Announcer: [00:00:03] Welcome to the Science is the Best Medicine podcast with your host Dr. Abhinav Sharma. Exploring the pressing scientific and health care issues of our time.

Dr. Abhinav Sharma: [00:00:14] Hello everyone. Thank you very much for joining us today on the Science is the Best Medicine podcast. I'm your host Abhinav Sharma.

Dr. Abhinav Sharma: [00:00:22] Today we'll be talking with Dr. Mona Fiuzat, the chief scientific adviser to the FDA Commissioner. You may have heard of a lot of breakthroughs happening in science, whether it's treatments of heart attacks, or treatments of cancers, but often it takes a long time before these breakthroughs actually are used in routine clinical practice. Why exactly does this happen? And what are some of the reasons for this?

Dr. Abhinav Sharma: [00:00:46] Today Dr. Fiuzat will be giving her insights as to the scientific process, and why it could take so long for some discoveries in innovation to actually be used in day-to-day practice. Now also, Dr. Fiuzat is a very interesting person, given her role at the FDA. She's going to give us a bit of a behind the scenes look at what exactly happens at the Food and Drug Administration.

Dr. Abhinav Sharma: [00:01:07] What exactly do they do? And, what does a role in the regulation of drugs in other devices? In addition Dr. Fiuzat is the executive director of a very large academic journal called *The Journal of the American College of Cardiology-Heart Failure*. She'll be giving us a bit of the behind the scenes look at what happens at a major academic journal. Let's dive into it.

Dr. Abhinav Sharma: [00:01:30] So Mona thank you very much for being with us on the podcast today. Why don't you tell us a little bit about your background and what exactly it is that you do right now?

Dr. Mona Fiuzat: [00:01:40] Sure. So I trained as a pharmacist in Atlanta and I went from there to work for the pharmaceutical industry in clinical trials. And that led me to 15 years of working in clinical trials. I then went over to work as a clinical pharmacist at the V.A., and one day Mike Bristow, who I'm sure many people know, came to give grand rounds about pharmacogenetics and heart failure. So I spoke with him quite a bit. I was very interested in what he was presenting, and he recruited me to a startup company where we filed the first pharmacogenetically targeted NDA for a heart failure drug which is a beta-blocker that's currently under trials, undergoing trials. So from there I was recruited to Duke to expand the pharmacogenomics program and work with the heart failure research team. From there I went to the FDA to work with Dr. Califf. That's 30 years in a nutshell.

Dr. Abhinav Sharma: [00:02:37] Well, it definitely seems that you've transitioned a fair amount from the pharmaceutical industry, to clinical pharmacists, to academic position, and now the government. What has influenced your decision to transition from all of these roles?

Dr. Mona Fiuzat: [00:02:50] Yes. So honestly the biggest factor in these decisions has been the person you know has been recruiting me, so Mike Bristow was a huge influence, and really my mentor in pharmacogenetics and heart failure.

Dr. Mona Fiuzat: [00:03:02] Chris O'Connor, who you knew was also a big influence, and wanting to do more clinical research, and work at Duke. And then this position now was this amazingly unique opportunity to work with Dr. Rob Califf who mentored me a little bit at Duke, but also the opportunity to work with the top of the agency with someone as transformative as him I thought was something I could not pass up.

Dr. Abhinav Sharma: [00:03:26] Well, definitely sounds like a lot of phenomenal people that you've had a chance to work with, and so can you tell us a little bit about what you do at the FDA, and how is this role different than some of your previous clinical and academic positions?

Dr. Mona Fiuzat: [00:03:40] Sure. So this is a really unique position and one that Dr. Califf personalized for me, utilizing my skill set, and it is supporting Dr. Califf academically, scientifically and helping to achieve some of his priorities in a very short time. As you may know, he's only been the commissioner for less than a year, and I just started last November so I'm coming up on my one year anniversary.

