Note: There were numerous times where the connection cut out in this recording. Words were filled in when they were intelligible, but otherwise <audio cuts out> or <inaudible> was inserted to indicate words that were missed. – Production Transcripts

**KT:** So we have to have verbal consent by each of the participants according to California State Law to being recorded and I consent and [redacted]?

**KP:** I'm [redacted] and I consent to be recorded.

**Interviewee:** I'm [redacted] and I consent to being recorded.

**KT:** Great. And we understand that you had said we could take a shot at redacting the transcript, send it to you, you can see if you want to make further changes or if you want to let us post the redacted transcript or if you don't want to make any changes but just don't want the transcript posted and that will be done later on and no action from any public identification would be made in any event of who we interviewed. So starting out, I wonder if maybe you could just give us some of your background and how you got involved in research in genome editing.

**Interviewee:** Excellent. My background is in [redacted], my work in graduate school was on self \_\_\_\_\_\_\_ 00:02:21 molecule modeling, there was a lot of transferable skills to software develop for bioinformatics which is how I found myself with an [redacted] position at the Food and Drug Administration working with their [redacted] and the [redacted] team at FDA developed an in-house bioinformatics platform for analysis of next generation sequencing data to be used by researchers at FDA. There were several instances of this platform, one specifically dealing with regulatory data, other than generating software that might have been able [ph?] to make it onto that platform, I had no access to or knowledge of what was on there. And then there was a second platform used for the FDA where I had a more direct <inaudible 00:03:17>. After some time at FDA I had taken a job before I defended, after I defended, it was time to move on, not because I didn't want the position but because it was time to make a little more money, I took a position at [redacted] and afterwards I went to [redacted]. I was hired at [redacted] primarily because of my background with bioinformatics software. <inaudible 00:03:44>.

**KT:** We're sort of dropping out a little bit, [redacted] are you getting a clear signal?

**KP:** No, it's dropping out a little bit for me too.

**Interviewee:** Okay. Is this more clear?

**KT:** That's better, yeah.

**Interviewee:** Okay, what did you last hear?

**KT:** Well we heard I think generally that-- and then it was sort of fading a bit, well actually maybe if you just the last bit of when it was time to move on and you went to [redacted] .

**Interviewee:** Yeah, I went to [redacted] as an assistant research professor, taught some bioinformatics courses, was involved in the development of a web platform for [redacted] on proteins and then in [redacted] of [redacted], I moved from [redacted] to \_\_\_\_\_\_ 00:04:32 [redacted] where I work again in bioinformatics and in structural bioinformatics.

**KT:** And what's the current focus in industry, can you give any more detail? This is the sort of thing that we might very well redact from the transcript if it gets…

**Interviewee:** Yeah, this is something that I would probably need redacted, I hate to say that but I work on the [redacted], whether or not we can make improvements to that protein.

**KT:** Okay, enough said. And you use bioinformatics on that, you're not at the bench, is that correct?

**Interviewee:** That's correct, yeah.

**KT:** So how would your relationship be with people who are at the bench?

**Interviewee:** I consult with them to design assays to validate hypotheses that I may generate.

**KT:** So you would develop a hypothesis about some way to improve on the protein and then they would develop an assay to-- okay, that's helpful. What percentage of your work is currently devoted to the area of genome editing and genome editing therapies?

**Interviewee:** Indirectly in that way I just described, it would be probably 100 percent.

**KT:** That's what you do, okay. Have you had any contact with the FDA about commercial applications in gene therapy or other therapies?

**Interviewee:** I have not, no.

**KT:** Okay. And then could you talk a little bit about what you were doing at the FDA and when they were not as familiar with that program as others at the FDA and whether that for example is a program that's more providing training opportunities or whether it's something where the FDA is also, you know, the participants are providing resources to the FDA?

