

Presenters and Their Backgrounds:

Tim Fitzgibbon

- Outside General Counsel to American Society of Hematology
- Partner in Washington, DC Office of Nelson Mullins and former Managing Partner of that Office
- 40 years of experience in representing Defendants in federal and state court litigation.

Trish Markus

- Certified Information Privacy Professional; Partner in Raleigh, NC Office of Nelson Mullins
- Represents health care providers and health technology companies, focusing on health information privacy, security, and technology issues
- Recognized by Chambers USA as a Leading Lawyer for Business in Healthcare in NC each year since 2016
- President-Elect of the American Health Law Association.

Kraig Long

- Managing Partner of Nelson Mullins Office in Baltimore, MD
- 25 years experience defending employers against discrimination claims and advising clients about creating diverse and inclusive workplaces while minimizing litigation risks in the workplace
- Frequent author of articles on labor and employment issues
- Recipient of numerous awards and honors for his work, including being honored as a Leader in Diversity by the Baltimore Business Journal in 2021.

Public Service Announcements (Disclaimers)

The views we express today are our own and do not necessarily reflect the position of Nelson Mullins or any of its clients on these issues.

We are not providing legal advice today. We have not been retained as counsel by the Health Research Alliance. Also, the specific facts and circumstances of each case would be critical to the rendering of any legal advice. We will leave time for questions at the end, but if you have specific issues you would like to discuss, please contact us separately.

The issues that we will be discussing are complicated – they reside at the intersection of several different areas of the law, regulation and public policy, potentially including discrimination; employment; privacy and security; data collection and retention; risk management; and litigation -- just to name a few.

In a relatively short period of time, we will try to identify the different parties that are passing through this busy legal intersection and their respective interests, and to provide some suggestions to try to minimize risk and avoid costly collisions, recognizing that the road surfaces and the street signs around this particular intersection are constantly changing.

Update on *Do No Harm v. Pfizer, Inc.*

Pfizer's "Breakthrough Fellowship Program" was intended to respond to challenges in recruiting, retaining, and promoting diverse talent, and specifically to increase the number of African-American, Latino/Hispanic and Native Americans in leadership positions at the company. The BFP offered various benefits to Fellowship recipients over a multi-year period, including professional mentorship, internships, post-undergrad and post-grad school employment and full scholarships for master's programs.

Fellowship applicants had to meet certain requirements, including citizenship/residency, undergraduate enrollment, specific fields of study, minimum GPA, leadership potential, etc. Applicants also were required to "meet "the program's goals of increasing the pipeline for Black/African American, Latino/Hispanic and Native Americans." The principal claim in the suit by Do No Harm was that Pfizer's BFP "categorically excluded" White and Asian-American applicants, thereby discriminating against them.

Ultimately, the suit was dismissed (without prejudice) by the US District Court for the SDNY largely on procedural grounds (based on DNH lack of standing to assert the claims on behalf of two DNH members who were not specifically identified). Rather than amend the Complaint, DNH has filed a notice of appeal and the case is now before the Second Circuit awaiting briefing.

Drivers At the Intersection:

- 1. Grant Applicants/Recipients** – Potential Providers of Demographic Data
- 2. Grant Funders/Implementers** – Recipients and Users of Demographic Data
- 3. Private Interest Groups** – Substantive and Fundraising Interests
- 4. Government Players** – DOJ/FTC/State Legislatures/State Attorneys General
- 5. Insurance Companies** – Coverage Issues Relating to Claims; Cost of Defense
- 6. The General Public** – Data Used in Support of Programs that Ultimately Benefit the Public

Collecting Demographic Information from Applicants

What Kind of Entity Is Collecting? – Different rules for employers, housing providers, federally funded entities, state agencies and universities, etc.

What, if any, State Privacy Laws and Regulations Apply? -- Increasing State activity in this area. (California/Colorado/Connecticut/Utah/Virginia)

How Will the Data Be Collected? -- A particular caution re “data scraping” on web platforms

How and Where Will the Data Be Stored? – Individual or Aggregate? Third-party server? Outside the US?

Voluntary Participation/Consent – Applicant sharing not required/No “penalty” for refusal to share

Purpose of Collection/Use/Retention/Sharing of Data – Is there a written policy that controls (beyond overall Privacy Policy and Terms of Use on website)? Has counsel reviewed the specific wording of: the grant application form; statements about collection and use of demographic data; questions used to collect the data; website and other descriptions of the particular program(s) for which the data is being gathered.

Suggestions to Try to Limit Exposure

Obtain, and retain confirmation of, consent from the applicants

Carefully review (with counsel and with funders) the language used to describe the Program and how the demographic data will be used in the Program (including measuring the ongoing need for, and efficacy of, the Program). Can we say it better?

Wherever possible, keep demographic data in aggregate or anonymized form

Periodically review (and revise if needed) website privacy policy and any other written policy applicable to the gathering of demographic data from the applicants. Are we doing what we say we are?

Anticipate a complaint and examine what legal and factual defenses would be available to respond

Check your cyber policies and other insurance policies.