Dr. Mona Fiuzat: [00:04:08] A lot of what we do is still academic, doing a lot of writing, disseminating our information to the public. Making sure people are aware of what the FDA is doing. Some priorities are medical staff recruitment, commissioner symposia, and CME for the medical staff, and then one of the really unique programs that Dr. Califf has implemented is getting together stakeholders in various therapeutic areas. And this is one of my big projects, I have helped to put together stakeholder meetings with various therapeutic societies, and patient advocacy groups, and we've done cardiovascular, endocrine, renal, pulmonary geriatrics, Alzheimer's, mental health substance abuse. So, quite a wide range of various therapeutic areas, and we're going to be ending the series with some general health care professionals such as the AMA Pharmaceutical society's nursing surgery dental, and it's been hugely successful really bringing them to the FDA to talk about their priorities and also how they can engage the FDA in making sure their priorities get addressed.

Dr. Abhinav Sharma: [00:05:27] That seems like a very substantial portfolio of work that you're doing, just taking a step back in terms of some of the things you mentioned that the FDA is holding these stakeholder meetings. Would you mind talking a little bit about why this came about, how it came about, and what is the need for this type of engagement?

Dr. Mona Fiuzat: [00:05:44] Sure. So I think in the past, the FDA had an image that it was the FDA against their world, really. You know that they were a roadblock to innovation, and assisting in moving the needle on development. And so Dr. Califf really has tried to change the paradigm of what the community thinks the FDA is doing, and what we should be doing. And so he's brought together these large societies, and patient advocacy groups to hear from them, where they see the FDA's role in helping them achieve their priorities, and also how to engage the FDA going forward.

Dr. Mona Fiuzat: [00:06:26] So it's not just a one off meeting, but a continuous dialogue between the FDA, and the societies, and perhaps in turn from suitable companies stimulating innovation and growth in each of their therapudic areas. So it's been wildly successful and we're working on a white paper now that incorporates some of the discussion from the cardiovascular, pulmonary, renal and endocrine, so stay tuned for that paper, I think it will be of real interest.

Dr. Abhinav Sharma: [00:06:55] Well that's absolutely fantastic. And then even taking a further step back, when people hear FDA they mostly think about drugs. What exactly does the FDA do, and how does that affect the daily lives of Americans?

Dr. Mona Fiuzat: [00:07:08] Well this is a great question Abhinav, and I think most people think about drugs, but many people don't realize that the FDA regulates 25 percent of all products that impact the global economy. So it really has a huge impact on not only public health but the economy and where these diseased states and innovation are going. So drugs of course are a big part of the FDA. But we also regulate devices, biologics, veterinary products, cosmetics, the nation's food supply, which is a very big role, and tobacco.

Dr. Mona Fiuzat: [00:07:46] And one of the things that people may not realize is that the FDA understands that we need regulation without stifling innovation, and they really have tried to play a very big role in promoting innovation while ensuring the safety of Americans.

Dr. Abhinav Sharma: [00:08:03] OK. So you seem to have a huge breadth of experience in a number of different fields, and you're also heavily involved in the medical editorial field as well. Through your association with the *Journal of the American College of Cardiology-Heart Failure*. Would you mind telling us a little bit about that role, and how does that intersect with your role at the FDA, and potentially your previous role as an academic scientist at Duke.

Dr. Mona Fiuzat: [00:08:27] Sure. So *JAC-Heart Failure* has been a huge passion for me, and we started the journal about five years ago as a spinoff of the *JAC* family. And this has really been a labor of love, myself and the associate editors really enjoy having our calls, and everyone says that's the best part of our week, it's a lot of work, but it really is an amazing experience interacting in the journal space. So a lot of people don't realize how much work goes into a journal, there's a lot that happens behind the scenes. And so as Executive Editor I support the Editor-in-Chief. I handle a lot of editorials, other papers, I work closely with authors, reviewers, associate editors, and then we have a whole slew of other things that need to occur such as selecting the line-up, selecting social media, press picks, CMEs. And then as you know Abhinav, you were part of our *JAC-Heart Failure* fellows program. This was unique to our journal, it was an idea of Dr. Connor's, the Editor-in-Chief, and I think it's been really well received, really helping train the next generation of authors and reviewers for a journal, which I've been in charge of that program, and so those are all different parts of things that occur at the journal in addition to reviewing many many papers.