**Interviewee:** Of course. So I was in [redacted] at the FDA although my work was with a [redacted] at FDA.

**KT:** The what [redacted]?

**Interviewee:** [redacted].

**KT:** Oh [redacted], okay.

**Interviewee:** Are you familiar with it? I don't know how many people you've interviewed <inaudible 00:07:11>.

**KT:** No.

**Interviewee:** Okay, great. So researchers at the FDA needed a way to be able to analyze next generation sequencing data and they didn't necessarily want people to have to analyze even the way that was traditional at that time, command-line interface, Unix tools, the work the [redacted] at the FDA sought to do was to develop a web-based platform for [redacted] where people would be able to revise pipelines and we wrote the software, in addition, we did train several of the researchers at FDA on how to use it. So our functionality was kind of twofold, we would run some analyses ourselves and we would spend the rest of our time running the software and training people. This was used in my experience for the basic research functions at FDA, so there are some groups at FDA looking at [redacted] for instance or [redacted] but there are also needs for analysis of NGS data that comes with regulatory submissions, [redacted] fellows though as a rule are not allowed to interact with regulatory data, so I was not privy to how the platform was being used in that capacity other than knowing that it was.

**KT:** So the regulators, you and other fellows were developing, helping researchers develop a software platform that was then available not only to the researchers but also to the regulators for use in a way but you don't how they used it, is that a correct summary?

**Interviewee:** Yes.

**KT:** How did you come to work at the FDA?

**Interviewee:** So I was shopping around my resume, I did have the fortune of knowing people who were able to put me in touch with people at the FDA they knew were hiring.

**KT:** So at that point you were late in your [redacted] stage?

**Interviewee:** Yeah, I had an interesting trajectory, [redacted].

**KT:** So when you took the job, you contemplated you would stay past the-- a PhD wasn't required for the job but you contemplated you would be staying beyond the-- yeah.

**Interviewee:** Yeah, the [redacted] was primarily-- there were some biologists but the primarily was primarily software engineers and in that capacity most people would not feel the need to have a PhD.

**KP:** So if you'll forgive my use of [redacted], [redacted] says your PhD is in [redacted] although you do have some expertise in [redacted] that came out of that but then you've moved on sort of in the direction of bioinformatics, was that a pivot for you, was that a natural fit or is it something that you sort of pivoted to and have followed through with?

**Interviewee:** So that was a natural fit, I entered graduate school in the [redacted] biology program but I ended up doing all of my graduate work in a lab in the [redacted] Department that created models for structural biology so I have not been at a lab bench in over a decade, I have no business there.

**KP:** It's all right, that's all right. One more follow-up there is when you came to FDA or even in the time since, was gene editing or [redacted] and the sort of platform you eventually developed, was it sort of widely understand that this sort of bioinformatics data problem was a central part of [redacted] and gene editing or was that sort of a new frontier that the FDA was forward, behind or what on?

**Interviewee:** Yeah, I don't think that was on my radar at the time, so I-- yeah, it wasn't widely discussed.

**KT:** Genome editing wasn't on your radar.

**Interviewee:** Correct, yeah. There was somebody in my group who was working on analysis on the [redacted].

**KT:** And so you were hired specifically to fill in-- I mean they were advertising for a position in this [redacted] group?

**Interviewee:** Yeah.

**KT:** For someone who was a bioinformatics specialist who could assist the researchers.

**Interviewee:** Who could assist the researchers but primarily people who would be able to write code in C, C++ who had an understanding of biology.

**KT:** Oh yeah, I didn't mean to help the researchers directly but I meant to develop a platform that could help the researchers.

**Interviewee:** Oh sure, yes.

**KT:** So the FDA identified that for their researchers, they-- do you know how they came to realize they had this need and they didn't have a capacity in-house or…

**Interviewee:** So the development of [redacted] started, gosh six or seven years before I got there, it was already a pretty mature project by the time I…

**KT:** It was a pretty much?

**Interviewee:** It was a pretty mature project by the time I joined.

**KP:** Mature project.

**KT:** For some reason that-- oh, mature project when you-- is that-- okay, I didn't-- mature project was hard for me to hear. So you're not sure of the origins as to how they identified that need.

**Interviewee:** I do not know. There are other people who I could recommend you interview who you may be able to find on LinkedIn who were involved with the project earlier.

**KT:** We were going to ask that question at the end but I guess maybe [redacted], can you take the names down now or…

**KP:** Mm-hmm. Whenever you're ready [redacted].

**Interviewee:** Sure. So [redacted] … [redacted]. [redacted], [redacted] pretty high up in [redacted], or [redacted] sorry, I forget her last name and I should know it and [redacted] also from [redacted] currently have oversight functions over that group. And then some of the [redacted] would be [redacted].

