DOCTOR'S CROSSING
CARPE DIEM PODCAST
TRANSCRIPT

Episode 30 - What's it like to work for the FDA

With guest Dr. Andrew Mulberg

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HF: Welcome to The Doctor's Crossing Carpe Diem podcast. If you're questioning your career in medicine, you've come to the right place. I'm Heather Fork, a former dermatologist and founder of The Doctor's Crossing. As a master certified coach, I've helped hundreds of physicians find greater happiness in their career, whether in medicine, a nonclinical job, or something else. I started this podcast to help you discover the career path that's best for you and give you some resources and encouragement to make it happen. You don't need to get stuck at the white coat crossroads. So pull up a chair, my friend, and let's carpe that diem.

Hello, hello and welcome back to The Doctor's Crossing Carpe Diem podcast. Today, we're talking about an organization that has been in the news almost daily during this pandemic. We are going to be talking about none other than the FDA. Even though the FDA is very familiar to us, it can still feel like a black box when it comes to the question of "What would it be like to work there?"

I've been looking for someone to open up this black box and help us peer inside. Thanks to a great referral I have just the right person. His name is Dr. Andrew Mulberg and he is a board-certified pediatric gastroenterologist, who has not only worked at the FDA, but in pharma and academia as well.

In this episode, Dr. Mulberg shares very useful and insightful information about working for the FDA and why he has such positive feelings for this organization. You'll hear thoughtful and concrete advice you can use to further explore and consider a career at the Food and Drug Administration. In addition to the specific details and information, you will also gain a sense of what ultimately motivates Dr. Mulberg to do the work he does in his career, bringing new drugs to market. It is a true honor to welcome Dr. Andrew Mulberg to the podcast.

AM: Heather, it's a real pleasure. Thank you for asking me.

HF: I think you're the perfect person to help us learn more about the FDA, because not only have you worked extensively at the FDA, but as I mentioned in my intro, you also have a lot of experience in industry in the pharmaceutical world. I'd love it if you could tell us how you got into working for the FDA and a little bit about your background.

AM: Sure. It's my pleasure. I am a pediatrician and board-certified pediatric gastroenterologist and hepatologist. I was fortunate to do my training at the Children's Hospital of Philadelphia. One of the foremost children's hospitals in the country, if not the world, where I was really able to participate, learn from great mentors and develop really more of my passion for taking care of children while they often fight certain diseases.

And this experience at the job, really launched me to pursue a career in pediatric gastroenterology and hepatology at the medical center where I really pursued further training in those specific areas and did specific basic science training in membrane,

transport and translational medicine. And I really developed a keen interest in the development of drugs really at that early point.

But I first entered academia at the University of Pennsylvania and joined the staff at CHOP as a fellowship director and mentored many young fellows in pediatric gastroenterology, had an active research laboratory in cystic fibrosis and continued my clinical care of children.

And during that point, as anyone tries to transition through their professional development, I initially thought I would be remaining in academia, but became very enthralled with the need of developing proper therapies for children. There were so many diseases for which there were no therapies and children have always been referred to as therapeutic orphans, first by Dr. Shirkey in the 1950s.

And what that means is that most drugs, if not the great majority have never been tested for safety and efficacy in children and in the world of pediatric gastroenterology that's often a very high percentage of those drugs that use them as referred to as off label.

So, I pursued my initial career in pharmaceutical development at AstraZeneca and Johnson and Johnson developing therapies for approval in cystic fibrosis and pediatric reflux. And really through those interactions with the Food and Drug Administration I was struck by the fact that there were no gastroenterologists on staff in the division of gastroenterology and nutrition. And I therefore really decided to apply to the Food and Drug Administration and try to very emphatically try to serve as a source of education and professional experience to help drive more efficient drug development, not just in children, but adults. So, I applied on the traditional way, usajobs.gov, one of the most difficult websites one could ever imagine.

HF: I can second that from everything I've heard.

