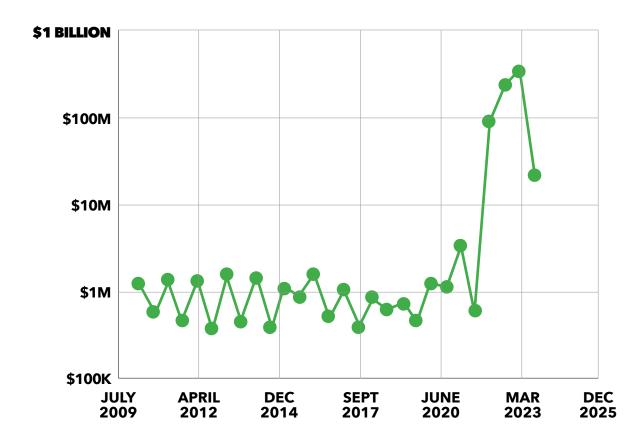
A complicated formula governs the split between NIH inventors, according to the NIH website:

"Inventors receive the first \$2,000 collected from a licensee. Next, they receive 15 percent of royalties above \$2,000 and up to \$50,000. Finally, they receive 25 percent of royalties in excess of the first \$50,000 collected each year."

Additionally, scientists cannot receive more than \$150,000 per calendar year. <u>Laws</u> passed by Congress in the 1980s set these limits to reduce conflicts of interests between scientists and the companies licensing their inventions. Inventors receive payments after they've left the agency, and their estates will receive payments after they die.

During the pandemic, recorded royalty payments to NIAID inventors in this time are so high, and the number of scientists receiving such payments are so low, that with no such limit, some of the scientists would certainly be getting far more than \$150,000 per year.

PAYMENTS TO SCIENTISTS



Case in point, in FY 2022 the NIAID records \$325 million inventor awards to about 240 named scientists. Theoretically, if this funding was evenly distributed each of those scientists would have received over \$1.3 million.

But if scientists can only get \$150,000 a year, where do the rest of the royalties go? That answer is not clear.

According to the NIH technology transfer <u>website</u>, if an inventor hits the \$150,000 cap, funds are distributed to co-inventors until they also hit the \$150,000 cap. When those caps are hit, the royalties go to the Institute or Center the inventors are affiliated with, with most supposed to be going to the laboratory where the invention occurred.

Inventors can make more than \$150,000 a year if granted a <u>Presidential award</u>. It is currently unknown if or how many scientists received such an award after hitting their royalty caps.

But what happens to royalties after the caps are hit if no Presidential awards are given? The law <u>allows</u> NIH laboratories to give "incentives, from royalties, or other payments" to employees who are not inventors, but who "substantially increased the technical value of such inventions."

Afterwards, the labs have two years to use their funds, which they can use to reward employees further, or pay for professional development or other research. Royalties still left over after two fiscal years are turned over to the Treasury. We asked both NIH and Treasury whether any funds were voluntarily returned after the two-year period; neither agency has responded.

Likewise, 75% of royalties exceeding 5% of an agency's budget are also transferred to the Treasury. The NIAID's FY 2023 budget was over \$6.52 billion. Therefore 5% of that would be about \$328 million–just a little under the \$342 million in royalties to inventors passing through the NIAID during that year.

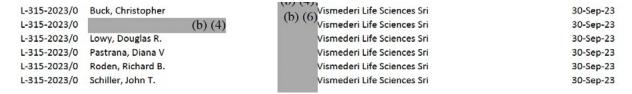
Despite years of headlines about royalty payments at the agency, NIH appears content to keep the complex impossibly opaque. We simply do not know enough about the flow of money from licensee to NIH.

How royalty funds are allocated among inventors, the lab, and the IC, and why "payments due to inventor by IC" and "inventor awards" are listed at amounts that would be well beyond the statutory \$150,000 cap are still a mystery. We reached out to NIH for clarity many times and have not heard back.

Because we do not know the answers to these questions, auditors have maintained that funds marked as "inventor awards" likely go to both scientists and the IC, as per the stated policy. We will continue to investigate this question until we receive confirmation with hard data.

REDACTED INVENTOR NAMES

OpenTheBooks.com auditors found 2,193 instances of inventor name redactions from FY 2010-2023. There are 248 licensees associated with redacted inventors.



Example of royalty payment data with redacted inventor name.

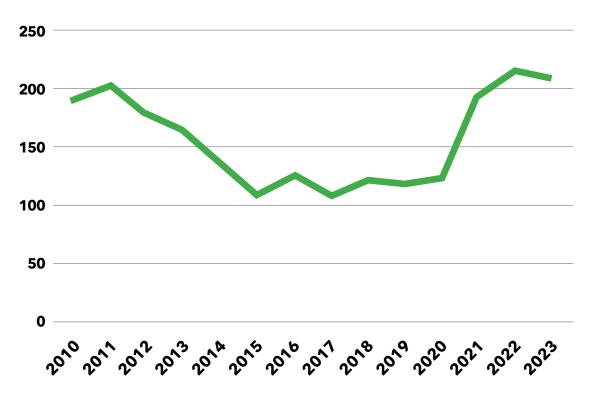
This example can be found here on page 218.

