UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ALABAMA

UNITED STATES OF AMERICA

v.

JOHN PATRICK COUCH, M.D.,
and XIULU RUAN, M.D.,

Defendants.

* * * * * * * * * * * * * * * * *

CASE NO. CR15-00088

COURTROOM 2B

MOBILE, ALABAMA

THURSDAY, JANUARY 26, 2017

TESTIMONY OF KEVIN McCASH
EXCERPT FROM DAY 13 OF TRIAL
BEFORE THE HONORABLE CALLIE V. S. GRANADE,
UNITED STATES DISTRICT JUDGE, AND JURY

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Judiciary Policies and Procedures Vol. VI, Chapter III, D.2.
Transcript produced by computerized stenotype.

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(In open court, 10:51 a.m., defendants and jury present.)

THE COURT: All right. Call your next witness.

MR. BODNAR: United States calls Kevin McCash.

THE CLERK: Mr. McCash, would you step forward and raise your right hand.

KEVIN McCASH, Ph.D.

was sworn and testified as follows:

THE WITNESS: I do.

THE CLERK: Thank you, sir. Please be seated.

DIRECT EXAMINATION

BY MR. BODNAR:

Q Good morning.

A Good morning.

Q Would you please pull the microphone a little bit closer to you.

A (Complying.) Is this better?

Q Yes. And could you introduce yourself to the jury?

A I'm Dr. Kevin McCash, Ph.D.

Q And Mr. McCash, where do you work?

A I work for Health Integrity, LLC.

Q And what is Health Integrity, LLC?

A Health Integrity is a government contractor that holds the NBI MEDIC contract, which is the National Benefit Integrity Medicare Drug Integrity contract.

Q And is it safe to say that your company works with Medicare data?
A Yes.
Q Is that what you do for your company?
A Yes. I work with Medicare Part D predominantly.
Q And what is part D of Medicare? What kind of data is that?
A That's the prescription benefit for Medicare.
Q You mentioned that you were a doctor. You are not a medical doctor, though; correct?
A No, I am not.
Q Are you a Ph.D. doctor?
A Yes.
Q And what is your Ph.D. in?
A Applied physics.
Q And what is it that you do at your -- what is your current title?
A I am the data analytics manager.
Q What does data analytics mean?
A Data analytics is a general term that means the manipulation and analysis of data in order to uncover facts and statistics to make conclusions.
Q Is another way to put it looking at data and seeing if you can find patterns within data?
A Yes.
Q And how long have you been in that position?

A I've been with Health Integrity for two and a half years.
Q And doing that type of work for Health Integrity?
A Yes.
Q Does Health Integrity have a program that is a doctor analysis project?
A Yes, we do.
Q Can you explain to the jury what is the doctor analysis project that your office runs?
A Sure. The doctor analysis project is a data analysis algorithm that runs against prescription information given to us by the Centers for Medicare and Medicaid Services , and it is intended to identify prescribers who are prescribing schedule II, III, and IV controlled substances to Medicare beneficiaries and identifying those that are at high risk for fraud, waste, and abuse in doing so.
Q Now, looking at the statistics, you don't know if someone actually is committing fraud, waste, and abuse, do you?
A No.
Q Are you simply looking at the data to see if certain prescribers may be abnormal compared to others?
A Yes.
Q And with the data -- the doctor data project that we just discussed, are there 17 factors that are looked at in the data?
A Yes, there are.
Q I'm going to show you now what has been marked as

Government's Exhibit 27-27.

MR. WILLSON: Your Honor, based upon our prior discussion, we object to that material.

THE COURT: All right. I overrule the objection. Mark it in.

(Government's Exhibit 27-27 was entered into evidence.)

BY MR. BODNAR:

Q I'm going to show you what has been offered as Government's Exhibit 27-27. Is that a listing of the 17 factors for this data project?

A Yes, it is.

MR. BODNAR: United States moves to admit 27-27.