**KP:** Could you say the last two names again please?

**Interviewee:** [redacted], he also works for [redacted] so if I'm able to spell the last name, you may be able to find him that way. And same for, he goes by [redacted]

**KP:** [redacted], okay.

**Interviewee:** [redacted]

**KP:** [redacted], sorry, thank you. Cool.

**KT:** So do you have a sense of how many people were involved in the [redacted] project?

**Interviewee:** Underneath [redacted], oh sorry, so you mean people actively writing software, actively training researchers or researchers who use the platform?

**KT:** Well not the latter but maybe the two former.

**Interviewee:** Yeah, the first two, this is just a rough estimate, when I left the team was approximately 15.

**KT:** And do you have a sense of what their expertise or skill sets were and level of training and work experience?

**Interviewee:** Yeah, there were some pure software engineers, maybe three or four of those maybe an additional four software engineers with high biology backgrounds, I would put myself, [redacted] and [redacted] in those categories, an additional-- I should include [redacted], a software engineer for front end develop and then there were people who were trained in biology who would either primarily train researchers or who would run analyses on the platform but not get involved in the coding.

**KT:** And do you have a sense of how many of these people were long term FDA employees or people like you who were sort of hired into the program to perform specific functions?

**Interviewee:** Most of the team if they were not ORISE, started off as ORISE.

**KT:** And ORISE is an external fellowship program that they have, could you…

**Interviewee:** Yeah, ORISE, so it's administered through the Department of Energy, Oak Ridge, it's a laboratory in Tennessee, basically they provide training fellowships for people of all levels and a federal laboratory.

**KT:** So the program that you-- sort of the master program is a federal program that's across departments and across labs and then they had a-- do you know does the FDA then ask specifically, "Could we get a bunch of ORISE fellows?" or how it came that they identified your position or created it?

**Interviewee:** I don't know the mechanism behind that.

**KT:** And did I recall correctly that you said that most of the people in the [redacted] program came in through that ORISE program?

**Interviewee:** A lot initially did, yeah and then at some point, so ORISE does cap people off at five years so after that point, some of the mature people were able to stay on as contractors.

**KT:** But were people, do you know if there are many people who sort of permanent FDA employees who were involved in the program other than getting the assistance you described in terms of researchers who got trained and got to use the software platform?

**Interviewee:** Full time FDA employees. [redacted] was a staff fellow, [redacted] may be of interest but I don't know if she left on the best of terms <inaudible 00:21:03>. She was full time, [redacted] is full time, I believe [redacted] is full time FDA.

**KT:** And were those more senior?

**Interviewee:** A lot of the more senior people, although it was a very egalitarian group. And so it's not really like say more senior in that capacity.

**KT:** Do you know if there are other programs out of ORISE like the [redacted] at the FDA?

**Interviewee:** Other programs that were…

**KT:** Developing technology or somehow supporting the research and regulatory functions.

**Interviewee:** I don't know.

**KT:** During your time there, you were there for a couple of years and science moves along and some of your colleagues were there, you saw five, six years, how did people maintain expertise, how did you maintain expertise and how did other people maintain expertise while you were working there?

**Interviewee:** We did do before implementing any new algorithm, it was quite an extensive and literature review before we adopted anything.

**KT:** I'm sorry, you would…

**Interviewee:** Yeah, I was speaking through my kid's head which is <inaudible 00:22:27>. So I don't want to say it was mostly self directed, when we attempted to do something new at [redacted] there was a large process, a large, I don't want to say a literature review but a lot of people were expected to do individual research and come together.

**KT:** So you all individually did literature searches and kept up through the literature and then would meet and somehow that was organized and that information was shared?

**Interviewee:** Yeah, I would say so.

**KT:** Are there other ways other than published literature, published journal articles that you were able to keep up and keep current or you saw that colleagues were keeping current?