AM: And I applied for the director level job, got interviewed and really went to the highest level. There was a choice between me and another person. Eventually, I was told that they chose the internal candidate, and it was disappointing, but I pushed on and persevered. And six months later, they called me back and asked if I would join. And I told them I would, and I would join really as the division deputy director, besides that I'm at this point, almost 15 years of postgraduate experience. And I really wanted to make myself available in the most expedited, most efficient way of really effecting change.

So, I joined there and worked there for six and a half years before I transitioned back to the pharmaceutical industry to pursue rare disease drug development in a company. And I recently have transitioned to another company pursuing gene therapy for children in neurodegenerative disorders.

HF: Well, you have a wealth of experience in this whole area and for a physician who's thinking about the FDA, what are some of the roles that they might be able to have and what might they be doing in an entry-level position?

AM: Well, the FDA is a megalopolis, frankly, it's the largest institution that I've worked for in my own career. Huge administration of tens of thousands of individuals who work in the agency. And depending on what one's professional interests are, you can really position integration into any number of different jobs.

Depending on what your real interests are, whether they are safety-related, epidemiology, clinical trials and drug development issues, one can become a medical officer in any number of divisions, which are important in the issues of drug regulation. And I believe that a physician is best suited in a division, usually having finished at least a residency or fellowship in a specific subject area. Really to provide the important,

relevant experience that allows you to become a truly critical and integrated subject matter expert.

It's not absolutely required, but if one was going to pursue any interest in drug development, for example, participating in pharmaceutical trials at a point of one's career or becoming a regulatory professional in a pharmaceutical company, I think that the best path is to pursue training at the Food and Drug Administration first, and then pursuing secondary career options.

HF: Do you recommend a certain number of clinical years before a physician tries to go to the FDA?

AM: I would. It's not mandatory for sure. There are a number of people I've met who've had really only post-residency training, no fellowship. I'm just offering my opinion. You can go in as a generalist and it doesn't have to be a pediatrician or internal medicine. It could be family medicine or any number, neonatologist really, there's an office of pediatrics. So, it really depends on really what one's professional experience is, but the number of years only influences, probably, your entry-level position at the FDA, as it would in any other kind of corporate or business environment.

HF: And you have a background in research, you have also experience in pharma. If a physician has been a straight clinician, say for example a family practice physician who has been working five to seven years and outpatient medicine, would he or she need to have something additional in terms of research or clinical trial experience to be able to be a competitive applicant for the FDA?

AM: Yes. I will start up by saying that the FDA, I believe is still desperate for smart physicians. The level of training that a physician undergoes, even without sub-specialty training, I think exemplifies the level of diligence that's really requisite, but depending on what positions are being either of interest or available may require additional requirements. I

would say that having at least an understanding of basic, say if one wanted to become a medical officer in a division, then one would ideally have at least some exposure to understanding safety reporting at any amount of preliminary exposure to clinical trials, which often happens in a fellowship trained individual, less likely in a pediatric or a internal medicine or family practice residency experience.
But as in my own tenure at the agency, I think there are people with any varied level of experience, masters of public health, masters of epidemiology, PhDs. There's really no rule, but I do think the more experience is always the better to be competitive.

HF: That does help. In another podcast (episode 27) that's coming out, we drill down on things that the physicians can do while they're actually in practice to increase their candidacy, for pharma and it could also apply to the FDA. So, we talk about a lot of those things. So, I won't take up time on this podcast for that, but just let the listeners know that that is going to be available as well.

I had a question the other day from a physician who's looking at the FDA and one of the things she was wondering is "What exactly I'd be doing day-to-day and how do I know if I'd like it or even be good at it?" Can you give us some insight into answering this question? I know it's a big one and there are different roles for sure.

AM: Yeah, it's a tough question because everyone wants job satisfaction, regardless of where one tries to pursue it. And I think that the most important way to enter that question is that I would say of all the different, arenas of medicine and translational work that I've done, I would say that the FDA's major factor of uniformity and a real concordance across members of the agency is a devotion to public health.

