[SQUEAKING]

[RUSTLING]

[CLICKING]

ERDIN BESHIMOV: The case study today, the protagonist is going to have to make a real decision. Do I enter that market or not? So the beachhead market is not as obvious. And I think that's another interesting skill to develop for an entrepreneur, to think about, what are the right markets for you?

Also, yesterday, I'm sure many of you caught it. John Konsin said something important, that for what he was doing and for many other fields of medicine which are specialized, you really have a very small community of specialists who are focused on that, and they all know each other. And so he said, if we can get access to three to five societies, and once we get approval, we will start talking to them. And by the way, they're in conversations now-- that's your market access.

So the case today is a different situation because we will be talking about hospitals broadly, and the case protagonist needs to think about, all right, how do we segment the market? What are the meaningful differences between hospitals if we are going to address that segment? How do we attack that? And what's more how do we really bolster our team to be able to do that.

So let's begin the case. I'm going to, again, call on you. And my first question will be to just summarize Tom Knight's background. Would you please go?

AUDIENCE: I don't remember the case.

ERDIN BESHIMOV: You haven't read the case? Well, if you have it on your phone, I encourage you to read it now. Actually, Tim, since you were up here earlier, would you summarize Tom's background for the class?

AUDIENCE: Yeah, so Tom Knight is the founder and CEO of Invistics Corporation. At the time that we meet him, his company is 15 years old, and he's thinking about what direction he wants to take it. He has an MIT background, he's an engineer, so he's got a master's degree in management science and engineering, as well as a bachelor's degree in mechanical engineering. Do you want me to keep going?

ERDIN BESHIMOV: Yes, tell us about his professional background prior to Invistics.

AUDIENCE: Sure, prior to Invistics, he worked for a company called Alcoa, which was a global industrial corporation in the business of aluminum extraction and manufacturing and then, ultimately, at Siemens. And it was while he was at Siemens that he had the idea for Invistics.

ERDIN BESHIMOV: Terrific. OK, thank you. Let's go to JP. Have you had the opportunity to study the case?

AUDIENCE: I wouldn't say I've studied it, but I reviewed it, yes.

ERDIN BESHIMOV: All right, so tell us about Tom's discovery of the opportunity for Invistics.

AUDIENCE: I think he discovered that people were pilfering drugs, but actually, that that's the main thing that I think he discovered.

ERDIN BESHIMOV: OK, great. That's part of it. Let's go to you, sir. Tell us your name.

AUDIENCE: [INAUDIBLE]. I'm from Sydney, Australia.

ERDIN BESHIMOV: Oh, how lucky you are. Yeah.

AUDIENCE: So the way you discovered it is he was in an NIH-funded study which asked him to look at--

ERDIN BESHIMOV: No, no, no, that comes later. First, first, the spark happens in the context of manufacturing.

AUDIENCE: Oh, yeah. I think he was presenting at a conference on manufacturing and inventory management. And then he got a lot of attention from the participants of the presentation. And then he pivoted as a result.

ERDIN BESHIMOV: Great. Here. Fill in the blanks, what is the opportunity there in inventory management?

AUDIENCE: Well, I'm Jorge Márquez, originally from Mexico and doing a masters at Harvard Medical School.

ERDIN BESHIMOV: That's great.

AUDIENCE: So I think, at that point, he discovered as well that that has a lot of potential to using another field. And I think he found out that, potentially, pharmaceutical industry could be the way to go. And I think that was the first direction for his company as well.

ERDIN BESHIMOV: So remember, around the time of Tom discovering that opportunity, manufacturing as a whole, as a field was going through just-in-time revolution. And many manufacturers were thinking about, how do you make manufacturing more efficient? And so it is as part of that thinking about, how do you manage your inventory and have fine-grained understanding of the variety of components that are present in your manufacturing process? That became very, very important.

And naturally, you start thinking about, well, can you utilize software to manage that process? Yeah. OK. Now, that is the beginning of Tom Knight's and Invistics' story.

Let's now shift. As you know, in the case, he begins thinking about drug diversion. I know some of you here in the group are in hospital settings.

And I'd like actually to call on you, and let's understand the problem of drug diversion. If you have examples of drug diversion, both how it happens and what medications are being diverted, that would be great to hear. Yes, please.

And you know what? I know that you know each other quite well within your teams, but my sense also that as a larger group, we still don't fully know each other. Let's just keep with the tradition of saying your name at least. Yeah.

AUDIENCE: Hi, everyone, morning. My name is--

ERDIN BESHIMOV: We know that you're from Scotland.

AUDIENCE: Yes, I'm from Scotland.

ERDIN BESHIMOV: Oh, yes.

AUDIENCE: Now, the thing about Scotland--

ERDIN BESHIMOV: Freedom!

AUDIENCE: Yes, indeed. Indeed. I didn't bring my blue face paint today, so don't worry. But the thing about Scotland is it's the sick man of Europe. So the number of opioids and substance-use disorder deaths is equivalent to Massachusetts, which makes it the highest number in the whole of Europe.

And actually, we had the highest number of HIV diagnoses as well from injecting drug use. So hence, my interest and coming over here. So--

ERDIN BESHIMOV: And why do you think that is? Doesn't relate to the case, but what's your understanding of--

AUDIENCE: So I think social determinants of health is really quite significant in Scotland. It's a poorer population. We've got poor weather. And I think actually, interestingly, in Glasgow, where there's a preponderance of peewits, the weather's poor.

There was a big translocation of population for the Glasgow shipbuilding industry. So there's issues around education. There's issues around demographics. There's issues around housing and jobs. So I think it's everything.

ERDIN BESHIMOV: Gotcha. Give us examples of drug diversion.

AUDIENCE: Yeah, so to give you my example or examples that I've seen in clinical practice, got to be careful how I phrase this, but I've seen examples of drugs including oral morphine that often is not very well controlled, often comes in a 1-liter bottle, and sits on a drug trolley that goes around the wards. Often, that's drug trolleys manned or with one nurse.

And I'm aware of incidences where there have been mismatches between the quantity of Oramorph left in the bottle after the drug war drowned and the amount that's been prescribed. And I'm also aware of incidences where pattern recognition's occurred between the nurse or people that have had control of that drug and their location in the hospital and a similar discrepancy of the drug.

ERDIN BESHIMOV: Yeah, that's very helpful, actually. Very informative. Yeah, thank you. Let's go here.

AUDIENCE: [INAUDIBLE].

ERDIN BESHIMOV: Just one second, the mic is coming. Thank you for your patience.

AUDIENCE: I'm one of those North Carolina people. This is something I touch on a daily basis as a practitioner. And suffice it to say that almost every imaginable operational technique that somebody could apply to divert opioids has been used.

What has been built is essentially a detection industrial complex to try and detect and identify the diversion and the diverters. And as that complex gets more sophisticated, the mechanisms of diversion get more sophisticated as well.

It's a little bit of an arms race. And to give you some specifics, one mechanism is that controlled substances are prescribed, checked out by a nurse or other mid-level provider. A portion of that dose is given to the patient, or sometimes none of that dose is given to the patient, and the other amount is pocketed by the practitioner.

Drugs come in vials. Sometimes people will take a dental drill, put a tiny hole in the vial, drain the contents of the vial, replace it with water, and put the vial back on the shelf. Pill counts can be manipulated. Drugs can be disappeared off loading docks.

Drugs can be disappeared in the wasting process. So for example, you may check out X milligrams, deliver less than X. You're required to waste the difference, yet you can put it in your pocket and mimic the wasting process and divert the leftovers. I could go on for the rest of the day, but I think you've got enough examples for the moment.

ERDIN BESHIMOV: This is excellent. Thank you. Very informative as well.

Let's take one more example. Yes, please, right there. No, that's right. That's you. Yeah.

AUDIENCE: Hey, I'm Jackie. I'm faculty, research faculty, and a physician at Duke. I do think it's interesting. When this topic comes up, there's a shift in the language because we're no longer talking about our patients and we're talking about our colleagues and a little bit of this bad-actor narrative and like ooh, this person is like manipulative. And the lens changes a little, and some of the compassion goes away in some instances.