Redactions are under the (b)(4) FOIA exemption, which "protects from disclosure trade secrets and commercial or financial information that is privileged and confidential," according to HHS FOIA regulations. It is unclear why an inventor on an NIH license would be considered a trade secret.

Instances of redacted scientist names ranged from 100-200 per year between FY 2010-2023.

NUMBER OF PAYMENTS TO REDACTED SCIENTISTS

FY2010-2023

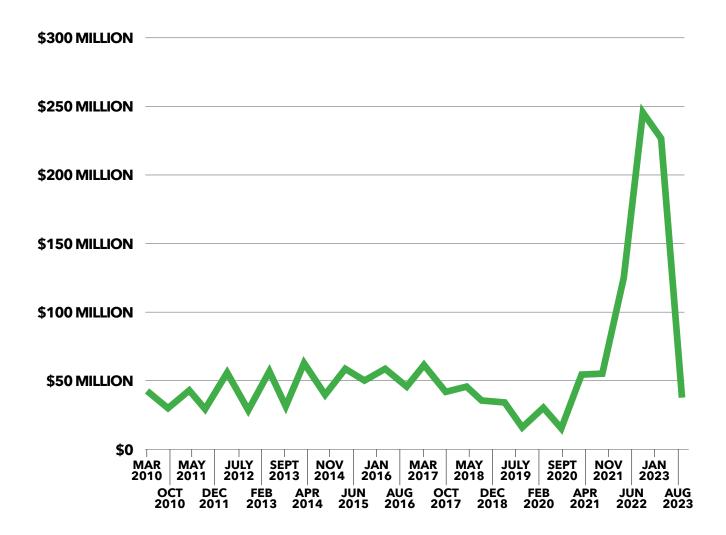


PAYMENTS TO INSTITUTES AND CENTERS

We do not know how much of the funds marked as "inventor awards" ended up in the coffers of an NIH institute or center. But we do know that the ICs are also paid directly by licensees as a part of the NIH royalty distribution system.

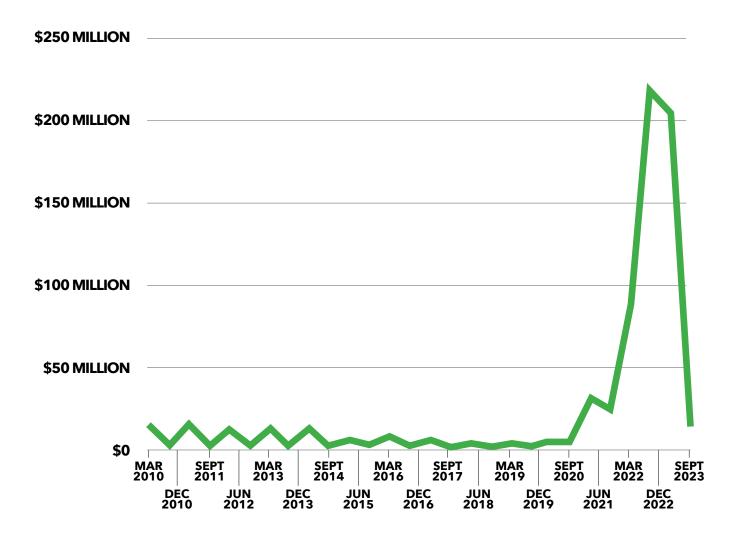
ICs received a total of \$1,649,534,342 from companies licensing their inventions from FY 2010-2023. Like their inventor counterparts, funding also spiked during the COVID era: \$633,124,700 was paid out to ICs in FY 2022 and 2023.

PAYMENTS TO NIH INSTITUTES AND CENTERS



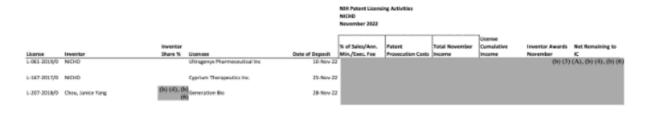
And yet again, the increase is almost entirely attributable to funds directed to NIAID, which collected about \$530 million in FY 2022 and 2023.

PAYMENTS TO NIAID



Institutes and Centers as Inventors

Along with the share due to them from the inventor awards, according to the data provided to OpenTheBooks by NIH, the Institutes and Centers also are getting paid as inventors. Auditors captured 2,450 instances of a center being paid directly by a licensee, under the category of "inventor."



