

## Gov/Big Pharma Conflict

The vaccine is called mRNA-1273 and was developed by NIAID scientists and their collaborators at the biotechnology company Moderna, Inc., based in Cambridge, Massachusetts. The Coalition for Epidemic Preparedness Innovations (CEPI) supported the manufacturing of the vaccine candidate for the Phase 1 clinical trial.

“Finding a safe and effective vaccine to prevent infection with SARS-CoV-2 is an urgent public health priority,” said NIAID Director Anthony S. Fauci, M.D. “This Phase 1 study, launched in record speed, is an important first step toward achieving that goal.”<sup>1</sup>

To receive a share of the profit from the sale of mRNA-1273, the inventors of this product within NIAID would submit an Employee Invention Report to the NIH Office of Technology transfer.<sup>2</sup> Each inventor stands to receive a personal payment of up to \$150k annually from the sales of mRNA-1273.<sup>3</sup> In addition, NIAID stands to earn millions of dollars in revenue from the sale of mRNA-1273.<sup>4</sup>

Moderna will pay license fee to NIAID to use its patents related to mRNA-1273 and a portion of those fees are then paid directly to the inventors within NIAID who developed those patents.<sup>5</sup>

NIH has produced reports which confirm that these individuals are listed as inventors.<sup>6</sup>

- Barney Graham, Deputy Director, NIAID Vaccine Research Center
- Kizzmekia Shanta Corbett, Scientific Lead, NIAID’s Coronavirus Vaccine Program
- Michael Gordon Joyce, NIAID
- Hadi Yassine, NIAID
- Masaru Kanekiyo, NIAID
- Olubukola Abiona, NIAID

HHS awarded \$483 million to accelerate development of mRNA-1273.<sup>7</sup> The US Government has reached a 1.525 billion deal to purchase 100 million doses of mRNA-1273.<sup>8</sup>

In 2013, the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program awarded grant funding to Moderna Therapeutics for the development of a new type of vaccine based on messenger RNA. The initial DARPA grant was W911NF-13-1-0417. ***The company used that technology to develop its COVID-19 vaccine, currently undergoing Phase I clinical trials in conjunction with NIH.***<sup>9</sup>

## FDA Vaccines and Related Biological Products Advisory Committee Roster

Content current as of 4/9/21<sup>10</sup>

Any consideration of financial conflict of interest at the Vaccines and Related Biological Products Advisory Committee must be set against the historical backdrop of the profound financial conflicts of interest seen in the during the H1N1 pandemic ten years ago. At that time, five of the sixteen experts were found to have ties to the pharmaceutical industry. There were “calls from the British Medical Journal, to release the names of committee members and their conflicts of interest, in the interest of transparency and to monitor any possible commercial influence.” That earlier “pandemic has proved profit-making for the industry, with one estimate (by JP Morgan) putting 2009 vaccine profits alone at \$7-10 billion.”<sup>11</sup>

There appear to be significant conflicts of interest today especially among committee leaders. The items reported in this memo are the results of a quick preliminary check on conflicts and are not a complete representation. Plaintiffs intend to conduct a more thorough investigation before trial.

### Chair

#### [Hana El Sahly, M.D.](#)

Expertise: Vaccines, Infectious Diseases

Term: 06/21/2019-01/31/2022

Professor

Department of Molecular Virology and Microbiology

Department of Medicine

Section of Infectious Diseases

Baylor College of Medicine

Houston, TX 77030

[hanae@bcm.edu](mailto:hanae@bcm.edu)