**Interviewee:** Other than literature?

**KT:** Right, conferences or…

**Interviewee:** I don't think we attended so many conferences, ORISE did provide some travel funding but I know I didn't use it. I think that's probably the cleanest way. We did, so [redacted] does have this style where he will kind of push the field along himself.

**KT:** I'm sorry, he has?

**Interviewee:** Oh, a style where he would want to push the field along on his own, his background is more of a, he would consider himself a physicist before he would consider himself a biologist. So a lot of the novel stuff we did try to do was things that he had tried to adopt from physics.

**KT:** So you said you were trying to do novel-- taking novel approaches to the software, the platform development?

**Interviewee:** Yeah.

**KT:** What about, did outside experts come in or did you consult with outsiders, any specialists, anything like that?

**Interviewee:** We did have some interaction with [redacted], with [redacted] which are both companies that provide what are now similar platforms to the [redacted] platform although we were ahead of them at the time we started.

**KT:** And what type of consulting or interaction did you have with them?

**Interviewee:** You know what, I may be mixing up my time at [redacted].

**KT:** Oh.

**Interviewee:** So we were involved in them at FDA because we were interested in standardizing bioinformatics analysis through something called [redacted], so not only FDA but several of these other platforms did attempt to take on this specification so while at FDA, the interaction with the platforms was primarily through adoption of [redacted] and then when I was [redacted] we worked more with them.

**KT:** Did people come and give presentations or did you have meetings together with the outside consultants?

**Interviewee:** I did not.

**KT:** Do you know if your colleagues did?

**Interviewee:** I think they did but I don't recall.

**KT:** And did you have any other perceptions about how you interacted with the FDA, it sounded like you worked somewhat, or you or your colleagues, your unit worked somewhat closely with the researchers and it's sort of was a black box as to how you were working with the regulators, would that be your perception?

**Interviewee:** That's absolutely my experience, yeah whereas fellows by law we're not allowed to interact with regulatory data in any way.

**KT:** What about interacting with the regulators, did you have any meetings or cross, sort of information sharing, workshops, anything like that?

**Interviewee:** That wouldn't have happened in my level.

**KT:** Okay.

**Interviewee:** It would have been [redacted] or [redacted] or one of the full time people.

**KT:** That may or may not have interacted with them but you don't know if they did.

**Interviewee:** Well they would have, yeah.

**KT:** So they would have been-- and that would be just sort of transfer the knowledge of the platform over to the regulatory side, is that…

**Interviewee:** I think that's fair to say, yeah.

**KT:** So higher up. And did you refer to [redacted] as having oversight or you said something with [redacted].

**Interviewee:** [redacted], no [redacted].

**KT:** Oh [redacted], okay, I'm not familiar with him. So someone from CBER, in the CBER hierarchy had oversight over this [redacted] program.

**Interviewee:** That's correct, yeah. Oh no, sorry, sorry, [redacted] and then I forget…

**KT:** Oh okay, all right [redacted] I know of.

**Interviewee:** Yes, because [redacted] reported to [redacted] and then after [redacted] left, [redacted]

**KT:** Oh we don't need that…

**Interviewee:** …sorry his last name will come to me but he took over, they're still searching for a new head of the [redacted] group and [redacted] took over oversight and still reports to [redacted] is my understanding.

**KT:** And the continues and it continues to develop software platforms for the next generation sequencing and other genomic sequencing activities?

**Interviewee:** Yeah, yeah. Things like right, variant calling, RNA-Seq analysis, genome assembly.

**KT:** And do you know how, the researchers who were relying on this work and using [ph?] this work, do you know what type of work they were doing and how they fit into the FDA structure?

**Interviewee:** So I never-- I can give you examples of several of them.

**KT:** That would be great.

**Interviewee:** So in my time at FDA, I worked with [redacted].

**KT:** And those were research topics identified by the FDA researchers.

**Interviewee:** Yeah, correct.

**KT:** Do you know how these research topics get identified or is this just sort of scientific curiosity research or was there a specific source of the question I suppose?

**Interviewee:** That is a very good question. I do not know how it is that FDA decides which basic research projects it dedicates its various \_\_\_\_\_\_ 00:31:14 funding for basic research towards.