Example of an NIHIC (in this case the National Institute of Child Health and Human Development, NICHD) receiving a payment from a licensee. This example can be found <u>here</u> on page 140.

It is unknown why an IC would be getting a payment from a licensee as an inventor. The documents produced by NIH reveal some related payment data, which does not necessarily increase clarity.

Some examples auditors found:

- An agency receiving funds under "payments due to inventors" (see here page 2, CDC is recorded with \$900)
- An agency with multiple recorded payments that equaled \$0 (see here pages 388-389, CIT has four recorded payments worth \$0)
- An agency receiving funds that all went to "net remaining to IC" (see here pages 426-427, NIAAA has three recorded payments worth \$61,375, which was also recorded as "patent prosecution fees")

TOP 5 ICs RECEIVING PAYMENTS	
National Cancer Institute	774
National Institute for Allergy and Infectious Diseases	361
Center for Disease Control	334
Clinical Center	199
National Heart Lung and Blood Institute	181

TOP 5 COMPANIES PAYING ROYALTIES DIRECTLY	TO ICs
ZeptoMetrix Corp.	57
Kite Pharma	53
Microbiologics, Inc.	52
NonoString Technologies, Inc.	46
Hope Pharmeceuticals	43

More data must be unredacted before we can understand why an IC would be recorded as an inventor, and what that means for payments to those ICs.

KEY FIGURES

The following are important facts and figures regarding royalty payments to the NIH during both the pandemic years and our entire timeline, from FY 2010-2023.

Pandemic royalty timeline: Fiscal Year 2022-23

- Number of payments to named inventors captured in FY 2022-23: 11,576
- Total number of named scientists: 1,416
- Number of payments to redacted inventors: 424
- Inventor Awards: \$724,595,856
- Payments direct to an NIH Institute or Center: \$633,124,700

TOP 10 PAYMENT RECIPIENTS (FY2	022-23)
Melinda G. Hollingshead	358
Kelly Dougherty	354
Carrie A. Bonomi	354
Suzanne D. Borgel	308
John D. Minna	203
Harvey I. Pass	201
Frederic J. Kaye	201
Bruce E. Johnson	201
Samir N. Khleif	201
Adi F. Gazdar	195



TOP 30 COMPANIES MAKING PAYMENTS (FY202	2-23)
Millipore Sigma	305
BioLegend	271
GlaxoSmithKline	209
Merck, Sharp & Dohme	178
Icosavax	136
BD Biosciences, PharMingen	123
lovance Biotherapeutics. Inc.	121
Life Technologies Corporation	116
Neogene Therapeutics, Inc.	100
Vanderbilt University	96
KeraFAST	94
Daiichi Sankyo	94
Meso Scale Diagnostics, LLC	92
Crown Bioscience Inc.	90
Janssen	86
InBios International, Inc.	86
Changchun BCHT Biotechnology Co.	86
BD Biosciences	78
Becton Dickinson	78
Abcam plc	78
Ceva Sante Animale S.A.	72
Regeneron Pharmaceuticals. Inc.	71
Massachusetts General Hospital	70
Brigham and Women's Hospital	70
Bio X Cell, LLC	69
BioNTech	69
BlueWillow Biologics	69
Santa Cruz Biotechnology, Inc.	68
Ventana Medical Systems Inc	68
AbbVie	66

Entire timeline: Fiscal Year 2010-2023

- Total inventor awards: \$1,036,176,058
- Total payments direct to an NIH Institute or Center: \$1,649,534,342
- Total number of all payments to named scientists: 68,295
- Total number of named scientists: 2,613
- Number of payments to redacted inventors: 1,769

TOP TEN PAYMENT RECIPIENTS	
Melinda G. Hollingshead	1,013
Kelly Dougherty	973
Carrie A. Bonomi	973
Suzanne D. Borgel	817
Ira H. Pastan	643
John D. Minna	590
Frederic J. Kaye	577
Bruce E. Johnson	577
Adi F. Gazdar	572
Samir N. Khleif	571

TOP 30 COMPANIES MAKING PAYMENTS TO NAMED SCIENTISTS IN FY 2010-2023	
BioLegend	1,556
Merck, Sharp & Dohme	877
GlaxoSmithKline	799
Santa Cruz Biotechnology, Inc.	768
eBioscience, Inc.	760
Abbott	711
Millipore Corporation	683
EMD Millipore Corporation	683
Life Technologies Corporation	583
Millipore Sigma	570
PharMingen, Inc.	544
BD Biosciences, PharMingen	532
Chemicon International, Inc.	518
Medimmune, Inc.	507
Becton Dickinson	490
List Biological Laboratories, Inc.	451
Sanofi Pasteur	439
Genzyme Corp.	436
Trinity Biotech	425
Quest Diagnostics, Inc.	408
Institut Pasteur	402
BD Biosciences	398
Research and Diagnostic Systems	387
Monogram Biologics	386
Genentech	383
Bristol-Myers Squibb Company	370
Icosavax	369
Upstate Biotechnology, Incorporated	348
Ventana Medical Systems Inc	345
KeraFAST	337



CONFIDENTIAL TOP ROYALTY RECIPIENT MELINDA HOLLINGSHEAD

The top recipient of NIH royalty payments is Melinda Hollingshead, former <u>Chief</u> of the Biological Testing Branch at the National Cancer Institute. Hollingshead has received 1,013 payments, outstripping the number two recipient, her co-inventor Carrie Bonomi with 973 payments. <u>Hollingshead retired</u> earlier this year.