Dr. Abhinav Sharma: [00:09:58] Okay. So you definitely see in science from many different aspects both from the pharma side of things, as a clinical pharmacist at the V.A. through Duke and now at FDA, and also you've seen the editorial process, and all the science coming through JAC heart failure. We do hear a lot that it takes a very long time for science to advance, when discoveries are made at the basic science level, all the way into going into drug development, or advances in humans. What are some of the reasons why it takes such a long time for advances to occur especially in the field of disease treatments and cures?

Dr. Mona Fiuzat: [00:10:36] Yes, so this is a really critical issue. And I think many people have heard Dr. Califf talk about this as a priority in terms of changing the paradigm of how we do research because it clearly takes far too long, it's too expensive, and it's not working in terms of getting new developments to patients quickly. So it's not only the approval process but also implementing into clinical practice.

Dr. Mona Fiuzat: [00:11:05] And so we've recently written a paper about the reduced pipeline for cardiovascular drug development, and how many drugs don't make it out of Phase one and Phase two, which is perhaps discouraging to companies not wanting to invest. So we really need to change this paradigm and make research more efficient, perhaps utilize technologies and the new medical system, like electronic health records and health system networks to contribute data to generate evidence, but still maintain the quality of evidence, and the level of evidence that we need to get therapies into practice.

Dr. Abhinav Sharma: [00:11:51] Okay. And so you mentioned making studies more efficient and maybe leveraging electronic health records. Can you talk even in very general terms, how can an electronic health record make a trial more efficient, or how can that actually be used in the context of a clinical study?

Dr. Mona Fiuzat: [00:12:08] Right. So this is, Dr. Califf and I wrote a paper in *JAMA Cardiology* on this very topic, about how you actually would go about doing this, and it is going to take some work to understand how we use big data, making sure that fields in electronic health records are standardized, and can be used to collect information, but also being able to utilize evidence from the real world, and that is, in many critical trials we don't study enough elderly patients, or patients on dialysis, or patients with all kinds of comorbidity, who are normally excluded from clinical trials. So using big data allows us to see what is happening in the real world, understanding if there are subsets of patients that may be benefiting from a therapy, or be harmed by a therapy. And so it really adds to our level of understanding, how drugs should be used. That goes beyond a company label.

Dr. Abhinav Sharma: [00:13:13] So it's very interesting you mentioned that because it almost feels like there are two worlds when you look at clinical studies, one is that of the trial which is very controlled, very specific in terms of the population that it's being used, or the population of the drugs being studied, and then in the real world as you mentioned which is far more complicated, there are patients who are older, many comorbidities, things which may not have been studied in the trial itself. Do you feel then that, or is the direction of the FDA moving where you could potentially get drugs approved just using trials launched from electronic health records? Is that the way that the future is going to move in terms of doing clinical studies?

Dr. Mona Fiuzat: [00:13:54] Well, we're a long way from that and we definitely recognize the value of a clinical trial. However there could be a number of other utilities for electronic health records such as remote monitoring, things that make trials more efficient, perhaps utilizing the big data to identify patients that can go into trials. So it's not meant to replace clinical trials, but rather to supplement our level of evidence that's being generated, and perhaps have a better understanding of what we're doing with therapies in the real world. So really meant to be supplemental I would say.

Dr. Abhinav Sharma: [00:14:37] Okay. And looking at the editorial and this commentary that you wrote with Dr. Califf, you make a very interesting point stating that a lot of our clinical practice is not really driven by evidence, and in fact only about 15 percent of our recommendations are being guided by high quality evidence. Why is this happening? You would feel that with the amount of science that's being done, we would probably have a little bit better quality evidence to guide our clinicians. Do you have any thoughts as to why this has happened?

