# The Rumble in Southern California

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# A Quick Sketch

Within the last month, a rather nasty academic and legal dispute has arisen between the University of California, San Diego, on one side, and the University of Southern California and UCSD's former employee Paul Aisen, on the other.

The dispute revolves around an Alzheimer's research institute at UCSD, formerly run by Aisen, the data associated with that institute, associated funding, and the departure of Aisen and colleagues for USC's new Alzheimer's center in San Diego.

For us, this is ethically and professionally relevant: Should research funding and data be tied to researchers or institutions? How should issues surrounding changing institutions be handled?

# A Timeline of Events

- 1991: Alzheimer's Disease Cooperative Study (ADCS) founded by the National Institutes of Health (NIH) and UCSD's Dr. Leon Thal. Center coordinates work of dozens of centers and supports with data services.
- 2007: Dr. Thal dies, Dr. Aisen hired to run ADCS.
- 21 June 2015: Dr. Aisen resigns from UCSD (other colleagues resign simultaneously). [SDUT, 14 July]
- 2 July: UCSD files suit against Aisen, USC, and colleagues. [SDUT, 14 July]

# A Timeline of Events II

- 8 July: Judge orders USC to "refrain from altering data and computer systems that are part of the study." [SDUT, 14 July]
- 13 July: USC files suite claiming that UCSD compromised the safety of the data stored on Amazon servers by using root access to change billing address to UCSD campus address, requests restraining order against UCSD.
- 15 July: Dueling editorials by Paul Aisen and UCSD administrators Brenner and Firestein appear in SDUT.

Disputes remain unresolved.

# What Appears to Have Happened

"Facts" such as they are are largely inferrable only from statements of players.

There clearly was some acrimony between UCSD administration and Aisen.

Beyond that, the points materially in dispute have to do with the accessibility, maintainability, and integrity of the data maintained by ADCS for the conglomerate of studies it supports.

# What's at stake

- Along with an estimated $100 million in research funding, data of more than 1000 research patients, and support for ongoing trials around the US. [LAT, 19 July]

- Without a solution which enables someone to take care of the data properly, all of these studies may be substantially disrupted.

- Questions of precedent regarding faculty raiding, control of data, and fiduciary duty abound.

## How Unusual is this?

"Richard Seligman, the associate vice president for research administration at Caltech who has more than four decades of experience dealing with grants, said he had never heard of such a lawsuit, even though competition for grants and noted faculty has gotten more fierce.

"It is common for researchers to jump from school to school and to receive permission from their original campus and funding agencies to take grants with them, he said. Universities are never happy to lose grants, portions of which help pay for overhead expenses such as utilities and administrative support [often $\geq$ half, SDUT 20 July]. But in most instances, 'universities are extremely collegial and collaborative and hardly ever get into disputes' about those moves, he said.

"In some cases, the original universities retain part of large grants for faculty who remain with them, and allow the departing researcher to take the rest. Seligman and other experts said such arrangements recognize that science transcends campus boundaries." [LAT, 19 July]

# The protagonists' views: Aisen

"[USC] is the ideal environment both administratively and academically for our research program. . . . I did not feel that our research had the proper [institutional administrative] support [at UCSD]. I tried to work out the issues over several years and especially in the last six months. In the end I felt that our research program would receive better support at USC. . . . My sole motivation in making this move was to provide the best possible home for our research. A set of administrative and bureaucratic challenges significantly slowed our ability to begin and conduct clinical trials."

Claims to have been "very open" with UCSD about his plans to change institutions, in the wake of failed meetings to resolve "challenges."

# The protagonists' views: Aisen II

"All data, all software, and all code was left in the hands of UCSD. ...UCSD is able to access all of the data, and everything that happens on the database is synchronized at least daily and remains transparent to the university.

"Clinical trial data are strictly regulated by the Federal Drug Administration and other agencies. Such data need to be securely managed, with a tightly controlled chain of custody and tracking. Our group created the software to manage the data and is uniquely qualified to administer the system. For that reason, it is critical for study integrity and patient safety that we continue to manage the data.

"UCSD has stated that it views this research program as a matter of business. I see this first and foremost as a matter of scientific integrity and patient safety. Decisions on where this program resides should be based on protection of participants in the study and enhancement of the public good."

# The protagonists' views: UCSD

"In academia, faculty members often move between institutions. They do so for many reasons. UC San Diego supports academic freedom in all forms and over the years has managed thousands of these transitions.

"Typically, these moves involve transition plans and careful discussions to arrange and assure safe, smooth, equitable, legal and appropriate transfer of personnel, information and resources so that no one is unfairly or unduly harmed.

"None of which applies here. Dr. Aisen's departure revealed that he and a select group of co-workers (who also simultaneously resigned) had apparently planned for months to appropriate critical information about ADCS clinical trials without authorization. The data were sequestered into an Amazon cloud account and all documentation for managing the data was removed, effectively preventing UC San Diego from fulfilling its obligations to protect and preserve the safety and integrity of trial data."

# The protagonists' views: UCSD II

"Dr. Aisen's assertion that he acted to protect public health are simply unsupportable, akin to an airline pilot hijacking a plane, then justifying the act by saying he's a better aviator than the airline's owners, other pilots, passengers and crew. Serious actions like moving clinical data must be approved in an orderly fashion with both university and funding agencies to guarantee patient protections and support the best science. NIH grants are made to institutions, not individuals; data cannot be commandeered by fiat based upon the aspirations of a single investigator

"These actions, clearly supported by USC and intended to kick-start its incipient institute, are breaches of academic, medical and legal standards of conduct. They put at risk decades of data and hard work. They go against the fundamental principles of good science and the University of California that support excellence in teaching, research and public service."

Who should data belong to? Research contracts? In general?
In this case? Has UCSD acted ethically? Aisen/colleagues?
USC?

Discuss!

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