**KT:** Then how are the questions that you addressed, how were those developed?

**Interviewee:** How were they-- so in that capacity we would serve as bioinformatics consultants, so researchers generally had an idea of what it is they needed but then would work with us instead of perhaps finding an external group.

**KT:** To attempt to identify a bioinformatics solution to a question that they had or a way to generate information.

**KP:** Can I ask real quick, so in terms of how [redacted] works organizationally, you mentioned that perhaps your higher ups would meet with the regulatory folks and then you might meet with some of the researchers with questions, so I guess the question is what that typical, was your sort of day-to-day that requests sort of flowed from them, you would design something, they'd give you feedback and it was sort of an interactive process or was it more of a sort of submission of tickets and then you'd provide a response?

**Interviewee:** I would say it was much more interactive.

**KP:** Okay. And then in general, is [redacted] I'm trying to think of comparators here so please forgive me if my software fu is not very good, but did [redacted] run more like a software as a service where you're sort of in-house, the devs [ph?] are there, when someone has a new problem, they can get an answer, they can get support or is it more of sort of like an open source platform more like R where people can publish things all the time, there's a lot out there but it's very much self directed and self supported?

**Interviewee:** Of the two you described I would say more software as a service. It is publically available on GitHub as far as I know, most people don't try to spin up [ph?] a [redacted] instance. There is a public instance of [redacted] run through [redacted] where they do have a couple of clients who pay to use it, as a service, so they'll pay for a log-on, access to the compute.

**KP:** All right, does FDA run their own instance of [redacted] that other people can log in to?

**Interviewee:** Nothing at FDA is accessible externally.

**KP:** Okay, but there is an internal one?

**Interviewee:** There are multiple internal ones, yeah, one for develop, one for basic research and one for regulatory data. Those are kept entirely segregated.

**KP:** For bureaucratic reasons or for…

**Interviewee:** For bureaucratic reasons, absolutely. It is the simplest way to ensure that proprietary data used in regulatory submissions is not accessible to anyone who should not have access to it.

**KP:** Yeah, just two separate towers, got you, thank you.

**Interviewee:** Two separate racks of-- two separate clusters, no communication between them, the only thing they have in common is the software running on each of them.

**KP:** Thanks.

**KT:** So might your group get requests for modifications that came in through the regulatory arm?

**Interviewee:** Sure.

**KT:** So you wouldn't directly interact but there could be requests that would come in and you would be supporting that or trying to develop something in response to that request.

**Interviewee:** Yeah, I would say that's possible.

**KT:** Any other ways that you might interact with or that the results of your work might interact with the regulatory group?

**Interviewee:** Only through the software that I wrote.

**KT:** I think you've probably answered this a couple of times but just in general, do you have any suggestions on how there might be improvements to the work of the [redacted] group's ability to support and advance regulatory science and decision making at the FDA, as you point the constraint you need to isolate the regulatory data and the regulatory submissions?

**Interviewee:** Yeah, do I think it would be better if Congress allocated the funds such that FDA could hire on a full time team to manage this particular bioinformatics project instead of going on necessarily parts <inaudible 00:36:27> remitted, training fellows then yes.

**KT:** Okay, well that's actually quite helpful and interesting. So it is something that's having in-house and funded by a professional group you said might be a next step up.

**Interviewee:** I wouldn't call our group not professional but yes.

**KT:** What I meant by professional not was at a skill level, I meant in the sense that that was the full time employee as opposed to a consultant kind of arrangement as you described.

**Interviewee:** Sure, yeah.

**KP:** Career path development essentially as opposed to a fellowship.

**KT:** Right. So now you find yourself in industry and it sounds like you're probably doing a similar set of activities in industry as you were doing at the FDA?

**Interviewee:** I was hired on for that FDA skill set but over time I switched much more to applications and structural biology as opposed to software develop and bioinformatics.

**KT:** So when you say that FDA skill set, you mean not the skill set of working with the FDA but skill set that you were applying while you working at the FDA.

**Interviewee:** That's exactly what I mean, I mean software development and engineering and bioinformatics, I don't meet knowledge or regulatory affairs, is quite limited in my case.

**KT:** Right. And do you have perspectives seeing how the bioinformatics and that general piece of the puzzle of understanding genetics, understanding genome, their implications for health and so forth, how you're seeing it being done in industry versus how you experienced it at the FDA?