Dr. Mona Fiuzat: [00:15:05] Well that's correct, and that's along the lines of what we were just discussing. You know most of the evidence that we have comes from drug company, frankly, promoting their drug in a certain population, utilizing the data from the clinical trial, and then it falls off a cliff. So once it gets to market, there's really not a lot of motivation from the companies to continue to invest in that product, to understand, for example, when patients should not be taking their drug. And so it's really up to the community, so it's up to guidelines, and societies, and perhaps the FDA, and this kind of ecosystem of researchers to further understand once a therapy is available, and this applies to devices and other products as well, are we using it correctly? And, can we generate evidence from electronic records, health systems, and safety databases, for example, the FDA now has the Sentinel safety database which has millions of records in it, and we can mine that data now to understand what's happening after a drug is on the market. So, these are really the waves of what we will be doing in the future.

Dr. Abhinav Sharma: [00:16:28] Now in this editorial you also do comment on the Precision Medicine Initiative. What exactly is precision medicine? I mean we hear about this term in the media quite a bit, and it's being mentioned by a lot of politicians, but what exactly is precision medicine?

Dr. Mona Fiuzat: [00:16:46] Yeah, so the Precision Medicine Initiative is a specific initiative of the president's, who launched in 2015 to really bring forth this priority of evidence generation again. And so his goal with the Precision Medicine Initiative is to enroll at least a million patients, and you may have heard Dr. Califf say this should be more like twenty million patients, and it's really to get everyone in the US to participate, to provide data to a database. You don't have to be sick to participate. Any one of us can go and participate, it's a simple consent form, a baseline exam, some questionnaires, and a baseline blood draw, and consent to use your data in the future. So it's really intended to help us understand diseases, understand prevention, understand the genetics of disease, and move that needle forward in terms of personalizing therapies and prevention strategies. So that sort of thing. So this is a really important initiative for the future.

Dr. Mona Fiuzat: [00:17:55] And there's actually 215 million dollars a year that has been resourced, mostly to the NIH, and also some to the FDA, and the national office of technology. So this is a real program that is just in its early phases, but it is being launched through the NIH primarily.

Dr. Abhinav Sharma: [00:18:14] So definitely seems like a lot of dollars are being put into this Precision Medicine Initiative and all of its subsequent studies and its utilization. You mentioned a comment on personalized medicine. What does that mean to actually have personalized medicine and what does it mean for the for the American population?

Dr. Mona Fiuzat: [00:18:35] So the term personalized medicine really has been mostly replaced by precision medicine, which is perhaps a little more accurate way to describe it. And as I mentioned, it's not only selecting the right therapy for the right type of patients, but also understanding whether genetics and certain markers may identify your risk of disease. What types of patients should be on various prevention strategies so that we aren't chasing diseases, but rather preventing them from occurring in the first place. And as you know that has a tremendous impact on the economic burden, healthcare burden, and society burden.

Dr. Abhinav Sharma: [00:19:17] So with regards to then precision medicine, is similar to your previous work in pharmacogenomics where using a very targeted approach to, at least in your case you mentioned a particular beta-blocker, where you can identify individuals who may have a specific gene or a specific protein, and then as a clinician you can decide whether or not a patient should be on drug A versus drug B, or whether they should not be on the drug at all. Is that the direction in which precision medicine is headed?

Dr. Mona Fiuzat: [00:19:44] Right. So that's an aspect of precision medicine. So there will be some identification of target genes perhaps that we may start to relate to specific therapies, but also having a genetic profile and a marker profile in every patients record. Just like you have their LBL, and their hemoglobin and their sodium. And this should really become part of the record that helps you understand the entire picture of the patient.

Dr. Abhinav Sharma: [00:20:15] OK. Now I just wanted to go back to some of the comments you talked about with regards to moving the needle, and accelerating drug discovery. You mentioned that a lot of drugs don't make it out of the Phase 1 and Phase 2 level. Is it just because the drug fails to show benefit at that point? Is it because the money is running out to do further studies? What is the major roadblock that company is both pharma and entrepreneur and academic institutes come up at that Phase one and Phase two level?