- Top FDA vaccine adviser recuses herself over tie to Moderna.<sup>12</sup>
- Associate Professor Baylor. She currently serves as the Principal Investigator of the Vaccine and Treatment Evaluation Unit at Baylor College of Medicine.<sup>13</sup>
- Federal database shows since 2013 \$693,001.78 in general payments and \$5,315,014.60 in research payments made to “Chi St. Lukes Health Baylor Med Ctr” – 6720 Bertner Ave, Houston, TX from various companies.<sup>14</sup>
- Dr. El Sahly was appointed as one of three lead investigators for Moderna’s 30,000-person trial in July. Reuters reported that Dr. El Sahly had to recuse herself from an important committee meeting on Oct. 22, 2020.<sup>15, 16</sup> There are multiple citations of this. e.g. 17, 18, 19 & 20 Ironically, there is no compensation of Dr. El Sahly reported on the [openpaymentsdata.cms.gov](http://openpaymentsdata.cms.gov) website. This raises serious questions as to the completeness of the conflict

data reported on that site. The University of Florida Conflicts of Interest Program and the Project on Government Oversight reported conflicts of interest of Drs. El Sahly, Monto, and Chatterjee.<sup>21, 22</sup>

**Paula Annunziato, M.D**

Expertise: Industry Representative

Term: 02/01/2020-01/31/2024

Vice President and Therapeutic Area Head

Vaccines Clinical Research

Merck

North Wales, PA 19454

- Past (or current?) involvement in supervising Moderna's Covid-19 vaccine clinical trial.<sup>23</sup>
- Not listed in the openpaymentsdata.cms.gov website.

**Acting Chair**

**Arnold Monto, M.D.**

Thomas Francis Jr. Collegiate Professor of Public Health

Professor of Epidemiology

Department of Epidemiology University of Michigan

School of Public Health

Ann Arbor, MI 48109

- Acting chairman of the committee, Dr. Arnold Monto received \$54,114 from 2013 through 2019 from vaccine contenders Sanofi, GlaxoSmithKline, Pfizer, and Shionogi, according to the database. He also received \$10,657 from Novartis, which has a deal to manufacture a coronavirus vaccine.<sup>24</sup>
- Dr. Monto received a total of \$194,254 from pharmaceutical companies.<sup>25</sup> The largest contributor was Seqirus, a company developing COVID vaccine in Australia.<sup>26</sup> The University of Florida Conflicts of Interest Program and the Project on Government Oversight reported conflicts of interest of Drs. El Sahly, Monto, and Chatterjee.<sup>27, 28</sup>

**Archana Chatterjee, M.D., Ph.D.**

Expertise: Pediatrics, Infectious Diseases

Term: 06/21/2019-01/31/2023

Dean Chicago Medical School

Vice President for Medical Affairs

Rosalind Franklin University of Medicine and Science

North Chicago, IL 60064

- A federal database shows that, in 2019, advisory committee member Dr. Archana Chatterjee, for instance, received \$23,904 from Pfizer (including Pfizer International LLC), \$11,738 from Merck, and \$11,480 from Sanofi, each of which is in the race for a coronavirus vaccine. Since 2013, she has received more than \$200,000 in consulting fees, travel and lodging, and other payments from those companies and others working on coronavirus vaccines, according to the database.<sup>29</sup>
- She is a professor of epidemiology at the University of Michigan, which has announced that it is partnering with pharmaceutical company, AstraZeneca on a clinical trial of a potential Covid-19 vaccine.<sup>30</sup>
- General payments to Dr Chaterjee total \$245,810. Associated research funding totals \$142,344. Largest funders include: Pfizer Inc., Merck Sharp & Dohme Corporation, Seqirus USA Inc., and AstraZeneca Pharmaceuticals.<sup>31</sup> The University of Florida Conflicts of Interest Program and the Project on Government Oversight reported conflicts of interest of Drs. El Sahly, Monto, and Chaterjee.<sup>32, 33</sup>

**CAPT Amanda Cohn, M.D.**

Expertise: Pediatrics, Vaccines  
 Term: 02/01/2020-01/31/2024  
 Chief Medical Officer  
 National Center for Immunizations and Respiratory Diseases  
 Centers for Disease Control and Prevention  
 Atlanta, GA 30333  
 Telephone: (404) 639-6039  
 E-mail: [acohn@cdc.gov](mailto:acohn@cdc.gov)