Before retiring earlier this year, Hollingshead worked at the National Cancer Institute campus in Frederick, Maryland—the same location as Fort Detrick, a U.S. Army installation involved in the U.S. biological defense program. When OpenTheBooks.com requested her financial statements, which are open record for NIH employees, we were told that her filings were "confidential."

We also asked for the financial statements of Carrie Bonomi (973 payments), Kelly Dougherty (973), and Suzanne Borgel (817). None were available, because these top NIH royalty recipients don't work at NIH–all three work at Leidos Biomedical, a contractor also based in Frederick, Maryland. All were frequent collaborators with Melinda Hollingshead.

We received your OGE 201 request and my apologies for the delayed response. I have attached the requested reports for Christine Grady and Richard Hodes. However, the files for the following people are not included as stated below.

- . Bonomi, Carrie Not a filer
- Borgel, Suzanne Not a filer
- . Dougherty, Kelly Not a filer
- · Hollingshead, Melinda Confidential Filer

Thank you for your time.

Message from NIH regarding the Bonomi, Borgel, Dougherty, and Hollingshead financial statements.

One of Hollingshead's primary responsibilities was overseeing the <u>Patient-Derived Models</u> <u>Repository</u> at the National Cancer Institute. This project develops biological models from samples supplied through NCI-supported clinical trials.

A model could include, for example, a Patient-Derived Xenograft, which is when cancerous cells from a human patient are grafted onto a mouse. The mouse then develops that cancer in a comparable way to the human patient and can be studied. According to the NCI <u>website</u>, "these models will serve as a resource for public-private partnerships and for academic drug discovery efforts."

Hollingshead's 2023 NIH salary was \$184,250.

The proximity of Hollingshead and her co-inventors with a major U.S. bioweapons lab seems to indicate a melding of the military industrial complex with the American healthcare industry, a trend we see repeated in former NIAID director Anthony Fauci's funding of gain-of-function research at the Wuhan Institute of Virology.

THE TOP FIFTEEN COMPANIES PAYING ROYA	LTIES
TO MELINDA HOLLINGSHEAD	
Genentech	17
Tocris Bioscience	16
Glenmark	14
Codiak Biosciences	13
Alkermes	13
Merck, Sharp & Dohme	12
Aragen Bioscience, Inc.	11
Yuhan R&D Institute	11
Dicerna Pharmaceuticals, Inc	11
AstraZeneca	11
Champions Oncology, Inc.	11
Kineta, Inc.	10
Pfizer	10
Pionyr Immunotherapeutics, Inc.	10
Revolution Medicines, Inc.	10

Other Notable Scientists

Top royalty recipients still at the NIH occupy high-level positions at the agency, weighing in on decisions like grant dispersal and the direction of laboratory research. Some, and their number of royalty payments, include:

- <u>Jeffrey Schlom</u>, National Cancer Institute, Co-Director of the Center for Immuno-Oncology, 485
- Steven Rosenberg, National Cancer Institute, Chief of the Surgery Branch, 348
- <u>Ethan Shevach</u>, National Institute of Allergy and Infectious Diseases, Chief of Cellular Immunology Section, 342
- Bernard Moss, National Institute of Allergy and Infectious Diseases, Chief of Genetic Engineering Section, 322. The House Energy and Commerce Committee recently released a scathing report on Moss' lab after Moss gave an interview saying he planned "to insert segments of a lethal strain of MPXV (formerly known as "monkeypox") into a more a transmissible strain of the virus."
- Frank Gonzalez, National Cancer Institute, Head, Nucleic Acids Section, 268

DOUGLAS LOWY

Some top receivers direct entire institutes at NIH, like Douglas Lowy. Lowy is the current Principal Deputy Director, and three-time NCI Acting Director, of the National Cancer Institute. He has received 207 royalty payments from FY 2010-2023.

Top royalty payee Douglas Lowy served as acting director of NIH's National Cancer Institute from May-September 2022, a position he held twice previously from April 2015 to October 2017 and April 2019 to October 2019.

His usual title is NCI principal deputy director, which he's held since July 2010. In the capacity, according to the NCI website, he helped "lead NCI's key scientific initiatives," among other things.