Dr. Mona Fiuzat: [00:20:42] Right. That's a great question and actually we addressed this in an editorial that I wrote with Dr. Califf and Norm Stockbridge at the FDA addressing some of the

reasons why drugs aren't making it, and why the pipeline is seemingly being reduced. So there are a number of reasons, one interesting point is that most drugs don't make it past their Phase one or two studies based on efficacy, not safety. So it's really, there are issues of planning the right end-points, understanding the drugs and to put in a plug for another series that's going to be in JAC heart failure. We've written a series of four articles called FDA in the 21st century, and it talks about initiatives that the FDA is taking to help speed innovation and development.

Dr. Mona Fiuzat: [00:21:38] So the first in the series is about devices and policies, and on the device side, they've put in place a number of new policies to make it a priority to get devices to patients faster. One such example is the early feasibility studies program, this utilizes smaller amounts of data needed to get early phase studies initiated in patients. The next in the series is on the Center for Drugs, and what they're doing on that side, and that includes things like the biomarker qualification process. And so this will be an initiative that helps to identify biomarkers that may be utilized in direct development. The third and fourth are focused on prevention. And as you know this is a huge area of focus for cardiovascular disease, and we talk about policies and tobacco as well as nutrition that are influencing cardiovascular disease prevention, such as many people have heard in the news there's new nutrition facts labeling, menu labeling, sodium reductions, sugars and trans fats. So these are all various policies that the FDA is addressing to help reduce the burden and help with innovation. And again, the first of the series will appear in *JAC-Heart Failure* in the December issue. So stay tuned.

Dr. Abhinav Sharma: [00:23:03] Definitely looking forward to that series. Although, one comment on some of these techniques to help accelerate innovation, and accelerate moving potentially beneficial drugs and devices to the public. You mentioned things such as early feasibility. We have heard in the past of drugs that have been approved and subsequently signals of harm came up, and then they were either withdrawn or the labeling has changed. Is there any risk that as we try and rapidly push things to market, and to get them to patients that we could be missing, or overlooking signals of safety or signals of harm?

Dr. Mona Fiuzat: [00:23:41] Absolutely. You know this is always the struggle for the FDA. And just to clarify, that early feasibility study is only on the device side right now. And so one of the other things that complements the early feasibility program is a new national identifier system for devices. So every device will be registered and tracked and so this is one of the counterpoints to getting devices into patients faster.

Dr. Mona Fiuzat: [00:24:08] However, our monitoring of devices and safety is also growing, and so we talk about this balance in the first of that series, and that will be coming out in December.

Dr. Abhinav Sharma: [00:24:19] OK so potentially while things may be moving more rapidly in terms of getting products on the market, the monitoring and the follow up of these devices is going to be under greater scrutiny. So if there are potentially some harmful signals, they could be readily and rapidly identified.

Dr. Mona Fiuzat: [00:24:39] Absolutely. Yes that's always at the forefront of the FDA's initiatives, is making sure that products are safe.

Dr. Abhinav Sharma: [00:24:47] Absolutely. And so one other question going to your thoughts about making trials more efficient, and more reflective of real world data. You mentioned that elderly patients patients who have many co-morbidities, or other diseases such as kidney issues or even cognitive impairment, these patients may not be enrolled in trials.

Dr. Abhinav Sharma: [00:25:09] Do you mind commenting very briefly given that you've had

experience from the pharma industry and academia and industry, why is it that these people are not being included in current trials? Is it an issue of not having benefit in these populations, or is it just that these are individuals that are harder to follow. Any thoughts or comments on that?

Dr. Mona Fiuzat: [00:25:29] Sure. That's a great point and another thing that I think the entire academic community struggles with. This was raised at all of these stakeholder meetings that we talked about, the renal group, the pulmonary group, the mental health group and geriatrics, have been very supportive of including their patient populations. However even on the FDA side while we would like to have information on those patients, it creates a lot of noise that is hard to discern in a clinical trial environment. And then we really lose signals on whether or not the therapy itself is effective.

Dr. Mona Fiuzat: [00:26:11] And so what we're proposing to do is bring those clinical trials forward in the usual approval process fashion, but use generation of data from electronic health records and other big data sources to further examine, take it to the next level, make sure guidelines are incorporating data on special populations.