And I do think I know of scenarios where colleagues or not are aware of diversion amongst their colleagues. And there is no real mechanism to report concerns in a way that's not just going to immediately land that person the office of the supervisor. So I think that I have heard about, how are there ways to develop a mechanism that people feel comfortable reporting instances that can maybe be somewhat anonymous but start some of investigation process, so more humane processes. Because I do think that we're under detecting situations for that reason.

ERDIN BESHIMOV: What about personally having a conversation with a colleague and saying, hey, I observed this. I could be wrong.

AUDIENCE: Yeah, yeah, I think that potentially happens, but I think that it still taps into the same fear that if the person even starts that conversation with that person, then they're aware now that that other person knows and that could kind of spiral into a lot of consequences where they leave that job or they're worried that that person is then going to be reactive to their knowledge, if that makes sense.

ERDIN BESHIMOV: It does. It does. Thank you. That's a great addition too. Now, let's move to the next question.

We now know that drug diversion happens. It's a fact. It's broadly known. Now we need to understand, is it a problem? Because the fact that it happens doesn't mean that it's a problem.

A problem in the sense of it's a problem for a specific stakeholder. And that problem has specific outcomes that cannot be tolerated. Therefore, a solution is necessary.

So let's talk about the impact of drug diversion. Would you like-- yeah, please. Let me. Impact of drug diversion.

AUDIENCE: Start small. One of the major impacts is on the patient who didn't get the pain-relieving drug that they needed. And that happens a lot. One of the consequences of that is that, as they ask for more pain medication, they get labeled.

ERDIN BESHIMOV: They get what?

AUDIENCE: Labeled as drug seeking.

ERDIN BESHIMOV: Oh, I see, I see.

AUDIENCE: The bottom line is they're in pain.

ERDIN BESHIMOV: So it creates a vicious cycle.

AUDIENCE: Correct. Ironically, evidence suggests that medical professionals who use controlled substances, performance is not that impaired. It can be, but they're actually relatively high functioning. And their high functioning is not that affected by misuse of controlled substances.

Go all the way up to the institutional level where it is highly regulated. There's a very large legal infrastructure around monitoring and inventory control of controlled substances. They can suffer massive penalties.

And every year, there's multimillion-dollar cases where major health care institutions get tagged with mega fines for poor control of controlled substances. So there are a number of, for lack of a better term, victims, if you will, or individuals and organizations who feel the consequence of diversion.

ERDIN BESHIMOV: When you say, on the institutional level, that organizations get fined for poor control, can you define poor control? Because here's where I'm leading it. A hospital may choose not to implement preventative measures.

It can implement investigative measures. When something happens, you investigate, you punish whoever is involved. And that would mean that this is good control over your inventory or substance management.

So where I'm leading this, do we believe that, for hospitals, accessing Tom Knight's solution is a necessity or not? Because-- certainly, a question for him. Yeah, please jump in and say your name too. And I can come--

AUDIENCE: I'm Tara Wright-- Tara Karns-Wright. I'm in San Antonio, UT Health San Antonio. And I direct some projects.

It's a statewide state-funded treatment virtual project. And we contract with a pharmacy that mails prescriptions to patients, including our buprenorphine or Suboxone. And we had an instance where our pharmacy couldn't get the supplies they needed because of the regulatory controls on the distributor that they utilize.

And so we had a huge supply issue. And when I talked to our local DEA, they said that it was because of the way that they have to-- they can only distribute a certain amount during a specific time. So there was actually a supply issue in getting treatment to our patients, as an example.

ERDIN BESHIMOV: Yeah, OK. That is helpful. Let's take one more comment over there.

AUDIENCE: My comment just goes to--

ERDIN BESHIMOV: And say your name again for everyone.

AUDIENCE: Hi, Jolene. I'm one of the previous cohort members and back here as a community member.

ERDIN BESHIMOV: It's amazing, it's amazing to have people back from last year.

AUDIENCE: Thank you.

ERDIN BESHIMOV: I hope many of you, some of you come back next year as well. Please.

AUDIENCE: My experience as a pharmacist in a hospital setting has been that, oftentimes, hospitals care a lot about liability because they get hit with a lot of if they find a problem of diversion in the system, it's not only labeling of the person as the problem employee, but also the labeling of that entire department or that entire hospital.

And how can they, from a risk-aversion standpoint-- even though it may not play out as far as impairment in long-term patient outcomes as the other participants said, there are a lot of legal outcomes around perception if it goes to a court setting.

ERDIN BESHIMOV: So what could have been a one-person problem could lead to a full organizational perception. OK, understood. Thank you.

Now, Tom-- have to make a decision on the data that they have, on the data that we're fleshing out. Should they enter the hospital market with a drug-diversion technology? They know that drug diversion exists.

They know that it has real impact on certain stakeholders. They also know that their technology works. And what's more, it is superior to existing solutions.

However, it's not clear that they should be entering the market because they were focused on the manufacturing and the pharmaceutical manufacturing segment. Their sales force is attuned to serving that market. And how you access that market is very different from how you access the hospital market.

You're going to have to redesign, among other things, your sales force. That will imply cost. And so Tom has to weigh, are the gains that we expect from the hospital market going to be sufficient to compensate for the cost of the transformation of our company?

So I want you to think for a moment and think about yourself being on Tom's team. You're making that decision. Make the case for whether they should or should not enter the hospital segment.

And if you're making the case-- and I do encourage you to also make the case that they shouldn't because deselecting certain market, deciding not to do certain things is just as valuable as choosing to do some things. And if your argument is they should enter the hospital market, I want you also to make the case for what hospitals they should target first. There are different kinds of hospitals, so make that case.

So take a moment to think. And then we'll get your perspectives. And at that point, Tom will come, and he will comment on your perspectives. And we'll have a Q&A. Two questions over here. First.

AUDIENCE: Not a question, an answer.

AUDIENCE: Yeah, same.

ERDIN BESHIMOV: Huh?

AUDIENCE: Responding to what--

AUDIENCE: Responding to your-- yeah, I have an answer to that question.

ERDIN BESHIMOV: Oh, you're done thinking. Wow, you're fast. OK. First, let's address the--

AUDIENCE: Can I give you a question first before you--

ERDIN BESHIMOV: Yeah.

AUDIENCE: I guess, so my understanding is is they are used to being in the manufacturing area, correct?

ERDIN BESHIMOV: Correct.

AUDIENCE: And in the pharmaceutical manufacturing area? Or is it in any manufacturing?

ERDIN BESHIMOV: You will hear from Tom, but I would say not just pharmaceutical manufacturing.

AUDIENCE: OK. I guess, in my head, there's a trickle-down effect. If you're already in that pharmaceutical manufacturing industry and you're monitoring there, it's, again, supply and demand. So aren't you already monitoring what's happening at the hospital level?

ERDIN BESHIMOV: That's a great question. Let's hold it for Tom. That is a great question. And is that a question or is that a response?

AUDIENCE: It's not a response. It's a perspective, software perspective.

ERDIN BESHIMOV: Well, let's do it. Give it to us. Yeah.

AUDIENCE: Hi, my name is Razi Masood, Minneapolis. I've been an entrepreneur for 12 years. And my background is software. So we've heard medical perspectives. And I thought, let me throw in $0.02 of software perspective.

So Tom sees here an opportunity. What they're doing in pharmaceutical manufacturing inventory management is totally different than what the problem is at the hospitals. The software is totally different, but there are some similarities. But it is very different, pattern management, pattern identification.

So the inventory management is we are just keeping track of what items are there, what items are needed, what items are anticipated. So that is a different problem altogether. But Tom sees an opportunity at the drug diversion problem. It's very different, identifying how the drugs are getting diverted. It's a totally different algorithm, but if you have a sense, you can apply that logic from the pharmaceutical manufacturing to the drug diversion problem.

ERDIN BESHIMOV: How do they say thank you in Minnesota? That's what I want to say because, see, what he's-- the decision is not obvious. These software approaches, packages are going to be different. That will have implications for the team. So thank you, yeah.

AUDIENCE: You're welcome.