While serving as NCI's deputy director, he also held the title of chief of the Laboratory of Cellular Oncology in NCI's Center for Cancer Research. He has directed a research laboratory at NCI since 1975.

In 2022 Lowy's NIH salary was \$359,622.

His work as both a director and a scientist call into question Lawrence Tabak's statement that those making recommendations to agency leadership and the scientists themselves are separated.

Lowy is still very active in scientific research. He has been listed as an author on numerous recent scientific papers with NIH affiliation, including several published in 2024.

Some of these recent studies are related to human papillomavirus (HPV) vaccines, an area in which Lowy is an expert and holds relevant NIH patents.

Lowy's patents were licensed to pharmaceutical corporations Merck and GlaxoSmithKline. The companies then <u>marketed</u> inventions that used these licenses as Gardasil, Gardasil 9, and Cervarix, respectively. Those patent licenses have since expired.

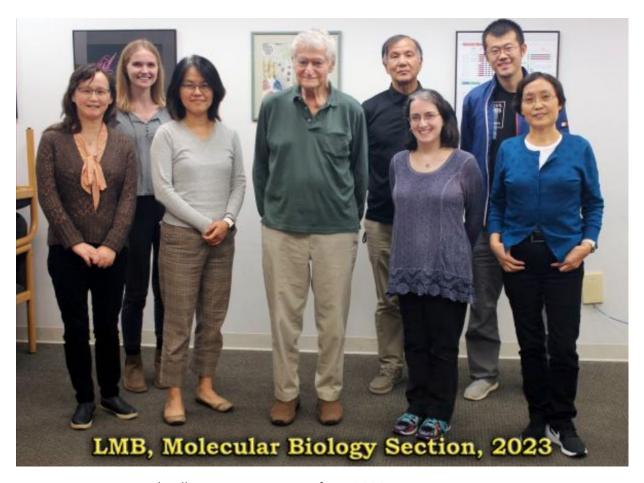
His co-inventor John Schiller is also a top NIH royalty receiver (and NCI's Deputy Chief of the Laboratory of Cellular Oncology), with 245 payments. 16 payments were from GlaxoSmithKline to each of the men and 33 went from Merck to Lowy and 32 to Schiller.

Until 2022 both Schiller and Lowy put conflict of interest statements on their scientific research involving HPV vaccines, but now those conflict of interest statements say they no longer receive patent payments from Merck and GlaxoSmithKline.

Gardasil and Gardasil 9 generated \$1.5 billion in sales for Merck in 2021.

Other top Lowy patent licensees are: MedImmune, 24 payments; Cytos Biotechnology, 15 payments; Indian Immunologicals, 12 payments. Other notable licensees are the Chinese state-run Wuhan Institute of Biological Products, and Shanghai Institute of Biological Products, which each gave one patent payment to Lowy.

Lowy was <u>mentored</u> by Ira Pastan, another top royalty recipient (643 payments), who at over 90 years old is still <u>working</u> at NIH as a "distinguished investigator." 2023 pay: \$309,452.



Ira Pastan, center, and colleagues in a picture from 2023.

JOHN MASCOLA AND BARNEY GRAHAM OF THE VACCINE RESEARCH CENTER

John Mascola joined the NIH in 2000, and since 2013 directed the Vaccine Research Center, an office under the NIAID. Mascola was charged with leading Operation Warp Speed, which worked on developing a COVID-19 vaccine. Barney Graham was the deputy director of the VRC, also joining the office in 2000.

Mascola and Graham were widely <u>credited</u> for leading collaboration with Moderna to design the mRNA vaccine that would eventually be approved through FDA's Emergency Use Authorization and forced on many Americans at the penalty of their jobs and access to social institutions. The collaboration went forward with then-NIAID director Anthony Fauci's <u>blessing</u>.

The pair also spearheaded work on COVID monoclonal antibodies with pharma company AbCellera.

Both men had patents licensed to Moderna and AbCellera in the years before and during the COVID pandemic response.

Moderna gave Mascola and Graham eight patent payments each from 2018-2021. The two are co-inventors and were listed on the same patent licenses, along with several other NIH scientists.

Tensions between Moderna and the NIH were revealed in a rare public patent dispute, where the agency accused the company of wrongfully leaving NIH scientists—including Graham and Mascola—off a lucrative patent related to COVID-19.

Moderna eventually settled the dispute, adding the NIH scientists to the patent and paying out \$400 million to the NIH, also <u>promising</u> payments to the agency in the low single digits of future vaccine sales. It is unclear how much of those payments went to NIH scientists, and if that amount is reflected in the NIH data provided to OpenTheBooks.

The federal government granted Moderna nearly \$10 billion from 2020-2022 to develop a COVID-19 vaccine and to deliver doses. From 2013-2017 the Department of Defense gave Moderna \$60 million for mRNA technology.