**Interviewee:** I'm sorry, can you repeat that, I didn't quite catch the question?

**KT:** Well I'm wondering if you see ways, if you have perspectives as to how it's similar or different the role of you as a non bench informatics related person integrated into a team that is doing therapeutic development, how that might be similar or different from being at your role at the [redacted] supporting researchers and regulators at the FDA, not you personally as much as the broader functional group.

**Interviewee:** I think if-- it feels to me on this side that for certain bioinformatic analyses which may become more standard as genome editing therapies progress, I think-- it feels to me as though the FDA is waiting to see what those analyses look like from industry instead of perhaps figuring it out what those should look like and dictating what sort of depth of analysis is needed. I don't know if that answers your question.

**KT:** Oh no, that's very helpful, it's actually, it's a slightly different point but a very important one that maybe we could follow up a bit. So in a sense it sounds to me like you're saying there's an opportunity to be proactive or reactive in terms of setting a framework and standards for information technology that's being applied and the outputs that it's generating in a regulatory framework and that the FDA could be defining those in sort of whether if the [redacted] team was more robust and maybe full time and that there was an interest in doing that as opposed to-- or you're saying your perception is it seems that the industry is defining what they view as a kind of regulatory submissions and data analyses that are appropriate and then they would be evaluated by the FDA.

**Interviewee:** I think that's so. I also though, I don't want to give the impression that the analysis is not thorough, I think the industry as a whole does understand that if body [ph?] analysis were to <audio cuts out 00:41:45> it could cause people to lose faith in their entire sector but that's not to say that the methods that are currently being applied are perfect or standardized across companies.

**KT:** Right, and do you think there would be benefits if the FDA took a leadership role in terms of the standardization?

**Interviewee:** Perhaps, yeah. I should specify right, in my position I do discover research where things that may end up in a future therapeutic though I'm not involved in things that are actually being submitted, formally submitted.

**KT:** But I'm just wondering if you could give any examples or any perceptions as to if there were a previously identified standard that that standard articulated by the FDA, that might be somehow would be a different and perhaps superior approach to some of the informatics.

**Interviewee:** Sure. So the <inaudible 00:43:18> [redacted], the beautiful thing about [redacted] is it allows you to [redacted] the genome, what doesn't typically get stated is that the enzyme is not perfect and can occasionally cut things that are similar to what you would want to cut but is not exactly what you would want it to cut. So there are certain NGS and bioinformatic techniques used to track down these \_\_\_\_\_ 00:43:48 target sites and as far as I know there is not guidance from the FDA on how companies doing genome editing should prove that there either are not off target sites or the off target sites that may be present <inaudible 00:44:10>.

**KT:** And are there ways that you think that-- how do you-- I know this is speculative but what do you think would be a good approach for trying to develop the appropriate sequencing tools for identifying off target effects for regulatory purposes?

**Interviewee:** I don't know, I think that would take a lot of minds who are more familiar with the technology than mine is.

**KT:** But you're saying just currently that absence of a standard exists and it might be superior to having something…

**Interviewee:** I think <inaudible 00:44:59> better it might be better if there was a standard than companies trying to figure out…

**KT:** It wasn't coming through quite clearly, could you just repeat, you started saying it would be a better standard than companies…

**Interviewee:** Oh, I think a standard from the FDA if it does not exist is better than—well, maybe I falsely believe, but what I believe is happening <inaudible 00:45:23> companies are left on their own to show that there are not or that there are <inaudible 00:45:31> coming events or there are <inaudible 00:45:33> coming events <inaudible 00:45:34>.

**KT:** No, I think it's absolutely the case, I know that there are a number of efforts to try and develop those standards and so forth. [Redacted], did you have any-- we're getting close to the hour, I'm wondering if you had any follow-up questions?

**KP:** Yeah, so I guess what I hear you saying right now [redacted] is that in the absence of the FDA saying sort of a universal or a uniform standard for how we prove whether our technique is meeting a certain performance level or non performance level with the off targets versus sort of effecting the change that there's a lot of companies essentially making claims, making assertions that this is better than that but there lacks a sort of uniform yardstick, is that where we've been going with this?