ERDIN BESHIMOV: Well, let's reward your fast thinking. Do you mind if I go here first and then come back to you? Right over here.

AUDIENCE: Whitney-- oh. Whitney Menarchek, former counselor turned entrepreneur.

ERDIN BESHIMOV: So I'm going to enter over here. Do not enter over here. Which way are you going?

AUDIENCE: I'm going to enter. So I put a lot of thought into this. And one of the things in my experience in the health tech side has been the lack of understanding the burden of implementation and how you have to integrate it into existing workflows. So I thought about what would be the least-disruptive setting, which made me think of outpatient surgery centers because there's a high rate of opioid prescribing while also a smaller system to ask for buy in.

ERDIN BESHIMOV: OK, so that's the beachhead market that you're targeting, but you haven't made the case for why they should enter the hospital segment. That's the case I want you to--

AUDIENCE: Oh, I apologize. I thought you meant which one to target first.

ERDIN BESHIMOV: Yeah, but you're deciding whether to enter the market or not.

AUDIENCE: Oh, I see.

ERDIN BESHIMOV: What is the case-- no, no, no, nothing to apologize--

AUDIENCE: Well, I would enter it because you've already proven that you're able to do this prediction based off of the data analysis. And there's a high need. There's a lot of attention and funding and focus. And for hospitals and, in my experience, incarceration settings, the thing that will get them to take action the fastest is to reduce that liability and risk mitigation. And so if it's something that is going to not only control so that they don't have some lawsuits because of poor health, it also controls the expenses spent on the medications.

ERDIN BESHIMOV: Great, so what you're saying is that there is momentum in society. The society cares about it. There will be opportunities for funding.

You will get attention, which actually is a great argument. Excellent. Now let's go back to you. And which way are you arguing?

AUDIENCE: Both feet in.

ERDIN BESHIMOV: All right, OK, what's your case?

AUDIENCE: First of all, there's a tremendous unmet need. Second of all, you have a natural constituency. Every large health care institution has an entire staff of individuals who are paid to look after controlled substances. That costs those--

ERDIN BESHIMOV: That's a very big point. Did you hear what she said? That there are specific people whose jobs depend on being able to do this well. Thank you.

AUDIENCE: That institutional cost generally runs to six figures a year. Third is I look at ways of judging markets by saying, is there a cognizant agency that has self-organized around that market? And in the world of controlled substances, there is an entire organization called the International Health Care Facility Diversion Association, which tells you the size of the need and the potential market. The last reason is that--

ERDIN BESHIMOV: And what's more, this organization is going to be interested in promoting technology.

AUDIENCE: They're going to love it.

ERDIN BESHIMOV: --disseminating the message. Excellent.

AUDIENCE: The other is that you've got a technology around inventory control and supply chain management. I'm not an MBA, but inventory control and supply chain management, my guess may be somewhat indifferent to what it is that you're managing and supplying or controlling the supply of. So you just take your tool and apply it to a different end product. I think the leap here was in the development of algorithms to detect diversion, not just supply chain management and control.

ERDIN BESHIMOV: Yeah. And they made that leap. Yeah, excellent. Thank you.

All right, in the back. Now I want you to start shifting to making the case against it. Is your case against or is it for?

AUDIENCE: It's actually for.

ERDIN BESHIMOV: Ah, and is it a different factor than what we have on the board?

AUDIENCE: It's about building up-- actually, from a clinical perspective, as someone who was dispensing controlled substance and who understands very well the state and federal laws, how you have to reconcile the controlled Substance at every shift at the clinical level and document and then the issues with compliance. Definitely, there is a case for entering the market because all registered stuff, there are issues of liability, institution, institutional issues and then around the same medication administration and so on. Several partners that would be very interested in that.

ERDIN BESHIMOV: Excellent, all right. Thank you. Let's make the case against. Who is making the case against? Right, there we go. Thank you.

AUDIENCE: Hi, folks. My name is [? Amar, ?] coming from Boston, VA, psychologist and researcher. Case against is mainly coming from the idea, if you're using machine learning models, the training data you used needs to be informed by the kind of problem you're focused on. If the training data they already have is not actually built on diversion cases and not actually in the same system, there's no guarantee that it's actually going to predict the same outcome just because you use it in a different case.

ERDIN BESHIMOV: Yeah. So that that's a question. What was the training data?

My understanding is they did use relevant data which gave the confidence of accurate prediction. Who also is making-- please, right here in the middle. Thank you. Right in front of you, yes.

AUDIENCE: Hi, Brandi Fink, University of Oklahoma Health Sciences clinical psychologist. So I think sometimes there are entities that become socialized. So detecting drug diversion within a health care system, everybody's socialized in how to think about that. And a product that comes in that might be too innovative would have a difficult time coming into the market even though it might be more effective.

ERDIN BESHIMOV: Product too disruptive.

AUDIENCE: Yeah.

ERDIN BESHIMOV: OK. Cuts against the habits will have poor utilization. Yeah, I'll come to you in a moment. Right over here.

AUDIENCE: Joao de Aquino, physician scientist at Yale. I'm actually for, but I'm playing devil's advocate here.

ERDIN BESHIMOV: That's great.

AUDIENCE: So just being on committees and understanding how decision-making in large organizations work, even when the benefit is obvious, the financial bottom line, it can be a very lengthy and complicated process involving pharmacy, ethics committees. So if you are going to invest in this venture, those factors need to be considered. Who are the stakeholders? How complicated the decision-making processing and purchasing procedures are, especially coming from a different sector.

ERDIN BESHIMOV: It's excellent what you're saying, that the implementation process could be lengthy, complicated. And lengthy implementation process, that's cost for Tom. He will have to front the sales force while all of that is being implemented. Thank you.

Right over here, just pass it down the line. Let's make it the last comment. Then we have the case protagonist.

AUDIENCE: Todd Durniak with the HabitHalo. I was thinking about what he just said, but the commercial team that you have to put together. Can you hire them? Are they expensive? How many do you need?

ERDIN BESHIMOV: Exactly.

AUDIENCE: I think about how they're going to create their message and actually get the stakeholders in line to adopt, and then you have to implement. And then you've got the IT teams to work with all these disparate systems within hospitals. So how much is that cost?

ERDIN BESHIMOV: Right, before he can go to market, he needs to build a team. So his actual time to launch could be significantly into the future. That's a possibility, and you have to think about it in--

AUDIENCE: --money to that side?

ERDIN BESHIMOV: Here?

AUDIENCE: Money, right?

ERDIN BESHIMOV: Of course.

AUDIENCE: Yeah, it's expensive.

AUDIENCE: I'm fine. I'm just thinking like is it worth the investment?

ERDIN BESHIMOV: Yeah.

AUDIENCE: Revenue versus the expense of doing all that.

ERDIN BESHIMOV: Absolutely. Now, hold your questions, please, because I think it's really important to have-- Tom, please, welcome. Thank you for being here. Tom traveled here from Georgia.

[APPLAUSE]

So, Tom, as a first matter of business, I would love it if you could weigh in on the comments provided by the students. So thank you so much for being here.

TOM KNIGHT: Pleased to be here.

ERDIN BESHIMOV: The stage is all yours.

TOM KNIGHT: Good morning.

AUDIENCE: Good morning.

TOM KNIGHT: Thanks for including me in your discussion.

[INTERPOSING VOICES]

--the back and listen to the discussion. You're right on in terms of the challenges and the decision that the case is at 15 years after we started the company. And I'm glad-- who made the last comment about the team and the money? That was my biggest concern.

We had a successful company for 15 years serving pharmaceutical manufacturers and other types of manufacturers, and the product worked, and everything was built to deliver that product to those customers. And this was a very different set of customers. We were talking about selling it to hospitals and selling it by people that didn't know the first thing about hospitals, myself included.

So I'm so glad that you've teed up the case at this moment. And it's fun for me to get to listen to a memory of our team's discussion-- should we, in fact, enter or not enter? So rather than me lecture, I'd love to keep the conversation going.

I will tell you that this was the number one question. We had a team at that time of about 15 people. We knew how to sell supply chain management software to pharmaceutical manufacturers.