The FDA is an arm of public health. It is commissioned and mandated by Congress to protect the well-being of the American public. And I think that if one has a keen interest in either public health or in the mission of medicine as we all have always envisioned as caring for others, then I think your role at the FDA would be equally fulfilling. Again, the

FDA is probably the penultimate example of collaboration, because in order to approve a drug, there are so many key personnel that are needed for the review of one application from one company.

And the onus is really upon everyone to really perform their own functional area work. And then to really have the integration of all of that together to make a decision whether the drug is proven as effective and safe for the American public. Because there are obviously well-known examples of really how the FDA has been created often on the backs of children, unfortunately. The elixir sulfanilamide tragedy, the vaccine's initial diphtheria toxin, and thalidomide. I think these are all examples of the impact that you have, and can make in the agency, even though these were necessarily touted as one individual effort. We all know that never is one individual always responsible for a success.

HF: I really like how you framed up working at the FDA as public health, because when you talk about it, it's very obvious, but I don't think we necessarily think of going into public health and then, "Oh, the FDA is a place I could work". So, I think having that as a mission of really wanting to care for people and help protect them in this agency helps people answer that question of "why? Why do they might want to do this?" And that can help translate into enjoying the day-to-day work. Could you give us an example of what a day-to-day experience might be for a medical officer in one of these roles?

AM: Yes, absolutely. I think that a medical officer is one of the key components, frankly, of how a review will ultimately be returning a decision about whether there has been proof of efficacy and safety. The medical officer is a coordinator often as a team leader, but the medical officer is directly responsible for review of the clinical trial data to interpret and to understand both, the relevance and the integrity of the data, to support a decision that supports efficacy and safety. And there is a tremendous amount of understanding science and translational medicine involved in that, in understanding clinical trials and statistics.

I see the medical officer being a role that if one really enjoys the multiple elements that integrate both basic and clinical science into making decisions that benefit us as human beings in our country then I think there's no more fulfilling a role that isn't filled with lots of work and energy and requires motivation and spirit. I would say that it does because the FDA as we discussed is often desperate to find individuals that are really apt to filling that role and responsibility, which to me is one of the highest of importance, because if you think about the impact of a decision, it impacts more than just one, it impacts the health and the wellbeing of our country.

HF: It's obvious that this work that you do, Andrew, is very much connected to who you are and your values. And something that we really talked about before we started recording, which is this love of children, which really comes through in speaking with you.

AM: I would be lying if I said that I would rather work with adults than with children because children have an energy and a spirit and an innocence that is just, for me, infectious. And if we remembered what Robert Fulghum spoke about, what I learned in kindergarten, but forgot, I think we'd have a better world.

Children are a spirit and a motivating force for me. And there is no higher honor than to have cared for children, especially at times when they are suffering, and potentially even may pass and die from a disease. But it's the motivation for me that I believe that we are only one generation of many generations to come and we really need to support our children more than any of our part of our population.

HF: Well, they have a wonderful ambassador in you, and I'm sure in the work that you've done you've saved a lot of lives and the work you're doing will continue to save more lives. So, thank you.

Now, we're going back a little bit more to the day-to-day role. Could you give us a picture of sometimes how the time is spent? Some of it is spent reviewing documents on the computer and then meetings and then maybe doing some presentations. And again, I know it's variable, but how might that time be spent during a day?

AM: Now with the impact, especially of COVID, the FDA, like many businesses, are remote. So, the love of our Zoom meetings and our teleconferences is really even more accentuated. But when I was at the FDA, pre COVID, really, we spent the day in any number of meetings, either focused on the sponsor meeting, or in the preparation for the sponsor meeting in which the team would be responsible to answer the questions provided by the sponsor as part of their application. And that will often be at least one hour or an hour and a half meeting.

For a medical officer a lot of the day is spent really on data interpretation and writing up of interpretations and preparing for the multiple steps in the review process engaged or approval of a drug. This is a very organized process, which takes anywhere from 10 to 12 months, depending on the level of priority of the application.