**Interviewee:** I think that's possible, yeah.

**KP:** Okay. I wanted to ask I suppose, I mean for the way I phrase as sort of orthogonal question which is you mentioned that you see sort of FDA as being a bit more reactive or sort of surveying industry as opposed to driving industry on some of these standard setting practices. But I was wondering if in the various positions you've held and I know of course there's this sort of confounding variable of your career has gone, proceeded sort of through time and your experience level has gone up but I was wondering, when you were at FDA, did it feel like you were sort of more of a reactive force than a proactive force versus when you were at [redacted] versus when you were in your current position in industry, is the perception of FDA's either current or ideal performance, did you see it vary across your various experiences or was it sort of uniformly, this is sort of how FDA and industry work?

**Interviewee:** I would say I believe FDA was proactive at least the [redacted] was proactive. Of course when I was there in 2017 they probably, the FDA should have been considering some of these genome editing questions and perhaps they were on a level that I was not privy to.

**KP:** Okay. Do you think the perception of FDA, either in your current position or in your primary academic position, is it a similar sort of point of view that the FDA is being relatively proactive here or are they seen as more of an impediment or a hurdle or a partner or, I could list 1,000 variables sort of…

**Interviewee:** Yeah, in academia, the FDA was definitely a partner, I did work with the group that did commercial as [redacted] so we were very closely affiliated there. I would say within industry we feel that FDA is a partner, we understand that everyone needs to get it right especially in a new industry such as genome editing therapeutics.

**KP:** Thank you.

**KT:** Thank you very much. I wanted to ask you just in closing, I think [redacted] mentioned that you had mentioned that you felt very positively about the ORISE program and certainly our conversations today have been very helpful, I was familiar with it at only the most superficial level and today certainly sort of explained more and [redacted] being a concrete example of its contributions. I'm wondering just from your perspective what was important about the ORISE program that makes you feel so positive about it.

**Interviewee:** Yeah, there is a lot of really great work happening in government laboratories that does not get the kind of recognition it often deserves and I think it's phenomenal that the ORISE fellowship allows people at various stages of training to embed in those laboratories. I did software engineering in graduate school, I would say I had my greatest period of growth technically in terms of proficiency during those years as an ORISE fellow. So I really do have to credit the FDA, ORISE and the [redacted] group in particular with my development professionally.

**KT:** And is that because of the work you were challenged to do or the peers you were doing it with or both?

**Interviewee:** Yeah.

**KT:** We usually wrap up by asking any recommendations for other people that you think would be important for us to talk to and you've done that and then also if there was anything you thought that we might ask you that you think it might be important for us to know that we didn't ask.

**Interviewee:** Yeah, so recommendations, I do want to stress speaking to [redacted] or [redacted] and I can follow up with [redacted] once I have their last names, would be really great because they would have the regulatory perspective that I lack, they've also been at [redacted] for decades each and would be better be able to answer the longer term and vision of [redacted] questions. And then as far as software developers, full time [redacted], part time, not part time but no longer there, [redacted], he was probably one of the most senior software engineers there and in terms of \_\_\_\_\_ 00:51:49 being a professional group, [redacted] ago but still phenomenal work and [redacted]. [redacted] is actually very friendly and might be a good perspective on somebody who wasn't a software engineer but ran the program for the researchers.

**KT:** And how do you spell his name?

**Interviewee:** Yeah, [redacted], her name is [redacted]

**KT:** Great. Well that's very helpful. Anything you thought we were going to ask that you think we should have?

**Interviewee:** I think that given my lower level at FDA, there isn't probably much else you could have asked, I feel like we were kind of-- the bottom of my barrel of FDA knowledge unfortunately so I think wish I could have been more helpful and then similar with my positions at [redacted] and not in a regulatory finding group or makes regulatory claims often. But no, other than, thanks for your time, I hope this was helpful and I hope this research does something to <audio cuts out 00:53:20> ORISE fellowships and build up respect for our much maligned regulators. That's all.