And the question we kept returning to was, we're tracking these drugs, these opioids and other controlled substances, like mixed amphetamine salts. And we were doing a great job helping pharmaceutical manufacturers take really tight control on these products, controlled substances, comply with all the regulations. And we'd even track it out into the supply chain, where it'd go from the R&D lab and product development into the manufacturing plant and from there, into the distribution center.

But when it got put on a truck and shipped to the hospital, we stopped tracking it. And I would go to these conferences and people would say, there's a lot of diversion happening after it's shipped to the hospital-- nurses, pharmacists, anesthesia providers. And they would actually ask me, why can't your software continue to track it after it's on the truck and being administered to the patient?

So the more I learned about the unmet need and the liability that hospitals face, the DEA will find a hospital $8, $10 million. But it's even worse, patients will sue. Somebody's from Yale.

Yale New Haven, there was one nurse stealing medications from patients in their reproductive health clinic during egg collection procedures. Patients were being given saline instead of fentanyl. They were waking up mid-procedure saying I'm in pain. It's all in the news. Google it.

AUDIENCE: [INAUDIBLE]

TOM KNIGHT: Yeah, so the legal settlement is large. You can read it. And I don't want to pick on Yale. There's a lot of facilities where one person who's diverting can injure many patients and lead to a lot of liability for the institution. The other thing I learned-- and this wasn't mentioned-- is there's another victim of diversion. It's the person who is diverting.

Nobody starts diverting, saying, I hope I get addicted. They start diverting because they think they understand the risks. These are physicians, nurses, pharmacists, but these are powerful medications.

One pill leads to two to 20. We've heard touching stories and thank you for sharing your stories on recovery. The more I learned about this, the more I realized, if we could detect the diversion effectively and early, we could, hopefully, get help to the people who need it the most, which is the person who's diverting.

And understanding the challenges of substance use disorder, the earlier we could detect somebody, the more their probability of success in recovery because they haven't been taking the drug for two years. It's two months. So ultimately, it was the unmet need and all these victims that led us to take a chance and enter the market despite some of the challenges. Was that a good summary?

ERDIN BESHIMOV: Excellent.

TOM KNIGHT: Anything more we should add-- I should add?

ERDIN BESHIMOV: If you could just double-click once on the challenge of building the team, the cost, how you were thinking, and why you decided to then, still, despite that, go ahead and enter the market.

TOM KNIGHT: Yeah, we were very fortunate. And Elena's here with NIDA. NIDA has the Small Business Innovation Research program, and they would do presentations available online on how they wanted to fund innovative technology to address the challenges of substance-use disorder. And it was a result of that outreach that I said, this might be a source of money and also allow us to build the team and go into hospitals with the backing of NIH.

So that led us to propose an SBIR grant, and fortunately, we were awarded the grant, a very competitive process. And that allowed us to get a few million dollars over the course of two and half years that allowed me to go out and hire people with the clinical background and health background, particularly on the sales side, but also on the implementation side.

And while the money was good, I'll say what was even better was being able to go into a hospital and say, not would you like to buy software? Which is hard to get a yes to. But would you like to participate in an NIH-funded study to detect drug diversion? And there was a segment of hospitals, which is a lead-in for the next section, that really liked to participate in that.

ERDIN BESHIMOV: Thank you. Well, let's open it up. Students, please. Tom, thank you so much.

TOM KNIGHT: It's a pleasure to be here. And one other thing I wanted to point out. I appreciate you naming me and letting me stand up here, but it was really a team effort at Invistics.

And I wish they could all be up here. I love that we're videoing it. I'll share it with them as well, but this was a great chance for me to represent the full team, and it was their efforts that led to ultimately to the future you'll hear.

AUDIENCE: Thank you so much. It must be really awkward to have us all talking about you while you're sitting in the back of the classroom. I always think that about these.

But I guess, I had a question. What did, if you don't mind, the study look like from-- I'm a scientist at heart. So what is the NIH clinical study look like for something like this?

TOM KNIGHT: Yeah, so it wasn't a clinical trial. But we did want to, in phase I, prove the feasibility of the technology. And we didn't look at all types of health care facilities.

We focused on acute care inpatient hospitals. We didn't focus on all types of clinicians in those hospitals. We focused focus just on nursing.

And there's a point. Nursing, when you study this field, nurses probably divert less as a percentage than other types of clinicians. But there's just so many nurses in a hospital. Even a midsize hospital's going to have 1,000 nurses, but they only have 15 pharmacists and maybe 10 anesthesia providers. So that was the place we focused because we had the most data on nurses.

And it was-- back to this point, we were going to be able to get to training data for nurses faster than we could for specialties that were not as numerous in these hospitals. And so what we did in the phase I study, which is the first six months of the SBIR project, is we worked with a handful of hospitals that had a very mature drug diversion-prevention program.

They were spending six figures per year to detect diversion. So they had found close to a dozen cases, and we were able to get longitudinal data that the hospital already had to start training a model to find these patterns of diversion. So in the first phase, we had the pleasure of working with two hospitals, one in Georgia, one in Philadelphia. And that gave us the feasibility study to say, this is encouraging. And that allowed us to continue with the phase II part of the project, which was the next two years.

And that's where things lead to. And that study ultimately led to some supplements from NIDA where they funded-- because we were successful with nursing, they funded an expansion into pharmacy. And then they funded an expansion into anesthesia providers.

AUDIENCE: Great. Thank you.

ERDIN BESHIMOV: Oh, Tom, you decide.

TOM KNIGHT: Oh, great. Right here in front. I think we'll wait for the microphone.

AUDIENCE: Yeah, thank you.

TOM KNIGHT: And could I trouble someone for a little water?

ERDIN BESHIMOV: I got you.

TOM KNIGHT: Thank you very much.

AUDIENCE: Yeah, again, Brandi Fink, University of Oklahoma. So I'm interested, who did you contact to have to gauge their interest in participating in this?

TOM KNIGHT: Yeah, one thing I learned from a great hire we made early on is the major pain of diversion falls in the pharmacy department. So the director of Pharmacy is the one whose license is on the line for compliance. So everyone's impacted when diversion happens, but it's the pharmacist who gets fired, the director of pharmacy or chief pharmacy officer.

So those were the people we contacted first. And we would go to meetings of pharmacists, the American Society of Health-System Pharmacy, ASHP. It was a great way to talk to people and learn who wanted to invest proactively in detecting diversion. Thank you very much.

AUDIENCE: Great, thank you.

[LAUGHING]

TOM KNIGHT: This is fantastic. Thank you, thank you. As I was getting on the plane yesterday, I said, I hope there's a lot of questions. So let's go right here in the back corner.

AUDIENCE: Hi. Oh, OK, perfect. Hi, I'm Mira. I'm a social worker from New York. And I'm a multidisciplinary addiction treatment fellow through NYU Langone.

I was wondering because, as mentioned, it's an arms race of the detection industrial complex. Were you worried about-- or are you worried about obsolescence of your product?

TOM KNIGHT: Great question. Yeah, I heard arm race. I like cat-and-mouse game a little better because, no matter how sophisticated our detection methods, these folks are very motivated to get to the medications, get to the drugs. Their brain chemistry has been rewired to find a way to get to the drugs.

So long story short, we had to develop a release cycle where we could detect certain types of detection. We could detect certain type of diversion at a certain point in time. We would deploy that software to the customers using it. And we were constantly asking them, have you found any new patterns of diversion that are not currently detected?

And fortunately, we got to the scale where, when our software failed to detect, we called that a false negative, our customers would come back and say, in the next release, can you wire this additional alert that you didn't check for in the past? So within a few months-- we released generally every three months-- we would find one other way to, if I can speak metaphorically, prevent the mouse from getting to the cheese.

AUDIENCE: I have a follow-up question.

TOM KNIGHT: Please.

AUDIENCE: In your business model, are you also advocating for behavioral interventions to prevent diversion as well?

TOM KNIGHT: Yes, and I'm glad you asked that. What I learned is the software alone is not sufficient. You really needed an organization that was wanting to prevent diversion for the right reasons.