So, even though that seems like a long time, when the application comes in with really the equivalent of thousands or tens of thousands of pages provided electronically, there's a huge amount of effort and time in review, especially for young medical officers who don't have the experience to really understand initially the language that's required from statute, regulation, from legal issues.

So, really, it's a voyage into a really interesting morass of data. But when you finish the job, there's a pride that I think doesn't come from many other positions, because what you have done is participated in making something, likely to improve the quality of life, the wellbeing, and the health and safety of an American citizen.

HF: That's a tangible result. And we're all seeing it today with how the FDA is in the news, involved with the COVID vaccine and having to expedite things, and also try to keep the public safe at the same time. That's a fine balancing act.

AM: I agree. And I think especially when you see that necessarily expediting vaccine development doesn't necessarily remove the risk and you see that from the recent announcement of at least several vaccines that have been complicated by a serious adverse event. One that was not demonstrated in the thousands of patients that one was studying for the initial approval of these vaccines.

And I think that the relevance of a medical officer job, I think cannot be underscored, but as equivalently relevant to the people who do chemistry and manufacturing and statistics and pharmacokinetics, and any other scientific component of the review.

HF: One of the things that physicians wonder about the FDA is what is the difference between pharma if they were considering going into the FDA versus pharma or FDA first, and then pharma? What is a good way to think about this?

AM: Well again, it's very interesting because I've done all of the sectors, academia, pharmaceutical or industry and the FDA. And I would say that they're all partners in the issues of developing drugs and they all have different components of the algorithm and they each have their own bakeries and their own complexities and their own nuances, some wonderfully exciting and some boring, but it's no different than really any other job.

I think that to me, they're all parts of an equation and I've enjoyed really all spheres of what I've done, but for me personally, I think the greatest opportunity for impact and being a change agent is in the FDA. But I think to go to the FDA, then going to pharma will be equally as important as going to pharma and then to the FDA. And I did the

change transition from the industry to the Food and Drug Administration and then back. And I think I'm a different person growing from each of those experiences.

HF: I'm curious, you hadn't mentioned how at the FDA you felt there's a greater chance for an impact. Can you talk a little bit more about that?

AM: I think what you're doing is that you're working on multiple drugs when you are a medical officer. When you're a pharmaceutical physician in a company you're often working just on one drug at a time, maybe two. But when you're a medical officer, your breadth of experience will be really required to often do multiple things. So, you're having a tremendous increase in diversity and exposure and that may appeal to some and maybe not others. And that really becomes a personality issue as well. I mean, do you enjoy working on multiple topics at one point, or do you really prefer to work on a concentrated topic to the end? And I think that if you're the former the FDA medical officer job would give you the diversity. In pharmaceutical medicine, you'll be more waylaid into a really different kind of position. And one that's likely more controlled and more regulated.

HF: That's a helpful distinction that you made. When a physician is thinking about applying, you mentioned you went through the usa.gov site which is very challenging. I've also heard that in order to get into the FDA, you need to know somebody. What would you say about those two different approaches?

AM: Well, I would say that it never hurts to know anyone in any position for business. That's just really more to me functions as a reference and as a person who can speak on your behalf, but because the FDA is a government agency and there's strict rules that are likely to impact on human resource-related legal issues, it has to be a very standardized process. I don't believe that you need to know someone. I didn't know anyone at the FDA when I applied. It's an onerous process, which probably hasn't gotten easier over

time. But I think once you do that, it's one of those, maybe that's part of the test - Can you get through the website?

HF: All right. The gauntlet.

AM: If you do it, at least you must be somebody who's able to jump through it.

HF: Yeah, exactly. Are you able to talk a little bit about some of the perks in terms of flexibility at the FDA versus taking a bit of a lower salary that they might get if they went into pharma?