THE COURT: It's in.

BY MR. BODNAR:

Q Mr. McCash, I am now showing you what has been marked as Government's Exhibit 27-27, and we're going to take a look at these factors. What is the first factor we have here?

A This is the number of schedule II controlled substance beneficiaries.

Q And is that just the number of Medicare patients that receive schedule II from any particular prescriber?

A That is correct.

Q And for number two is that -- number two and number three, are those the same, the number of Medicare patients that receive schedule III or schedule IV controlled substances?

A Yes, it is.
Q And if a patient is receiving schedule II, schedule III, and schedule IV, will they be counted in each of the factors?
A Yes, they will.
Q Looking down here at number four, what is the 30-day equivalent prescription drug event records for schedule II controlled substances? What does that mean?
A Prescription drug records are the records given to CMS that contain the prescription information. A 30-day equivalent would be a standardized way for us to analyze the number of those types of events, those records, so that the number of days is equivalent across all of the counts that we make. Some prescriptions can have many, many days worth of doses while some may only have a few. So instead of using the raw number or the actual number of prescriptions that were written, we use an equivalent number that's standard.
Q And if, for instance, the prescription is written for just five days, let's say it's five pills for five days, would the 30-day equivalent be 30 pills for 30 days?
A Yes. A 30-day -- a 30-day equivalent would be -- excuse me -- six five-day -- five-day prescriptions.
Q So it would count as six then?
A No. It would count as one -- one-sixth of a 30-day equivalent PDE record.
Q So even though -- so because it's not multiplied times six,

you just take a 30-day equivalent and say this is one-sixth of it?
A Yes.
Q And is that the same for schedule III and IV drugs here on factor five?
A Yes, it is.
Q Why does factor six differentiate and say new fills?
A The difference between six and five is that the prescription had to have been a new prescription without the refill indication. That's simply to say that a new script had to have been written and processed by a pharmacy rather than just a refill in which a pharmacy can dispense the drugs without getting the new prescription.
Q And do we not have a similar one for four because there are no refills for schedule II?
A Yes. Due to regulations, there are no -- refills for schedule II controlled substances are not allowed.
Q What is number seven and eight?
A Number seven is the quantity of schedule II controlled substances that have been dispensed to beneficiaries.
Q So does that look at a given doctor and how many schedule II drugs were prescribed to Medicare patients during that time period?
A Yes. This is the physical quantity of doses or capsules or tablets that are -- that have been prescribed.

Q And what's the difference between seven and eight?
A Number eight looks at the number of tablets or capsules that have been prescribed in a given month, and it is the total of all of the quantity divided by the number of months in which the prescriber had prescribed that particular class of medication.
Q So, for example, if there were 1,000 pills of schedule II, to come up with number eight you would divide 1,000 by 12?
A If they prescribed in 12 months.
Q And if they only prescribed in five months, would it be divided by five?
A It would be divided by five, yes.
Q And I believe this should say for number eight -- for number nine schedule III controlled substances. Does nine and 10 and 11 and 12 work the same way you just explained seven and eight?
A Exactly.
Q So the total number of schedule three and then divided by the number of months prescribed?
A Yes.
Q And for schedule IV?
A Yes.
Q Now, for 13, what does it mean number of beneficiaries exceeding travel threshold? What does that mean?
A In this particular factor we look at the distance listed

between the listed address of a beneficiary and the listed practice address of a prescriber in order to see if that beneficiary had to travel over a specific distance in order to see the particular prescriber.

Q What is the particular travel threshold?

A If the beneficiary's address is located in a county that has been designated as a rural county, it's 120 miles. If they live in an urban-indicated county, then the threshold is 30 miles.

Q So if there is one patient that travels 35 miles but lives in an urban area, is that counted as one time here in factor 13?

A Yes.

Q And how does number 14 correlate with number 13?