Dr. Abhinav Sharma: [00:26:38] That's a wonderful point, and just to talk a little bit more about guidelines. For those of us listening who don't know, what exactly is a clinical guideline? And you mentioned that sometimes it takes a long time for evidence to get incorporated into these guidelines. Would you mind commenting on some of the reasons why that's happening?

Dr. Mona Fiuzat: [00:26:56] Sure. So the guidelines are very complex, and you know they're put together by groups people, as you know there's committees, often societies have their own guidelines committees, and these are people who pour over the evidence, usually from clinical trials, and that's been presented to them, and we developed a system that's fairly good where we can identify levels of evidence that support the recommendations.

Dr. Mona Fiuzat: [00:27:24] And so sometimes recommendations are made that they acknowledge that there's very little evidence to support those guidances, and others have very strong evidence supporting them, but it still takes quite a bit of time to have data reviewed. Have it discussed within a committee and then incorporate it into a publication which we know as the guidelines that come out.

Dr. Mona Fiuzat: [00:27:51] Recently there's been several changes to the heart failure guidelines of new therapies that have been incorporated. But nonetheless when there's new therapies on the market, it's very specific to a population that has been studied because we're not aware of how the real world will respond. So for example, Entresto, and there's been some safety warnings with African-Americans, and elderly patients in terms of the potential for developing Alzheimer's or severe hypertension. And so the guidelines committee have to be cognizant of who was actually studied in the trials. And do we know if this could be applied to a broad population without harming the population.

Dr. Abhinav Sharma: [00:28:36] That's actually a great idea of what exactly a guideline is and how they incorporate data. This may be a little bit out of the scope of this discussion but is there ever any perceived bias with regards to prior affiliations? I mean when people are on guidelines there's often some concern brought up in the public that you know people are very much pushing these pharma drugs etc. you know is there a concern for that happening and how does that play into how we view the evidence?

Dr. Mona Fiuzat: [00:29:04] Of course and this is an issue with the FDA as well. It's very difficult to get people on committees and advisory groups who have no conflicts because usually those

people have then not been working in the fields. Most of the people who were really been part of the trials have received money from the companies, have received research support. And so it's very hard. You really have to rely on integrity to be able to exclude people with all conflicts that will really be doing the right thing for patients. So this is really a struggle.

Dr. Abhinav Sharma: [00:29:40] So with regards to some of the evidence that's coming into the FDA, is there a difference in how regulatory agencies will view evidence from pharma companies versus evidence coming in from academic institutions, and how does that play into some of the recommendations and the labelings that come out of this?

Dr. Mona Fiuzat: [00:30:00] Right. That's a great question, and I think that there's a perception that the FDA is skeptical of data that comes from pharmaceutical companies, and this really is not the case. The FDA has very strong relationships with the companies that bring forth developments and new products. So they really are working very hard to have meetings with these companies during their development process and guide them to have the most efficient product development system, so I think that's one of the new novel shifts in people's thinking, is that the FDA is very open to constant communication. They have a number of meetings with the development teams of the various programs, and they take it very seriously when a company comes in with new data.

Dr. Mona Fiuzat: [00:30:54] You know just as much as companies have a financial interest, academic institutions and investigators may also have financial incentives and so they view all the data, they review it carefully. They have their own statisticians and the reviewers are quite experienced in understanding data. And so you know like we talked about before, they don't want to stifle innovation but they do want to ensure that everything's been considered. And so in answer to your question, I don't think they view that data any differently coming from a company versus an academic institution. It is all important data that's considered.

Dr. Abhinav Sharma: [00:31:35] Although can one say that you know this very close relationship between FDA and pharma. I mean people, especially some in the general public may be hesitant to hear that that there is such a close relationship and there may be some potential for bias. Or, a potential for products or drugs moving through when they may be have some reason to be paused in terms of the approval process. Can you talk a little bit about the checks and balances that may be there in terms of what exactly does the FDA do when reviewing this type of data?