AbCellera sent eleven payments to Mascola and nine to Graham from 2020-2023. The monoclonal antibody treatment developed from collaboration between NIH and AbCellera was authorized under EUA in February 2021. AbCellera <u>began</u> working with NIAID in 2018 on an influenza project but pivoted to COVID-19 in 2020.

According to pharma watchdog KEI, the federal government played an essential role in AbCellera's technological developments. In 2018 the Defense Advanced Research Projects Agency (DARPA) awarded the company up to \$30 million to create a "rapid response antibodies discovery platform."

In 2022 the AbCellera was given a contract worth \$688,000 for "transgenic mice for human genome antibodies" by the Centers for Disease Control and Prevention.

While it was publicly known the people in charge of leading vaccine research—principally Mascola and Graham—were on some patents used by the pharma companies they worked with directly, it was not a point of emphasis when NIAID leadership was pushing these inventions on the public.

Graham and Mascola have since left the agency; Graham retired in 2021, later taking a university position, and Mascola joined pharmaceutical company ModeX in 2022–a company with other curious connections to the NIH, expanded on in the next section of this report.

THE COMPANIES PAYING ROYALTIES TO JOHN MASCOLA (2013-2023)	
AbCellera Biologies Inc.	11
ADMA Biologics, Inc.	1
Beijing Advaccine Biotechnology Co., Ltd	1
Changchun BCHT Biotechnology Co.	1
China National Biotec Group Company Limited	3
DelSiTech Ltd	1
Emergent Product Development	9
GlaxoSmithKline	11
Icosavax	10
Immunosciences, Inc.	2
Medigen Vaccine Biologics Corp	7
Merck, Sharp & Dohme	5
ModernaTx, Inc.	8
Novartis	4
Sanofi Pasteur	3
Spybiotech Limited	2
TaiMed Biologics USA, Inc	4
Themis Bioscience	1
Vaxess Technologies	1
ViiV Healthcare Company	6
Vir Biotechnology, Inc.	1
GRAND TOTAL	92

THE COMPANIES PAYING ROYALTIES TO BARNEY GRAHAM (2013-2023)

AbCellera Biologics Inc	9
ACROBiosystems Inc.	4
Adimmune Corporation	1
ADMA Biologics, Inc.	4
Beijing Advaccine Biotechnology Co., Ltd	1
BioNTech	2
BlueWillow Biologics	2
Calder Biosciences Inc	1
China National Biotec Group Company Limited	1
CureVac	4
Dynavax Technologies, Inc.	1
Emergent Product Development	7
ExcellGene SA	3
GeoVax, Inc.	2
GlaxoSmithKline	5
Icosavax	7
Medicago Inc.	1
Medigen Vaccine Biologics Corp	6
Medimmune, Inc.	5
Merck Sharp	5
Merck, Sharp & Dohme	8

Meso Scale Diagnostics, LLC	3
ModernaTX, Inc.	9
N4 Pharma UK Limited	1
Noachis Terra Inc	1
Novartis	10
Novavax, Inc.	1
Oncosec Medical Incorporated	1
OP Biotechnologies, Inc.	1
Ridgeback Biotherapeutics	5
RNAceuticals, Inc.	1
RSV Corporation	5
Sanofi Pasteur	10
Spybiotech Limited	2
The Binding Site Group Ltd.	2
Themis Bioscience	1
ThermoFisher Scientific	4
Toyama Chemical Co., Ltd.	3
Universiteit Ghent VIB vzw	1
University of Washington	1
Variations Biotechnologies Inc	1
Vaxess Technologies	1
VAXXAS	1
GRAND TOTAL	144

ModeX

ModeX began as a project called Breakthrough Laboratories within pharmaceutical company Sanofi. The project was founded in 2013 by 2002-2008 NIH director Elias Zerhouni and Gary Nabel, the founding director of the Vaccine Research Center at NIH.

Zerhouni joined Sanofi in 2011 and Nabel joined in 2013. While Zerhouni has no recorded royalty payments from 2010-2023, Nabel has 100, including three from Sanofi from 2013-2015.

The two founded ModeX in 2020, along with colleagues Zhi-yong Yang (Director of Vaccine Research Center's Vector Core laboratory from 2005 to 2013, and director of Breakthrough Laboratories from 2013), Chih-Jen Wei (VRC alumni, joining Breakthrough Labs in 2013), Elizabeth Nabel (Gary Nabel's wife and director of NIH's Heart, Lung, and Blood Institute from 2005-2009), and Ronnie Wei (no previous NIH affiliation).

In 2022 ModeX is acquired by OPKO Health Company for \$300 million, and brings on John Mascola as Chief Scientific Officer directly from the VRC at NIH.

In 2023, Modex <u>received a \$168M grant</u> from Department of Health & Human Services, including \$59M for developing an antibody with "broad neutralizing activity against known variants" of Covid-19. It's "one of the first companies to receive funding for a next-gen COVID program."