**Hayley Gans, M.D.**

Expertise: Pediatrics, Infectious Diseases  
 Term: 06/21/2019-01/31/2023  
 Professor of Pediatrics  
 Department of Pediatrics  
 Stanford University Medical Center  
 Stanford, CA 94305

**Holly Janes, Ph.D.**

Expertise: Biostatistics  
 Term: 02/01/2020-01/31/2023  
 Associate Member  
 Fred Hutchinson Cancer Research Center  
 Vaccine and Infectious Disease Division  
 Division of Public Health Sciences  
 Seattle, WA 98109

Phone: 206.667.6353  
Email: [hjanes@fredhutch.org](mailto:hjanes@fredhutch.org)  
Fax: 206.667.4378

**Michael Kurilla, M.D., Ph.D.**

Expertise: Infectious Diseases, Pathology  
Term: 08/06/2018-01/31/2022  
Director, Division of Clinical Innovation  
National Center for Advancing Translation Sciences  
National Institutes of Health  
Bethesda, MD 20852  
[Michael.kurilla@nih.gov](mailto:Michael.kurilla@nih.gov)

**Myron Levine, M.D., D.T.P.H., F.A.A.P**

Expertise: Infectious Diseases  
Term: 05/09/2018-01/31/2022  
Simon & Bessie Grollman Distinguished Professor  
Associate Dean for Global Health  
Vaccinology and Infectious Diseases  
Center for Vaccine Development  
University of Maryland School of Medicine  
Baltimore, MD 21201

- Dr. Myron Levine is associate dean for global health, vaccinology, and infectious diseases at the University of Maryland School of Medicine. The school is participating in a clinical trial of a COVID-19 vaccine being developed by Moderna and the National Institute of Allergy and Infectious Diseases.<sup>34</sup>
- Since 2013, for research in which Levine played a principal role, GlaxoSmithKline has paid the University of Maryland Baltimore Foundation Inc. and another institution more than \$2.3 million.<sup>35</sup>
- Dr. Levine received general payments of \$41,635 and associated research funding of \$2,314,178. Dr. Levin's 2019 funding was about six times the mean of similar physicians.<sup>36</sup> His largest source of funding was Sanofi Pasteur who is developing a COVID vaccine as above.<sup>37</sup>
- UM School of Medicine's Myron M. Levine, MD, DTPH, to Receive Prestigious Lifetime Award for Five Decades of Pioneering Vaccine Research<sup>38</sup>

- Was on a WHO sponsored advisory group that considered feasibility of doing Covid-19 challenge studies in young, healthy volunteers. No conflict of interest declared. Also on the panel was Sheng-Li Shi from WIV.<sup>39</sup>

### **H. Cody Meissner, M.D. (aka Herman Meissner)**

Expertise: Infectious Diseases  
 Term: 08/06/2018-01/31/2022  
 Professor of Pediatrics  
 Tufts University School of Medicine  
 Director, Pediatric Infectious Disease  
 Tufts Medical Center  
 Boston, MA 02111

- Tufts Children’s Hospital - Division of Pediatric Infectious Disease. Head of all clinical trials for all of Tufts Children’s Hospital.<sup>40</sup>
- Since 2013, Tufts University has been paid general payments of \$13,241,677.43 by companies including Pfizer, Boston Scientific, Gyrus Acmi, Inc., Janssen Scientific, Biogen, Inc., Bayer Healthcare, Sanofi-Aventis, Genentech, Otsuka Pharmaceutical, Amgen, Inc.<sup>41</sup>
- Since 2013, Tufts University has been paid research payments of \$34,183,399.06 by companies including Pfizer, Inc., Merck Sharp & Doh, Shire North America, Abiomed, Gilead Sciences, Inc.)<sup>42</sup>