Somebody mentioned earlier about the stigma that might be caused if you go to, say, a supervisor or even the person. So what we really wanted to do-- and that's why-- I wish I had written it down here, but the biggest victim we have to think about is the person who's diverting.

And so we encouraged our customers to not only use our software, but to develop education programs that focused on the why. Why are we doing this? Well, we're doing this because we're living in a-- or we're working in a dangerous environment around very dangerous medications. And if one of our colleagues starts to divert them, they're likely to develop a substance-use disorder and either hurt themselves or their patient. So we are helping them by detecting their diversion as early as possible.

AUDIENCE: Sorry, [INAUDIBLE].

TOM KNIGHT: OK, but only for you.

AUDIENCE: I'm very loud. I think I'm OK. Oh, it's for the film, OK. Hi. I'm also wondering, in talking about the why, it sounds like you're also making it sound more like an individual issue where it's like, this is an individual who's doing something versus an individual responding to a system of an environment that's encouraging their drug use.

TOM KNIGHT: Yeah, and I learned so much after we entered the market. There's been some really good studies on how often health professionals divert. Anesthesia providers are actually probably as a statistic, as a percentage, the most likely to divert.

And there was a study that was funded by the American Association of Anesthesia Providers where they actually went to anesthesia providers who had died and looked at their death certificate to ascertain the cause of death. And they just counted how many had died from a drug overdose. Read the paper. Great author out of Mayo clinic, Keith Berge, who joined our advisory board.

But long story short, it's more dangerous to be an anesthesia provider in this country than to be a commercial fisherman or a lumberjack because we're around these medications. So that's an example of what we want to get out to the people working in hospitals to say, hey, we're in a system where there's a lot of danger. It's worse than working on a commercial fishing boat.

We should be sure to come up with procedures and systems that if you want to divert, you are deterred from it. That would be a wonderful win. But if you have diverted, we wanted to detect that as soon as possible so we can get the help you need with your substance use-disorder before you hurt yourself or your patients. Yes.

AUDIENCE: Hi, Tom Kim, CEO of EpiVario in Philadelphia. So my question is, you're operating this company 15 years. You're successful. You're presented with this idea.

And from the outside looking in, my thought is you can translate into another manufacturing environment and distribution. What was the thought in now translating into hospital where I think the perception you already probably had was it's very different.

And we heard from some people here just the culture in the hospital and accepting a new oversight in terms of software is probably a huge burden. So can you talk about what you thought initially and what attracted you and then why you made that decision?

TOM KNIGHT: Yes, and the answer to your question is going to show you I'm not very brave. So somebody said this morning, I think it was Hanna said, you love it when you hear people pivot. Pivoting is the most valuable skill an entrepreneur can have. And more specifically, being willing to pivot when the market's telling you there's a better way you could serve it and a potential opportunity that's attractive.

So we had two main pivots. You've heard about the first one here, but we were working with big industrial manufacturing companies for about five years. And then we were approached by quite a few pharmaceutical manufacturers who had a lot of pain tracking these controlled substances. So that was our first pivot.

And it was a few years into that at the 15-year mark, but we realized that the pharmaceutical manufacturers weren't the only ones that needed to protect these drugs and mitigate the risks of diversion. It was any organization that was handling the drugs. And so thankfully, that was our second pivot, and thankfully, we did decide to enter the market. And at some point, we'll share what happened after the pivot.

But it was ultimately me sitting, after hearing the input from the team, saying this is a risk we're being willing to take. We're going to take money and time and talent that would've been invested in growing our traditional market, and we're going to reallocate it to see if we can help and be valuable to the folks with the pain in this new market.

AUDIENCE: Thank you.

TOM KNIGHT: Yes.

AUDIENCE: Tom, thank you very much for that.

ERDIN BESHIMOV: Sorry, one second.

AUDIENCE: There you go. Thank you. Thank you very much indeed for your presentation and the case discussion.

I've really got a question about the business model and the funding and the money because I'm interested. You've mentioned DEA fines as a cost. You've mentioned patients will sue, and those don't sound like they are predictable costs to the hospital system.

And then you've mentioned there's a cost for the compliance department, and that does sound predictable. So how have you priced your offering to capture those costs? Is it, are you pricing it as an insurance product for those hospital systems? I'd just like to learn more about that.

TOM KNIGHT: Yeah, and this is a good segue to our discussion about segmenting the market because there are very different types of hospitals, and some are proactively investing in a staff. Some recognize the risk before it's happened. But most do not.

There's 8,000 hospitals in the US. Many of them don't have one person working on drug diversion. If it is someone, it's 1/10 of their responsibilities. And they're constantly unable to get to that 1/10 of their priorities because something else is a higher priority.

So we had to find those hospitals that understood the risk and were willing to make an investment. And we would price the software as a one-time setup fee because implementation was a challenge. Because we had to get a lot of data from that health system, like electronic medical record data, automated dispensing data, and five other systems.

But we charged a one-time setup fee, and then we would charge them an annual subscription. And that scaled based on the number of beds in the hospital. And our basic calculus was a big hospital-- more patients, more clinicians, more risk of diversion plus their pockets are deeper. So they should be able to spend more than a midsize or smaller hospital.

What we also learned is most hospitals now are part of a group of hospitals called an integrated delivery network. And so it would be one thing to sell to one of those hospitals. It'd be even better to sell at the network level.

So we would give basically quantity discounts. If you came to us with 10 hospitals, the first hospital paid full price. The second one was a little less. And basically, the more hospitals that were being quoted for this particular project or customer, they got a bigger quantity discount. And that was a good way to help the biggest hospitals and the biggest networks who had the biggest risk to work with our software.

AUDIENCE: Thank you.

TOM KNIGHT: Yes. And thanks for your efforts to move the microphone around.

ERDIN BESHIMOV: Burn calories.

TOM KNIGHT: Yeah, yeah.

AUDIENCE: Yeah, JP Wollersheim. I mentioned I'm a techie dude. I'm currently at Meta, and we care a lot about intellectual property there.

And the question that I had, when you're talking about doing your machine learning and your AI models, I'm wondering if you would be willing to comment on how you manage the intellectual property transfer of getting all that data and bringing it in.

TOM KNIGHT: Yeah. So we needed our customers' data to train our model over time. And so we would write our licensing agreements with the hospital to ensure that we had the intellectual rights to use their data consolidated with all our other customers' data to train the model to get smarter over time.

And I will say that was a challenge for some customers, particularly hospitals or hospital networks that had provided their data to other third parties. And then the third parties had made money off of that data. So they had been trained to negotiate to not allow a third party to leverage their data in the way we had needed to.

And we, ultimately, had to say often-- I'd have to get on the phone with their senior business person and say, I know what your lawyers worried about, but we can only help you detect drug diversion if you allow us to use your data alongside our other customers' data to make the model smarter. And they would come back and say, well, will you agree to not sell it? Will you agree to not do this?

We said, absolutely, but we need the ability to have our intellectual property free and clear. And part of that is being able to use your data for that. I'm going to move around the room. Yes.

AUDIENCE: I'm [INAUDIBLE]. I'm a postdoc at MIT. I was curious on how you decided to pivot. And in particular, when you decided to enter, what could've been the issues that would've overturned your decision? What could have potentially prevented you from going in?

TOM KNIGHT: Yeah, what ultimately motivated our team to try this was the country had really started to recognize the extent of the opioid epidemic. Many people on our team had family members that had overdosed or faced addiction issues and challenges. Not me personally, but I could empathize.

And we said, well, we've got an opportunity to work with NIH and NIDA, who's obviously seeing this as a national problem and willing to fund this. If we do it and we fail, we're no worse off than where we are today. But if we do it and succeed, we could make a big impact for the country. And a lot of people and their families might have a better life as a result of this approach, this technique. And remind me the second part of your question.

AUDIENCE: What could've happened that would've prevented [INAUDIBLE]?

TOM KNIGHT: There were a couple of moments early on where I would go to hospitals, and I'd sit in an office with the director of pharmacy and I would hear them say, yeah, this is a pain for me. Yes, I'm investing. Yes, I think we need new technology. Yes, What you're proposing sounds like it might work.

But the question they couldn't get over the answer to was, which other hospitals are using this? Because the answer was no one. If you buy it, you will be the first hospital.