OTHER MODERNA PAYMENT RECIPIENTS

Moderna was started in 2010 explicitly to develop medicines using mRNA technologies (as their website <u>says</u>, their name combines "modified" "RNA" and "modern").

Moderna received nearly \$10 billion in grants and contracts from 2013-2021. About \$60 million from the Department of Defense from 2013-2017, but the vast majority came in 2020, with \$8.2 billion from the DoD. Another \$1.7 billion came from the NIH, also during 2020.

44 scientists received between one and nine royalty payments from Moderna, all from 2016-2023. Those include John Mascola, Barney Graham (with eight and nine payments, respectively) and top-recipients Melinda Hollingshead, Suzanne Borgel, Carrie Bonomi, and Kelly Dougherty (each with six payments). Moderna also issued 9 payments to scientists with redacted names from 2021-2023.



Example of payments from Moderna to scientists with redacted names. This example can be found <u>here</u> on page 123.

Other notable scientists, their relationship to NIH and their current positions, include:

Gwo-Yu Chuang, Sanofi, Senior Director

Co-head of the structural bioinformatics Core section at the Vaccine Research Center at NIH before leaving to Moderna in May 2021, where he was an Associate Scientific Director. Chuang joined Sanofi as in March 2023.

Total royalty payments: 116

Total Moderna royalty payments: 7

Wing-Pui Kong, NIAID Vaccine Research Center, Chief of Virology Core

Total royalty payments: 78

Total Moderna royalty payments: 8

Man Chen, NIAID, Vaccine Research Center, staff scientist

Total royalty payments: 116

Total Moderna royalty payments: 7

Ivelin Georgiev, Vanderbilt University Professor and Associate Director; NIAID Vaccine

Research Center until 2015 Total royalty payments: 114

Total Moderna royalty payments: 7

<u>Jason Gorman</u>, Postdoctoral Research Fellow at NIAID until 2017, joined biotech company Medical Science & Computing from 2017-2022, now a Principal Investigator at FDA since January 2023

Total royalty payments: 106

Total Moderna royalty payments: 7

Mansaru Kanekiyo, NIAID Vaccine Research Center, Chief of Molecular Immunoengineering

Section

Total royalty payments: 127

Total Moderna royalty payments: 7

<u>Peter Kwong</u>, former Vaccine Research Center, Chief, Structural Biology Section, in 2023 joined the Aaron Diamond AIDS Research Center at Columbia University

Total royalty payments: 164

Total Moderna royalty payments: 7

Jason McLellan, Postdoctoral Research Fellow at NIH, later joining University of Texas at

Austin in 2018

Total royalty payments: 128

Total Moderna royalty payments: 7

Kizzmekia Corbett, research fellow at the NIAID Vaccine Research Center from 2014-2021,

currently assistant professor at the Harvard T.H. Chan School for Public Health

Total royalty payments: 57

Total Moderna royalty payments: 3

THE FIGHT CONTINUES: LEGISLATION AND LITIGATION

OpenTheBooks auditors have utilized the highly redacted data grudgingly produced by the NIH to the utmost extent in producing this report. But there is so much more to learn about the royalty payment system at NIH. We have made many requests for comment to NIH over the years about various aspects of their royalty system and have never received a response.

This should come as no surprise, the past few months have revealed scandals in which NIH employees purposefully and illegally <u>collude</u> to evade Freedom of Information Act requests, and agency leaders craft statements to Congress intended to mislead and avoid answering questions.



Email from former NIH
Associate Director for
Legislative Policy and
Analyses Adrienne Hallett
to Francis Collins discussing
how to create a statement for
Congress that doesn't answer
any questions.

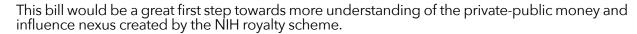
First <u>reported</u> by journalist Jimmy Tobias.

It seems as though the only way we can get more answers is through litigation. OpenTheBooks and our partner Judicial Watch are not giving up our fight for royalty transparency through our ongoing lawsuit.

In the meantime, we are grateful for leaders in Congress such as Senator Rand Paul (R-KY), who has repeatedly confronted NIH leaders like former National Institute of Allergies and Infectious Diseases director Anthony Fauci, and current NIH director Lawrence Tabak, about the potential conflict of interest these payments represent.

Bolstering these efforts, Senator Paul also introduced the <u>Royalty Transparency Act</u>, which <u>passed</u> unanimously out of the Senate Homeland Security and Government Affairs Committee in early March of this year. The legislation would:

- Require Executive Branch employees subject to the public financial disclosure reporting requirements of the Ethics in Government Act of 1978 to disclose royalty payments for inventions developed during their employment with the federal government.
- Require agencies to publicly post financial disclosure reports on their websites.
- Require applicants for federal grants and contracts to disclose royalty payments to the government for the 10-year period preceding the grant or contract.