### **Paul Offit, M.D.**

Expertise: Infectious Diseases  
 Term: 02/01/2018-01/31/2022  
 Professor of Pediatrics  
 Division of Infectious Diseases  
 Abramson Research Building  
 The Children’s Hospital of Philadelphia  
 Philadelphia, PA 19104

- Director of the Vaccine Education Center and an attending physician in the Division of Infectious Diseases at Children's Hospital of Philadelphia.<sup>43</sup>
- Since 2013, The Childrens Hospital of Philadelphia has received general payments of \$4,559,116.78 and research payments of \$32,013,340.94 from companies including Spark Therapeutics, United Therapeutics, Novartis Pharmaceuticals, Amgen, Inc., Pfizer, Inc.<sup>44</sup>
- *Vaccine Safety: Myths and Misinformation*. No Conflict of Interest Declared.<sup>45</sup>
- *The science of vaccine safety: Summary of meeting at Wellcome Trust*, Conflict of interest statement: Declaration of Competing Interest The authors declare that they have no known competing financial interests or personal

relationships that could have appeared to influence the work reported in this paper.<sup>46</sup>

**Steven Pergam, M.D.**

Expertise: Infectious Diseases

Term: 02/01/2020-01/31/2024

Medical Director

Infection Prevention

Seattle Cancer Care Alliance

Seattle, WA 98109

Phone: 206.667.7126

Email: [spergam@fredhutch.org](mailto:spergam@fredhutch.org)

- Associate Professor, Vaccine and Infectious Disease Division, Fred Hutch
  - Associate Professor, Clinical Research Division, Fred Hutch<sup>47</sup>
  - Since 2013, Dr. Pergam has received \$4167.00 in general payments from Merck and Gilead and \$140,311.19 research funding from Merck, Sharp and Dohme.<sup>48</sup>
  - ***Potential conflicts of interest.*** A. L. G. reports personal fees from Abbott Molecular outside the submitted work. S. A. P. reports grant support from Global Life Technologies, Inc, participates in research trials with Chimerix, Inc, and has participated in research with Merck & Co. He is currently participating in a clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID; U01-[AI132004](#)); vaccines for that trial are provided by Sanofi-Aventis.
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**Andrea Shane, M.D., M.P.H., M.Sc.**

Expertise: Pediatric & Infectious Diseases

Term: 02/01/2018-01/31/2022

Professor of Pediatrics

Director

Division of Pediatric Infectious Diseases

Emory University School of Medicine

Atlanta, GA 30322

404-727-9880 (direct)

404-727-5642 (main)

Email: [ashane@emory.edu](mailto:ashane@emory.edu)

- Medical Director Children's Healthcare of Atlanta; Curriculum vitae<sup>49</sup>
- Since 2013, Egleston Childrens Hospital at Emory has received \$114,148.01 in general payments and \$814,977.27 in research payments from companies including Jazz Pharmaceuticals, Genmark Diagnostics, WL Gore & Associates, etc.<sup>50</sup>

- Since 2013, Emory University Hospital has received \$44,133,351.66 in general payments and \$170,711,591.68 in research payments. At the top of the research companies are ER Squibb & Sons and Pfizer, Inc.<sup>51</sup>
- Since 2013, Wesley Woods Center of Emory University has received \$41,205.70 in general payments and \$3,429,327.48 in research payments. Topping the research companies are E.R. Squibb & Sons and Janssen Research.<sup>52</sup>

**Paul Spearman, M.D.**

Expertise: Pediatric & Infectious Diseases  
 Term: 05/09/2018-01/31/2022  
 Director, Division of Infectious Diseases  
 Albert B. Sabin Chair in Pediatric Infectious Diseases  
 Cincinnati Children’s Hospital  
 Medical Center  
 Professor, Department of Pediatrics  
 University of Cincinnati School of Medicine  
 Cincinnati, OH 45229  
 513-636-4509  
[Paul.spearman@cchmc.org](mailto:Paul.spearman@cchmc.org)