A Number 14 would be number 13 divided by the total number of beneficiaries that receive schedule II, III and IV medications from a specific prescriber.

Q So if there were 10 patients that counted in number 13 that traveled a sufficient far distance and there were a hundred patients overall, that would be 10 percent?

A That is correct.

Q Number 14?

A Yes.

Q What is 15? What does it mean prescribers with no part B claims?

A This particular factor looks into the Medicare part B claims. Part B are the normal doctor visit claims in Medicare. And if it sees that there are no claims at all for that particular physician under part B, this indicates that the physician has not -- the physician has not billed Medicare part B as a normal doctor visit and is simply writing prescriptions in large quantities.
Q And is this simply a yes or no as to factor 15?
A Yes.
Q Such as yes, the doctor does file office visit claims with Medicare and prescribes, or no, the doctor has not billed for any office visits?
A In this case it would be reversed. So a yes would be that they have no claims.
Q Okay. And number 16, what is number 16?
A Number 16 is the count of Medicare beneficiaries who have had a drug abuse or misuse diagnosis during an ER visit during the time frame of interest.
Q So if a particular doctor's practice has two people during the time period that went to the hospital and the hospital diagnosed them with drug misuse or drug abuse, that would count as two against the doctor?
A Yes.
Q And then by percentage, do they just take the number from 16 and divide it by the number of patients or Medicare patients

the doctor has?
A The number of Medicare part -- Medicare beneficiaries receiving schedule II, III and IV medications.
Q Can you explain to the jury how are these factors utilized? What -- how often are these factors looked at in the doctor analysis project?
A We run monthly updates on our algorithm every single month since December of 2014, and they are calculated using a rolling 12-month time frame. So that in a given month, the year previous to that specific month is the time frame of interest.
Q So, for example, this month is January of '17. For the analysis run this month does it cover January of '16 through December of '16?
A That is correct.
Q And next month we're in February, will it cover February of '16 to January of '17?
A That is correct.
Q When these factors are analyzed is a score come up with?
A Yes, we calculate a score.
Q And how -- what is the range for the score?
A Score ranges from zero to 1,000.
Q And how many doctors, roughly, are analyzed through this Medicare project each month?
A It varies from month to month, but it's usually between 60,000 and 70,000 prescribers.

Q And from zero to 1,000, which end of the spectrum shows the most abnormal as compared to other doctors?
A 1,000.
Q Is that the highest possible score?
A Yes, it is.
Q Roughly, approximately how many doctors score a 1,000 each month when this is run?
A Again, it varies from month to month, but usually it's between 15 and 25.
Q Out of about 60 to 70,000?
A That is correct.
Q Prior to coming here, had you checked to see if Dr. Ruan or Dr. Couch had ever been scored at a 1,000?
A Yes, I had.
Q How many times had Dr. Couch scored at a 1,000?
A Dr. Couch scored a 1,000 out of 1,000 17 consecutive times from December 2014 to April 2016.
Q And for Dr. Ruan did you check to see where he scored?
A I did.
Q And where did Dr. Ruan score?
MR. KNIZLEY: Your Honor, we would for the record object as to foundation and opinion.
THE COURT: Overruled.
BY MR. BODNAR:
Q Where did Dr. Ruan score?

A In the time frame between September 2015 and April 2016 he scored 1,000 eight times. In the time frame between December 2014 and August of 2015 he scored 996 eight times and 992 one time.
Q And each month when you run this project is a printout done of people that score 951 and above?
A Yes.
Q I'm going to show you now what has been marked as Government's Exhibit 27-28. Are you able to identify what this document is?
A I am.
Q What is this document?
A This document is a listing of the factors and scores for physicians in a specific run of this -- of the project from January 1st, 2015, to December 31st, 2015.
Q So does that mean it was considering data for the entire year of 2015, January through December?
A That is correct.
MR. BODNAR: United States moves to admit Government's Exhibit 27-28.
MR. WILLSON: Renew our objection, Your Honor.
THE COURT: All right. Overruled and mark it in.
(Government's Exhibit 27-28 was entered into evidence.)
BY MR. BODNAR:
Q Mr. McCash, I'm now showing you what has been admitted as

Government's Exhibit 27-28. I know it's small. We will blow this up. While the lettering is very small still, along the top are these the 17 factors that were discussed on the sheet previous?