Royalty payments have intermittently captured public attention, first during the Clinton administration and then again after an Associated Press investigation in 2015. But following the COVID crisis, never before has the spotlight burned brighter on NIH and the wider public health apparatus. After years of courtroom fights, and aggressive questions from Congress, we are closer than ever to gaining a clearer understanding of the \$30 billion nexus between government, private industry and the wider medical research community.

DATA



- Chinese Royalty Payee Data
- Inventor and Institute and Center Payments from NIH Royalty Production
- Redacted Names from Royalty Payments
- NIH Data on Companies, Licenses, Scientists

CONGRESSIONAL HEARINGS AND RELATED ARTICLES CITING OUR NIH ROYALTIES RESEARCH

Senate Committee on Health, Education, Labor & Pensions

An Update on the Ongoing Federal Response to COVID-19: Current Status and Future Planning | June 16, 2022

The National Desk

'It's all redacted': Rand Paul and Fauci clash over NIH royalty payments | June 17, 2022

Senate Committee on Health, Education, Labor & Pensions

Stopping the Spread of Monkeypox: Examining the Federal Response | September 14, 2022

The National Desk

Rand Paul and Fauci clash over NIH royalties: 'We are going to learn about it' | June 17, 2022

House Committee on Oversight and Accountability

A Hearing with Dr. Anthony Fauci | June 3, 2024

The National Desk | Dr. Fauci questioned on millions of dollars poured into NIH | June 5, 2024

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DUPLICATION NATION



SCHOOLS FOR RADICALS



THE COVID AID WASTE COMPENDIUM



U.S. ENVIRONMENTAL PROTECTION AGENCY

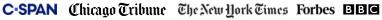


EARMARKS: RETURN OF THE SWAMP CREATURES



IMPROPER PAYMENTS

AS FEATURED IN

















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We are the world's largest private database of public-sector expenditures. We captured all disclosed federal spending since 2001; 50 of 50 state checkbooks; and 25 million public employee salary and pension records from 50,000 public bodies across America.

OpenTheBooks closed 2023 with the largest audience we've ever seen, the most investigations we've ever published, and more media interviews than ever before.

IN 2021-2022...

Identified Dr. Anthony Fauci as the top paid federal employee, quantified the staggering cost of U.S. military gear left behind in Afghanistan, cracked open California's state checkbook and Big Pharma's \$1.4 billion in third-party paid royalties – leading to four televised congressional hearings in 2022.

IN 2020...

The President's Budget To Congress FY2021 included a first-ever chapter, "Stopping Wasteful and Unnecessary Spending," which was inspired by our oversight report, Where's The Pork? A Study of \$600 Billion In Federal Grants. Included in the President's Budget was our report, Use-It-Or-Lose-It - How The Federal Government Spent \$97 Billion In September 2018.

IN 2019...

Our Top 82 U.S. Non-Profit Hospitals: Quantifying Government Payments & Financial Assets report launched on FOX News' Tucker Carlson Tonight and USA TODAY. This report backstopped President Trump's two executive orders on healthcare price transparency by showing that wealthy charitable non-profit healthcare providers and their CEO's were making big profits. Colorado Governor Jared Polis (D) also cited this data in his state of the state address while arguing for price reforms.

IN 2018...

Open The Books' Mapping The Swamp, A Study Of The Administrative State Media report launched on FOX News' The Ingraham Angle and directly led to Representative Judy Hice's (R-GA) legislation on pension and bonus transparency (H.R. 2612). Furthermore, we briefed the Executive Office of the President, Office of Management & Budget regarding our policy ideas to drain the swamp.

IN 2017...

The Tax Cuts And Jobs Act 2017, passed into law and included a claw-back tax on lvy League-style, excessive university endowments. The Boston Globe cited our lyy League, Inc. oversight report as a catalyst for the legislative provision. Coverage included The Wall Street Journal and eight segments on Fox News.

IN 2016...

We exposed the \$20 million luxury-art procurement program at the Department of Veterans Affairs, which forced a public apology from the V.A. Secretary and the adoption of new rules to stop the abuse. Coverage included Good Morning America and ABC World News Tonight.

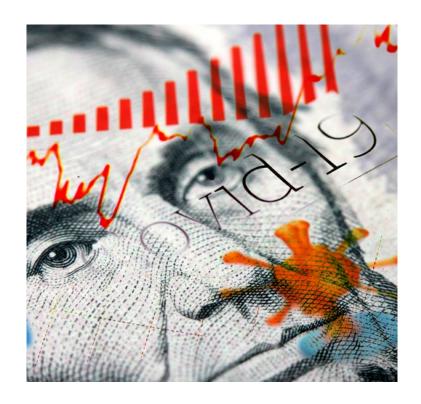
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