And I can't tell you how many hospitals said, we'll be willing to be the second or maybe the third, but we're not willing to be the first. And God love 'em, Children's Hospital of Philadelphia, Winson Soo-hoo, director of pharmacy, ultimately said, yes, I'll be your first. And he actually tied with a CEO of a hospital in Athens, Georgia.

And the two of them came in pretty much around the same time. So we had two hospitals willing to be the first. And that was the biggest challenge. And I can remember getting on planes, going to visit who knows how many others where everybody agreed it was a problem.

Everybody agreed with the NIH backing. They wanted to participate, but none of them wanted to be the first paying customer. Yes.

AUDIENCE: Sounds very familiar with investors. Do you use any of your data to look at-- so you're doing detection, but can you do prevention? Can you look at precursor signs? Do you have any explainability methods that can track back to before the diversion is going to happen?

TOM KNIGHT: I don't think we ever got to the point where we could predict it before it was started. But what we were really excited about was how much earlier we could predict it compared to state of the art. The state of the art was these monthly reports that looked at how much was dispensed from an automated dispensing cabinet, like a Pyxis machine or an Omnicell machine.

And even if someone was diverting for months, it might take them a year or more to be picked up by that report. And to make matters worse, that report had many, many false positives. Let's say I'm a nurse, and I have a patient or two that requires a lot of pain medication last month.

Well, I'm going to show up on that report as having dispensed a lot of opioids, and I wasn't diverting. I just had patients who needed it. So as a result, there's 10 false positives on the report for every one true positive. And who has time to look at all 11 people.

So we were able to put together the analytics that would often detect it within a few weeks of it starting. And one of the studies we did, which was published in a peer-review journal, which really helped credibility, is we looked at 22 known cases of diversion that our customers had detected before they bought our software, and we took that data blind into the model.

And we asked, who in this haystack of data does the model classify as diverting? And on which day would the model have first classified the diversion? And it found all 22, which was a good sign.

And it found that on-- I don't remember the exact number. It was roughly 32 weeks earlier on average. And that was exactly what we were hoping the technology would do. Because, again, if we can detect diversion within a few weeks of it starting, it's going to be a lot easier for that person to avoid the major problems caused by substance use disorder than they've been doing it for a year or longer.

AUDIENCE: Thank you.

TOM KNIGHT: And I should ask-- I should pick someone that's close by. So it's not so far to move with the microphone. Yeah, right here in the front row.

AUDIENCE: Hi, David Feinberg. I think this is a super interesting case because your business essentially has been on the expense side of the balance sheets from the beginning, just helping companies become more operationally efficient. So when a company gets a pill and gives a patient a pill, they make a little profit on it somehow, but you're not generating revenue for the hospital.

You're reducing expenses for the hospital. So when a hospital considers, buying your technology, they have to consider what the risk is of getting fined. So there's an actuarial process around that, and there's fear around it.

And so when you did your analysis, obviously, large institutions that have the potential to have huge fines, and there's a lot of potential diversion, the risk is very large, but when you start getting to smaller hospitals, maybe mom-and-pop hospitals where you have one person and maybe no people working on diversion, how did your segmentation come about where, with respect to scale, when you started getting to smaller hospitals, where did you see your sweet spot and where did you see markets that were just not worth it to enter?

TOM KNIGHT: That is a fantastic question. For the first few years, we were only able to sell into hospitals that recognized the risk. And some of them had actually had a recent diversion case, and they wanted to invest in more proactive tools to show their employees and their patients and their communities and their regulators that they were doing something more proactive.

But there were still the majority of hospitals that didn't see the risk or didn't have the budget to address the risks. So we started to hear from people that wanted to buy our software but couldn't get approval to make the spend, like a director of pharmacy that couldn't get the CFO or the CEO's approval. And so we actually started to meet with them and say, what are some other potential financial benefits that your C-suite would buy into?

Because, apparently, the risk of drug diversion isn't sufficient. And we happened, in one of these conversations to discover that not only does our software detect diversion, but it detects when a clinician accidentally forgets the chart that they administered the medication to the patient. They were busy. I forgot to chart it in the EMR.

Well, a lot of hospitals are bill on administration, so if I'm a nurse in a hurry or I'm a nurse with sloppy practice and I forget to charge chart the administration, we're now not going to charge that patient's payer for that medication. And it is a 10x markup. If I paid a nickel for the pill, I charge $1 to the patient.

And what we discovered was our software was just as good at detecting somebody diverted and didn't administer as someone who was busy and didn't administer. And so the financial benefits could then go back to the C-suite and say, listen, we measured, last year, roughly 5% of our administrations were missing. We don't think all those are diversion. We think the majority are someone who is in a hurry or honestly forgot.

But if we could turn that 5% into administrations or even half of that next year, we'd make an extra $3 million. Software only costs $50,000 a year, whatever it was. So that's a pretty good ROI. And the person who wanted to buy it for the reason we were developing it, diversion, got to justify it on the revenue increase that we would see from improved charge capture.

But that's an example of something we had no idea until we were trying to sell to another segment of hospitals where the leadership and the C-suite didn't understand the real risks, but we could motivate them to invest in it by showing them other benefits. Yeah. I think I called on you earlier, so I'll call on you.

AUDIENCE: Thank you. So first of all, thank you also for sharing the case. So I have two questions. The first one, after getting all these data from many hospitals and so forth and so on, so were you able to phenotype or characterize a specific situations where, actually, these could be a factor in common or a situation in common among all the hospitals and then go to the hospitals and say, OK, maybe these situations or these factors are actually reducing your risk based on, I don't know, five years of data and how was actually be part of the solution potentially to solve this problem.

TOM KNIGHT: Yeah, it was great to see that, as we had more data and more customers and more hospitals, we collectively got smarter. And what was interesting to me is, before, everyone who was investing in this at the hospital level were doing a at an independent island, and they could get smart. But there wasn't necessarily a way that they could learn from the hospital across town or across country.

So we developed what we called our customer advisory board. And every customer was invited to participate. These were virtual meetings held every three months. And we did what's called grand rounds, where we'd have one of our customers every quarter present how they had detected diversion in a way they hadn't seen in the past, either using our software or not.

And that allowed everybody across the country that was in that group, our customer group, to get a little smarter. So if there was a new way that one hospital detected a diversion and they shared that in grand rounds, then everybody across the country using our software got a little smarter.

AUDIENCE: Thank you.

TOM KNIGHT: Yes, please. We'll do both of you in this order.

AUDIENCE: OK. Hi, I'm Joe Gostkowski. I'm a clinician scientist at Boston Children's Hospital. So I think everything you discussed about why you went in makes a lot of sense, and I think it's a wonderful thing that you did.

I'm interested, though, as a CEO of a company in that where you were in-- or thinking about the pivot, did you decide to go full in this new venture? Or do you decide to have one leg still over here? How do you decide about the allocating of resources, risk management? I'm just interested in that process.

TOM KNIGHT: Yeah, we decided to keep the old and start the new, and there's risks that came with that. But my primary motivation was the prior team were really capable people. And I thought most of them would be able to pivot with us into the new field. I didn't want to just say, we're going to shut down everything you've worked on. We're going to hire a whole new team.

Now, being a small company serving two major different markets, that was a risk because a small company focusing on either one is still going to be overtaxed with its capacity. But I wanted to do this in a way that, A, if it failed, we'd be no worse off. And B, we didn't jettison the team that had been with us, in some cases, for 15 years.

AUDIENCE: And do you still have both segments running?

ERDIN BESHIMOV: Well, fast forward from this decision, nearly everyone, as the business grew to be 80%, 90%, 95% health care, each person had a choice. Did they want to learn a new market and a new technology and a new lingo and a new culture that is health care? Because if so, we needed them. And we needed their knowledge of the software.

And most people made that choice. There were two that said, I've been trained to help in manufacturing. I'm in supply chain. And I wish you well, but I'm going to go to this other position because that's what I want to do with my career, and we wish them well.

AUDIENCE: Evan Kharasch, Duke University, physician scientist. I happen to be an anesthesiologist.