Dr. Mona Fiuzat: [00:32:06] Right. Absolutely. Well the FDA is under very strict policies regarding conflicts of interest, and so they do assure that reviewers have no financial gain from any approvals that take place, or decisions that may take place and yet they understand that most of the innovation most of them are that the resources that are going towards drug development, and discovery or product development is going to be coming from pharmaceutical industry and device industry and product industries, and some of these products are really not very financially lucrative. And so the FDA is really working with the companies so that they are not wasting time and resources to come out at the end with an unapprovable product.

Dr. Mona Fiuzat: [00:33:03] So it's not so much that they're promoting the product to be approved but they're having meetings, they're encouraging meetings early in the development process so that the companies are utilizing the most efficient pathway to approval, or at least review.

Dr. Abhinav Sharma: [00:33:21] And as you mentioned there is a very strict guidance with regards to who eventually from the FDA reviews that evidence to make sure that is no conflict of interest. Is that right?

Dr. Mona Fiuzat: [00:33:30] Absolutely. And you know it's surprising that many of the medical

staff and the medical reviewers at the FDA have been there for 20 and 30 years, so they've been far removed from conflicts of interests. We Dr. Califf and I have recusals where we wouldn't be able to have any influence, make decisions, speak, or do any activities that would benefit a company that we've worked with in the past two years. So they're quite strict about making sure that the people involved in the programs have no conflict.

Dr. Abhinav Sharma: [00:34:07] So Mona, as we approach the end of the podcast here we've learned a lot about the role of the FDA in terms of the approval process, how and why it takes a long time for discoveries and innovations to really reach the market. And some of the challenges along the way.

Dr. Abhinav Sharma: [00:34:25] So I really want to thank you for your time and your thoughts and we're just going to dive into our sciencey section of the podcast, so a couple of rapid-fire questions for you here. If we were to look on your music device what would be on the playlist right now?

Dr. Mona Fiuzat: [00:34:41] Wow. Well I have one list that's for my cardio workouts which is a little more hip hop and then I have another list that is my kind of calming music so I have quite a variety of music. But it's everything from Timberland to Sia, and yoga music really.

Dr. Abhinav Sharma: [00:35:02] Fair enough. And take a look at your nightstand what book are we going to find there?

Dr. Mona Fiuzat: [00:35:06] I have a lot of books on my nightstand. A few years ago my new year's resolution was to read more books, and so I would say that my favorites are Wally Lamb books so I Know This Much is True, She's Come Undone. Those are two of my favorite books.

Dr. Abhinav Sharma: [00:35:20] OK wonderful, and what was the last movie that you've seen? And are there any that you're looking forward to in the future?

Dr. Mona Fiuzat: [00:35:27] Sure. So I just saw the Girl on the Train, which was also a book that I read and it was excellent.

Dr. Abhinav Sharma: [00:35:34] Wonderful, wonderful. Well Mona thank you very much once again for your time and your thoughts, it is very much appreciated.

Dr. Mona Fiuzat: [00:35:40] Thank you so much and I appreciate having the chance to catch up with you Abhinav.

Dr. Abhinav Sharma: [00:35:50] Today in our discussion with Dr. Mona Fiuzat we've learned a lot with regards to how and why science could take so long to bring innovations from their discovery, to their use in daily practice. To me, one of the most striking things was that it could take upwards of 10 years before major discoveries and breakthroughs that have happened, let's say in an animal lab to be brought forth in use among humans. One of the big factors in this long time is the need to balance safety with innovation.

Dr. Abhinav Sharma: [00:36:21] There have been many examples where drugs have potentially been rushed through and then signals of harm were discovered only much later on. It's people like Mona who have many hats, both in academia, in the scientific publication world, and in the FDA and government who are working really hard to balance the needs of safety along with innovation and advancing science. It's good to know that there are people like her out there who are working to make sure that the American people are safe, but also ensuring that we get the right treatments and

drugs that we need in order to make us healthier and live longer.

Dr. Abhinav Sharma: [00:36:59] Thank you very much for joining us today on the Science of the Best Medicine podcast. I'm your host Abhinav Sharma. I want to thank all of those who made today's episode possible.

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