AM: Well, I would say that from a salary perspective of the FDA is trying to be more competitive. I don't know where they are in terms of salary structure compared to an introductory medical officer in pharmaceutical. You clearly won't get stock options at the FDA and have the same bonus structure. Bonuses don't exist at the government level, beyond maybe nominal, $100, $500 or something like that.

There used to be the way we gave opportunities for recognition. They were called Time-Off awards, but a Time-Off award to me is equivalent to money, right? Because if you don't have to come in, it doesn't have the same impact. So pharmaceutical development companies obviously offer different financial stimuli, like short-term and long-term options in their stock. So, there's a different financial narrative that exists there.

And also, I will say that if one joins the agency after having or even before one entered the industry, has an extensive stock portfolio, often there's a lot of limitations on what stocks can be held. And then the higher you go, it's an issue of conflict of interest as one could imagine.

HF: I have heard from physicians working at the FDA, that they really like the flexibility. It's also a role that tends to be really great if you're raising children, you have a family. If someone comes into the FDA, is it often possible that they can keep advancing in their career and try on different roles?

AM: Within the FDA, there are opportunities that allow you to have a rotation in a different place. And definitely you'll have to get approved to do that, to work in a different unit, different area. They're called details. But that's often how the positions are fulfilled, usually with internal people, by having internal people to do the details. Not to say that the agency doesn't want people from the outside, they clearly do because there's more than enough lead, but there's always opportunity for advancement. I think that the agency is currently remote because of COVID. When it returns, I think we're all wondering when life returns to normal for all of us. So, this is a difficult time, but I would say for the end of the year, I would be shocked if the agency isn't still remote.

HF: And I guess it remains to be seen down the road, whether those positions that often required you to be in the DC, Maryland area might have more flexibility for physicians to work remotely.

AM: Right. I think everyone's working remotely currently, even when I was there, I was part of the mantra. And I think that really what one finds that when one does a hundred percent remote, it's often not as fulfilling because you don't have a human interaction with your colleagues. And I know that I desperately can't wait for COVID to be over, to get back to normal.

HF: Amen. I know. I think you have a lot of company there. We're getting close to finishing up here and I'm wondering if you have a couple of steps that you want to share if someone is considering going into the FDA or just exploring this as a possibility, what might he or she do?

AM: I think one needs to decide whether one is committed to public wellbeing and public health. If that is something that excites you, then the FDA is the place to go, because it really affords you the opportunity to do something that you really cannot do in any other job. I think it allows you the opportunity to be academic. I wrote my second textbook while I was at the FDA. And I think that I believe that we as human beings have no limits except the limits, we put on ourselves. So, I really don't believe that there's a magical answer for you. "You gotta do what you gotta do". I think that's from the Rugrats.

HF: Very quotable.

AM: Probably doesn't reflect on anyone that's listening to this webcast because probably they are 30 years younger than I am, but, it's okay. I used to love comics. Rugrats is one of my children's favorites.

HF: I love the Rugrats.

AM: And another voice says, "You gotta do what you gotta do".

HF: Yeah. And be who you want to be.

AM: And be who you want to be. And that's what I would say. You have to decide if that's what you want to do, and then you just gotta do it. And like everything in life, not everything in life, but if you don't like it, you leave.

HF: We chart our own destiny and you've offered a lot of great information here. And I love how connected it is to a personal mission, even though I don't remember you using that word, I feel that having that bigger picture of why you're doing something can fundamentally change how you do it and also the satisfaction that you get from it.

AM: I totally agree. I totally agree. I think that one has to think beyond oneself, if one wants to go to the FDA. People who work with the FDA are not those who are selfishly interested in only themselves, but to have a much larger mission, a mission beyond me.

HF: Well, I think you're a great example of that philosophy, Andrew and I really can't thank you enough for coming on the podcast and talking about this bigger picture here of serving the public. So, thank you.

AM: Yeah, my pleasure. It's been a lot of fun.

HF: All right. Well, I just want to say goodbye to the listeners too, and let you know that I look forward to seeing you in the next episode. And don't forget to carpe that diem. Bye for now.

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Podcast details

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