TOM KNIGHT: Were you familiar with that study?

AUDIENCE: Not the study, but I'm familiar with the market and the fundamental issues rather extensively. Just a perspective and then a question. The perspective is I want to emphasize a comment that you made, and that is the value of the software in distinguishing between medication reconciliation, true positives, and false positives.

And not listed on the impact list is the effect of a false positive, where somebody can be accused of diverting, and it can be devastating and ruin people's careers just from an accusation. So I think that that service, if you will, is fundamental, and there are a lot more non-diverters than diverters.

TOM KNIGHT: I'm so glad you raised the point.

AUDIENCE: Question, were you the innovator in the first to market? And are there now competitors? And what does that landscape look like?

TOM KNIGHT: Yeah, and I do want to echo your first comment, a false positive is capable of causing a lot of pain too, just like a false negative. That's why, when we did our implementation, we made sure that our customers, to the best of our ability, had an investigation process that was professional, was discreet, was assuming innocence before assuming guilt.

And we also did a lot to log false positives. We encouraged all of our customers that if someone was flagged as a false positive, they would log that false positive because then, the next time we train the model, we were less likely to raise that as an alert. So I appreciate that comment. Could you repeat your question again?

AUDIENCE: Were you the innovator in first to market? And are there now competitors? And what does that landscape look like?

TOM KNIGHT: So we were the third to market. There was one company that sold privacy auditing software to hospitals for HIPAA compliance. You can't have employees snooping around in electronic medical records, say, for a celebrity patient. And so they had discovered that that could sometimes detect diversion, like a nurse choosing to serve a patient merely because they had a lot of opioids to be administered, and they could detect some diversion that way.

And then there was a second company that entered the market just a few months before we did, and they were in the business of selling cartridges that held narcotics between central pharmacy and the OR and medication kits. And they had discovered that their RFID tracking could detect types of diversion. When a kit would come back from an or to central pharmacy, hmm, why is that morphine not on the tray? Because it wasn't given to the patient. Where did it go?

So there were three companies that entered the market and all great competitors. After we entered, there were three others that entered, so it got a little crowded there for a while. But we're now in a period of acquisition. And is this a good time to talk through what happened next, or how do you want to handle it?

ERDIN BESHIMOV: [? Details. ?]

TOM KNIGHT: So we were very fortunate. I want to thank again Elena and NIDA and the SBIR program because it was their funding that helped us have the courage to give this a try. It was their backing that helped us go into hospitals. The ones that we had segmented were most likely to be wanting to invest in this, and we were able to say, would you like to join this NIH study?

We eventually grew where we were serving some of the largest health networks in the country to close to 200 different hospitals, including many large academic medical centers, which was the segment of the hospital market that we found was the very best center of the bull's eye in terms of who was going to be most likely to buy. And that led us to be approached by a large multinational company. Anybody familiar with Wolters Kluwer? Out of the Netherlands?

And we were very fortunate that they acquired us in June of 2023. And it was a dream come true. Not only was it a fantastic financial reward for me and many people on the team, but they had the resources to triple the size of the team within a few months after the acquisition.

And they already sell software to 6,000 of the 8,000 hospitals in this country. So instead of us knocking on a door saying, would you like to buy software from Invistics? It was their sales rep who had already been calling on that hospital for 10 years, saying, we just bought the market-leading software for drug diversion detection. How many hospitals would you like to sign up?

And so we were on a tremendous pace of growth before the acquisition. We sold at a sold at a tremendous strategic price. And after the acquisition, they made a home for every one of our existing customers. And the rate of growth went like this on the chart.

So it was fantastic for my investors, my team, and our customers. And it was also fantastic because now they had the distribution horsepower and the install base that it could really penetrate the market. And what we saw was we were consistently-- back to your question, we were consistently rated as the best software among our competitors. And now that the acquisition's happened, the lead is increasing.

So I joke at this point in the case, everything went according to plan, the business plan, except the business plan was we were going to sell in three years, and it took 23 years. But other than that, everything went according to plan. Yes.

AUDIENCE: Stevie Burke, North Carolina. What was one of the biggest mistakes you guys made?

TOM KNIGHT: I can remember being tone deaf and not sensitive to the person diverting and the pain they were feeling. I can remember going into training some of our early customers and saying sentences like, the software will tell you who's probably diverting, conduct a professional and discreet investigation, and that will tell if they're innocent or guilty.

And I learned from talking to people who had substance-use disorder and learning more about the pain it caused them that they're the victim. And this technology, hopefully, will reduce the number of victims, starting with them. And I learned to use language like, let's detect this diversion to get them the help they need before they hurt themselves or their patient.

And that changed my why. So it was a mistake for me to go in thinking this was a police, law enforcement tool and to really realize it's a medical intervention, hopefully, before someone winds up dead of an overdose in the parking lot. Fair answer?

AUDIENCE: Oh, yes, thank you.

TOM KNIGHT: Yes.

AUDIENCE: So I'm thinking, so much is focused on the hospital system. They're the buyer. I appreciate that you recognize that the individual diverting is not a criminal and things like that. So that makes me think about the champions in the space, not only within the hospital, but also, there are a lot of-- with nurses, there are programs for nurses who have had some substance use, diversion of medications. Did you ever approach them to help them bring in that buy-in component as a champion within the DMU?

TOM KNIGHT: Yes. We were fortunate that, as word spread that the software worked, people were receptive to conversations either that we initiated or increasingly that they initiated. For example, we had a great conversation with the Centers for Disease Control and Prevention in Atlanta.

They have a group that goes out to hospitals when an infection occurs in the hospital for any reason. And sometimes that infection is because someone's been diverting the medication, literally, is putting the needle in their arm in the bathroom and then replacing it with water. And then that needle goes back to the OR and gets injected into the patient.

Well, if I had hepatitis or HIV, now, the patient has that infection. So we actually had conversations with them saying, we're constantly going out to hospitals, and all too often, this kind of infectious disease or this outbreak, it's caused by diversion. And that was interesting because they said, we can't work with you as a for-profit company, but maybe we could cofound a nonprofit that allows it to be a public-private partnership.

And so that's what we did. We founded a nonprofit called healthcarediversion.org. Nonprofit's still going great. It's completely different than for profit.

And that was a great way for us to get a lot of different stakeholders to the table, public and private. On the public side, most people don't realize that this is a state issue. State boards of health, state medical boards, state pharmacy boards, they're the ones that go into the hospitals when there's a compliance issue.

Now they call the feds the DEA if it's controlled substances, and they'll call the CDC if there's risk of patient infection. But this is largely a state issue, so we had to get a lot of representatives from the state level. And we were really fortunate that there are some great organizations.

The National Association of State Controlled Substance authorities, NASCSA, really took an interest in working together. The National Association of Drug Diversion Investigators, and the one that was mentioned earlier, the International Health Facility Diversion Association. So it was great to realize that we were a tool that could be used by lots of stakeholders, and again, that we were necessary but not sufficient.

We needed training programs. We needed regulatory oversight. We needed support for those who wanted to go through rehabilitation and recovery.

And the one I'll never forget, the state of New York has a peer assistance program for nurses. Most states do. They also often have peer assistance programs for pharmacists or physicians. And these are people who can provide recovery resources to someone who's diverting if that person is willing to get help. And they did a webinar with us.

AUDIENCE: That's exactly-- I was curious about that-- oh. That was really where I was interested in was because their role is to serve the nurse, the professional in all those safety occupations. And there's such a fear of, I'm going to lose my job and things like that.

So I was curious, how they could be leveraged to say to do what you were saying. We want to help the person before it gets to an extreme where they do-- can never work in the field again and that those organizations-- Pennsylvania has a nurses association and things for diversion and such. And I just see that as such a crucial point to address the fear of the result of being "caught," I'll say, in quotes by the innovation.

TOM KNIGHT: Yeah, and it was wonderful for us to partner with them, either through for profit or the nonprofit. And it was really touching. I'll never forget a webinar we did with the administrator of the New York peer assistance program, who invited three nurses to present on their personal lived experience of why and how they started diverting, how they were ultimately detected.