**KT:** And just to assure you of the usefulness, it's valuable for us to talk to people at all different levels of industry and of the regulatory body because it allows us-- you have different perceptions and oftentimes people who have been in a position for a long time in an affiliation have overlooked where there may be a hole or overlooked, it might be something that's common to them that the people in the lower down position in the hierarchy think is very important. So I think there are a number of perceptions that you had here and examples that are super, super helpful, so there's certainly no apologies necessary and only thanks on our part for you and your son giving his time. There were a few noises from your son and I'm not sure, perhaps we should get your consent on his behalf for having him be recorded as well. <laughs>

**Interviewee:** Yeah, if you need it I could probably grant that although I'm not sure how you would even transcribe the groans he makes.

**KT:** Right. <laughs> Well that's your challenge, not ours.

**Interviewee:** I don't think that's my challenge, I think that's [redacted] challenge <inaudible 00:54:46>.

**KP:** We use a professional transcription service, usually they just put <inaudible>.

**KT:** I'm at the challenge being day-to-day trying to translate what the younger generation's noises are.

**Interviewee:** He only has three functions at this age so even if I get it wrong, we'll quickly arrive at the right solution.

**KT:** Exactly. It looks like he's enjoying one of his main functions, sleeping right now.

**Interviewee:** Exactly.

**KT:** Very good, well thank you so much, I think we'll end now and we will be, just our plan, it'll be transcribing and analyzing the interviews over the next probably through the spring and then have the redacted transcripts for review sometime, what do you think [redacted], people in May?

**KP:** Sort of May or June piece is when we're looking at sort of doing the big push of getting the redacted transcripts out, letting everyone review them and provide comments. I do want to confirm [redacted] that the email I used to invite you to the [redacted] just [redacted] is that okay for contacting you?

**Interviewee:** That's preferable, yeah.

**KP:** Okay. The reason I ask is we are planning to send those transcripts using a sort of private Google Doc link so that only you could access them but I of course have to have an email they can use for that so since we originally reached out through in mail I wanted to confirm that that was the right email to use. But I think we're on board there.

**Interviewee:** Great.

**KT:** Great. And then we hope to submit some manuscripts for publications starting sometime over the summer, so we'll keep you advised of how things progress and the next thing would be the transcripts and of course if any time you have any questions or comments you have [redacted] and my email, feel free to contact us.

**Interviewee:** Sure, thank you. I do have one additional question.

**KT:** Sure.

**Interviewee:** Is it at the point that I receive the transcripts through the Google Doc link that I will have to say yes or no on the redaction or does that come afterwards?

**KT:** Well that would be a point where you could review it and then if you wanted to make other edits or say, "With these edits, I would approve it," or, "I approve it as it is," or, "I can't see any edits being made that would-- " or you might just say, "I can't take the time to make the edits but if you just generally-- " I mean there's some things that are obvious, you've mentioned a name of a company and some other things that we would take out, you've mentioned a particular educational background, we would delete anything referring to specific institutions you went to, those type of things would just right off the bat. But there may be some other, "This section, either take it out or cut it for these purposes," you may comment back on that. But that would be the time when we'd be offering you a transcript asking you if we could post something like this and that you would then let us know that that's the case.

**Interviewee:** Right. I'm asking you because some of the projects at FDA are still being written up so I'm not sure if the leads on those projects would want them being discussed in a manuscript that beat theirs to publication.

**KT:** Yeah, these would be just the transcripts themselves and so they wouldn't-- I guess, I mean they would be published in the sense that they would be on a publically available website, so they would be publically accessible, but that's the time, exactly the time of thing where we would look to you to say, "This should not be made public," and that's why we want to make sure you have plenty of time to review and decide and you're not in any way feeling pressured that we have to-- and, you know, you have a child, there's all this other stuff, you might say, "I can't get to this for a month," and that's fine, we can-- you won't be holding anything up by some type of response like that as well.

**Interviewee:** Great, okay. All right. Do reach out to me if you cannot find any of the peoples whose first names only I rattled off, I am going to get going. So just email me if you have any follow-ups.

**KT:** Right. Thank you so much and thanks to your son.

**Interviewee:** Yeah, he was a sport.

**KT:** Okay, bye-bye. Yeah, I know he was great, thank you.

**Interviewee:** Okay.

**KP:** Thanks.

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