- Between 2013-2015, Dr. Spearman received \$39,459.84 in research funding from Glaxosmithkline, LLC and Astrazenica. No data available for years 2016-2019<sup>53</sup>
- Since 2013, University of Cincinnati Medical Center has received \$2,236,276.81 in general payments and \$4,281,617.38 in research payments. Topping the list of companies on both accounts is Pfizer, Inc.<sup>54</sup>
- Had to be recused from some meetings because his hospital, Cincinnati Children’s Hospital is also a COVID vaccine clinical trial site.<sup>55</sup> Dr. Spearman received \$39,46060 in associated research funding primarily from Glaxosmithkline, LLC. and AstraZeneca Pharmaceuticals LP.<sup>56</sup>
- No conflict of interest declared in *Warp Speed for COVID-19 Vaccines: Why are Children Stuck in Neutral?*<sup>57</sup>

Conclusions: Children are at substantial risk of COVID-19. Delays in starting Phase II vaccine clinical trials in children will delay our recovery from COVID-19 and unnecessarily prolong its impact upon children’s health and emotional well-being, their education, and equitable access to opportunities for development and social success, as well as the country’s economy. Understanding the safety, immunogenicity, and efficacy of COVID-19 vaccines in children is critical to protect children and adults. For children, a vaccine has the added benefit of returning them safely to school and extracurricular activities, and allowing them to engage with their world face-



to-face once again. Ensuring acceleration of vaccine clinical trials to warp speed for children will be critical in making this our future reality.

**Geeta K. Swamy, M.D.**

Expertise: Infectious Diseases

Term: 08/06/2018-01/31/2022

Senior Associate Dean

Vice Chair for Research & Faculty Development

Associate Professor, ObGyn

Department of Obstetrics & Gynecology

Division of Maternal-Fetal Medicine

Duke University

Durham, NC 27710

- Since 2013, Dr. Swamy has received general payments of \$63,040.09 (Glaxosmithkline, LLC, Sanofi, Pfizer, et al) and research payments of \$206,038.64 from Glaxosmithkline, LLC.<sup>58</sup>
- Since 2013, Duke University Hospital has received \$7,599,234.72 in general payments and \$40,585,472.53 in research payments from various companies. Pfizer, Inc. contributed general payments of \$866,119.65 and research payments of \$2,677,484.45.<sup>59</sup>
- Dr. Swamy had to recuse herself from committee meetings because Duke University, where she is associate vice president for research, is a clinical trial site for the Pfizer-BioNTech and AstraZeneca vaccines.<sup>60</sup> Dr. Swamy received payments from pharmaceutical companies totaling \$63,040. Her associated research funding totaled \$206,039, about three times that of similar physician. Dr. Swamy's largest sources of funding are Glaxosmithkline, LLC., Sanofi Pasteur Inc., Pfizer Inc. and Novartis Vaccine.<sup>61</sup>
- ***Vaccination of pregnant women with respiratory syncytial virus vaccine and protection of their infants.*** Study funded by Novavax and the Bill and Melinda Gates Foundation.<sup>62</sup>

**Gregg Sylvester, M.D., M.P.H. ±**

Expertise: Alternate Industry Representative

Term: 02/01/2020-01/31/2024

Vice President

Medical Affairs

Seqirus Inc.

Summit, NJ 07901

- Chief Medical Officer, Seqirus - Dr Gregg Sylvester has led Seqirus Medical Affairs since 2016, overseeing the global team that scientifically differentiates our vaccines by generating Real World Evidence and presenting Seqirus research to national vaccine recommending organizations.
- According to the Federal database, Seqirus USA, Inc. has made general payments in the sum of \$569,854.35 and research payments in the sum of \$44,159,881.83. Topping the list of receivers of general payments are **Arnold Simon Monto and Archana Chatterjee**.<sup>63</sup>

## **DIRECTOR**

**Prabhakara Atreya, Ph.D.**

Division of Scientific Advisors & Consultants  
Center for Biologics Evaluation & Research  
Food and Drug Administration  
Silver Spring, MD 20993  
[CBERVRBPAC@fda.hhs.gov](mailto:CBERVRBPAC@fda.hhs.gov)