And all three of them said, I wish I'd been detected earlier. I didn't want to be detected at the time. I would've told you I didn't have a problem, but that was the moment-- that detection was the moment that forced me to make a decision that ultimately led to my recovery. Yes.

AUDIENCE: I'm Lauren. I'm a postdoc from Arkansas. Did your pricing model change when you went into hospitals?

TOM KNIGHT: Completely.

AUDIENCE: Can you just touch on the biggest contributing factors for those changes?

TOM KNIGHT: Sure. We were fortunate that we always sold our software as a service, and that meant a one-time setup fee and then an annual fee. But the way we priced for a factory was largely about the size of the factory or the number of products being manufactured or stored in that facility.

And every hospital has almost every drug, so it didn't make sense to scale based on number of controlled substances. And that's why we had to find something that scaled the price with the value. That's why we picked number of beds.

Anyone not had a chance to ask? I think we've got some in the back, and I'm happy to come back for additional questions, but I want to include as many people as we can.

AUDIENCE: All right, thank you, Tom, for such an insightful session. My name is Uchenna from Canada. So my question is around the data and how you and your team manage data drift, especially with the data that's collected from each facility. I'm assuming that there will be some interoperability issues and how that has led to collecting reliable data that will now be used for your supervised machine learning techniques.

TOM KNIGHT: Yeah, thanks for the question. From the engineering perspective, this was a big challenge. Our initial phase I project looked at just two source systems, the electronic medical record and the automated dispensing cabinet.

And there's only a few players in both of those systems. Epic is the majority of hospital beds in the country, and Cerner is number two. And then it's a long list of other players. So we had to really understand those two source systems because we saw them 80% of the time.

And we also, on occasion, had to say to a hospital, hmm, you're using an EMR that we've never seen before. There's going to be additional time to set it up. Do you want to have that? Or do you want to maybe start with hospitals using Epic or Cerner?

Similarly, on the ADC side, there's two big players. There's Pyxis and Omnicell. And so we had to be sure we could extract the data from those two automated dispensing cabinets and those two electronic medical records.

And it was not trivial because even though you're pulling from Epic, Epic's not the same in every hospital. There might be parts of the data that's the same, like the Medicaid administration record, where I chart that I gave my patient two hydrocodone. That's the same at every hospital running Epic.

But how about an infusion, an IV drip? May or may not use a smart pump. Those go into custom tables in Epic called flow sheets, and every hospital can implement that in a unique way. So we had to build, again, the team that could figure out, how did this particular hospital log administration of narcotics or other medications in an IV drip? And only then could we use that data to detect diversion from those sources.

Now, back to the cat-and-mouse game that somebody asked about earlier. We realized that those two sources were insufficient to detect all diversion. So we started to pull in additional systems, and we eventually got to seven total.

For example, we started to pull in the employee time clock records. So a lot of clinicians are paid by the hour, like a nurse, and they clock in and clock out at the beginning and end of their shift. That was an important data feed because we could find people that were coming in on days that weren't working and dispensing medication and then falsifying administrations. So they could cover it up with only two feeds, but they couldn't cover it up with three.

Then we started pulling in purchasing records from central pharmacy. We actually went to all the major distributors, like McKesson and Cardinal Health and AmerisourceBergen, and we said, our mutual customer, this hospital, is buying from you. Could you send us every night the data on what you shipped to the hospital?

And then we pulled in the data from the central pharmacy because they have these narcotic vaults on what was received. And in that way, we could know if the shipment that left the distributors dock made it into storage securely in the hospital. And by the way, that was a really eye-opening experience.

Everything we've talked about so far has been diversion for self-use, but there's a lot of diversion that's being done for resale on the street, particularly because so many of the opioids on the street could be illicit fentanyl that could kill you because the strength of the dose. So if I have the means, I'm going to find a way to buy US FDA-regulated narcotics. There were, in Atlanta, my hometown, at Emory Midtown hospital, two pharmacy technicians.

One worked in the office, and they would order hydrocodone, codeine cough medicine. And there was a second pharmacist technician that worked on the receiving dock that would sign for it and just take it out to their car. And they were distributing it through organized crime. In all these nightclubs in the Southeast, there's this drug called purple drank.

This was before Emory bought our software. They stole over a million doses. And they were only detected when somebody in the accounting department said, why are we spending all this money?

And we don't have a-- long story short, that's why we had to expand the number of data sources so we could cover more parts of the hospital because then if, after Emory had implemented our software, anybody chose to try and divert in that same way, a huge alarm would go off within 24 hours of the first theft.

And by the way, that makes my blood boil when people are diverting so that they can be resold because how many young people went to a nightclub and drank this purple drank cocktail and were then set on a course where they were looking for more opioids that led to substance-use disorder? So I was talking about segmenting the market, the why am I diverting? We'll catch them both, but I don't have a lot of sympathy for somebody who's stealing it so they can resell it and get rich.

AUDIENCE: Thank you, Tom. Mark Strand, North Dakota State University. So I work on the population side, so the human side of the issue. And your presentation is very inspiring because I think, sometimes, there's a concern that systems depersonalize this problem and make double victims out of the people who are suffering. So your testimony is really moving.

I think the alternative-- and this is the source of my question-- is concern that machine learning or artificial intelligence is even triply inhumane or nonpersonal. And your story would suggest that it can have human elements to it. Can you talk about the opportunities for AI in health care in a way that will preserve the humanity and the dignity of the profession and of the persons engaged with it, as opposed to just making it a faster, cheaper way to get to the end, but it loses any human element?

TOM KNIGHT: Wow, I love that question. And I know, I'm guessing, I heard that some of you are looking at application of AI to help patients or to help us provide good care to patients so this is a topic that's near and dear to my heart. I'll oversimplify for a little bit.

As an engineer, whether I think of any tool-- and I'll just say AI's a tool-- I can use a tool for good, or I can use a tool for evil. Take a hammer.

I can use that hammer to build a house for my neighbor. That's good. I can use that hammer to murder my neighbor. That's evil.

It's a harsh way to say it, but it's the same way with any tool. AI is the point of the question. We can use AI for good to help people get the assistance they need with their substance-use disorder, or we can use AI in an irresponsible, evil way, even if it's an unintended consequence, to go after somebody and ruin their career with a false positive.

I think there's incredible opportunity for the use of AI for good in health care and in other industries. So much so that I've started another company. Which isn't our focus today.

But I was so amazingly, incredibly, and humbly impressed with what AI did in this use case that I see opportunities for it to be used in patient-focused use cases. And while this helped the patient, this really helped the person who was diverting and everybody around them, including the patient. So at Invistics, we used large data sets, clinical data sets from the EMR, for example, to train supervised machine learning to detect when people are stealing drugs, hopefully, earlier than other methods.

The next company that I just started in October is called Optinosis. We're going to use large data sets, like electronic medical record. We're going to use supervised machine learning. We're hoping to detect cancer early because so many cancers are not diagnosed until their late stage, and they're very difficult to survive and treat if they're not detected until late stage.

Well, we've got over 10 years of longitudinal medical record data right now for everybody in the room. We're going to attempt to find patterns in that data years before patients in the past have been diagnosed with cancer. Because if the computer can find those patterns, then we can look at patients who have not yet been diagnosed with cancer and see if the model shows their behavior, their history is consistent with other patients who went on to be diagnosed with cancer.

And our goal is, if someone's going to get cancer, let's not wait until it's stage IV, and it's a death sentence, let's see if we can't flag them as high risk for that cancer and get them screened in stage I or II when the patient's life expectancy is 10 times higher. And the cost to treat them might be 10 times lower. And we don't have to go through all the challenges of a late-stage diagnosis.

So that's an example of what I'm picturing AI could be used to do for good. But already-- we only founded in October-- our phone is already ringing from applications of this technology that could be used for evil-- that's a harsh term-- like denying coverage, denying life insurance. So just my experience is you're going to have a tool, make sure you understand the why, and why you're building the tool because if it's a powerful tool, it can be used in ways that might not be consistent with your why.

ERDIN BESHIMOV: Friends?

AUDIENCE: Yes.

[APPLAUSE]

I love my life. Tom, thank you so much.