**DR. MARION GRUBER**

Director, FDA Vaccine Research Office

## **DESIGNATED FEDERAL OFFICER**

**Kathleen Hayes, M.P.H.**

Division of Scientific Advisors & Consultants  
Center for Biologics Evaluation & Research  
Food and Drug Administration  
Silver Spring, MD 20993  
[CBERVRBPAC@fda.hhs.gov](mailto:CBERVRBPAC@fda.hhs.gov)

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<sup>1</sup> <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins>

<sup>2</sup> <https://www.ott.nih.gov/resources>

<sup>3</sup> <https://www.ott.nih.gov/royalty/information-nih-inventors>

<sup>4</sup> <https://www.ott.nih.gov/resources>

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<sup>7</sup> <https://investors.modernatx.com/node/8671/pdf>

<sup>8</sup> <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-supply-agreement-us-government-initial-100>

<sup>9</sup> <https://crsreports.congress.gov/product/pdf/IN/IN11446>

<sup>10</sup> <https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/roster-vaccines-and-related-biological-products-advisory-committee>

<sup>11</sup> <https://www.ghwatch.org/who-watch/h1n1.html>

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- <sup>18</sup> <https://www.nbcdfw.com/news/coronavirus/texan-involved-in-covid-19-vaccine-trials-advises-against-half-doses/2521936/>
- <sup>19</sup> <https://www.pbs.org/newshour/health/watch-live-fda-advisory-committee-assesses-covid-19-vaccine-development>
- <sup>20</sup> <https://www.bizjournals.com/boston/news/2020/09/25/fda-official-involved-in-moderna-trial-steps-aside.html>
- <sup>21</sup> <https://coi.ufl.edu/2020/10/26/some-fda-advisors-tapped-to-review-coronavirus-vaccines-received-payments-from-vaccine-companies/>
- <sup>22</sup> <https://www.pogo.org/investigation/2020/10/some-fda-advisors-tapped-to-review-coronavirus-vaccines-received-payments-from-vaccine-companies/>
- <sup>23</sup> [https://finance.yahoo.com/news/fda-vaccine-committee-head-steps-055718018.html?guccounter=1&guce\\_referrer=aHR0cHM6Ly9kdWNrZHVja2dvLmNvbS8&guce\\_referrer\\_sig=AQAALNseSAkCAU\\_oXgLmONgHMz3p4FUoRtEgZv6xLICKnvY8bO\\_SPG8CWfHdbvZULO0xruuDmy7LIRVSQuQ\\_uWNGkXo58YlBrjD2co7KOVu2CRMOWippqce1pb6QhT5efYM5OMtuWYpQ9K3EzyR5yg-u1v\\_7VSbFCdGLHIFDP1kiJhj](https://finance.yahoo.com/news/fda-vaccine-committee-head-steps-055718018.html?guccounter=1&guce_referrer=aHR0cHM6Ly9kdWNrZHVja2dvLmNvbS8&guce_referrer_sig=AQAALNseSAkCAU_oXgLmONgHMz3p4FUoRtEgZv6xLICKnvY8bO_SPG8CWfHdbvZULO0xruuDmy7LIRVSQuQ_uWNGkXo58YlBrjD2co7KOVu2CRMOWippqce1pb6QhT5efYM5OMtuWYpQ9K3EzyR5yg-u1v_7VSbFCdGLHIFDP1kiJhj)
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- <sup>25</sup> Id.
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- <sup>51</sup> <https://openpaymentsdata.cms.gov/hospital/110010>
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- <sup>53</sup> <https://openpaymentsdata.cms.gov/physician/1036685>
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- <sup>61</sup> <https://openpaymentsdata.cms.gov/physician/292920>
- <sup>62</sup> <https://pubmed.ncbi.nlm.nih.gov/32726529/>
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