A Yes, they are.

Q And are the numbers below them the numbers that correlate with each factor?

A That is correct.

Q Let's see if I can blow up this one column so we can see what we're talking about. Looking at number of CS-II, what does CS-II stand for?

A Controlled substance.

Q And II stands for --

A Schedule II.

Q -- schedule II?

A Yes.

Q So this number underneath it in the line that says Xiulu Ruan, how many during this time period Medicare patients received controlled II substances?

A 822.

Q And for Dr. Couch how many received that?

A 1,163.

Q And do the numbers going across correlate with the factors that we just discussed on the other page?

A Yes, they do.

Q And I see right here it says predicted risk score. Why does its say predicted risk score?
A This is a standard column name that is used by my group. Some of our models are predictive in nature, and the first models we made were predictive. So they were predicted risk scores. In this case it's an anomaly detection project, which means it's an abnormality detection project and it's not a predicted score, it's similarly a risk score.
Q So this is not predicting anything in the future but looking back at a year's worth of data?
A That is correct.
Q Or whatever data was there during that one-year time period?
A That is correct.
Q Now, I see it cuts off here with 1,000. And do you see Dr. Ruan's and Dr. Couch's names listed next to a score of 1,000?
A I do.
Q Why does one start below Dr. Ruan and seems to skip a number for Dr. Couch here?
A As this particular document contained the names and identifying numbers of other physicians, they have been deidentified with only Dr. Ruan and Dr. Couch's names and IDs present.
Q So when this is actually run in your office, would this

include instead of numbers a bunch of doctors' names and NBI numbers?
A Yes, it would.
Q Are these numbers here just signifying the number of blank spaces?
A Yes.
Q Now, I see Dr. Ruan's name at the top and Dr. Couch about three levels below him. Within the grouping of 1,000, is there any ranking in that group?
A No, there is not.
Q So that just happens to be where their names fall on the page?
A That is correct.
Q So the individual who scored 1,000 here is scored at the same level as Dr. Ruan who is up here with 1,000? (Indicating.)
A That is correct.
Q And does it work the same way with all those that are 999, 998, and so forth?
A Yes.
Q Now this is simply statistics about the risk factors that we looked at previously; is that correct?
A Yes.
Q Nothing about the data can tell you what actually happened in the practice or how patients were treated or what they

had -- what their morbidities were; is that true?
A This is correct.
Q Is this simply a program set up to look for anomalies in the data?
A Yes.
Q And is 1,000 the top anomaly?
A Those individuals scoring 1,000 are most at risk for fraud, waste, and abuse.
Q But it does not mean that they necessarily are committing fraud, waste, and abuse?
A No, it does not.
Q You mentioned before that this -- this poll that's on this sheet was from January of '15 through December of '15?
A Yes.
Q If Dr. Ruan and Dr. Couch were only prescribing until May 20th of '15, why are they considered in a full-year chart here?
A It would be because the volume in which the months they did prescribe was large enough that they were allowed to be admitted into the project to be scored.
Q So does that mean in the five months their volume was large enough to reach a score of 1,000?
A That is correct.
Q Even though they didn't do a full year?
A Yes.
MR. BODNAR: One moment, Your Honor.

(A discussion was held off the record between government counsel.)

MR. BODNAR: Nothing further from this witness, Your Honor.

THE COURT: All right. Mr. Willson?

CROSS EXAMINATION

BY MR. WILLSON:

Q Good afternoon, Dr. McCash. How are you today?

A I'm very well. Thank you.

Q I have some questions for you about this, these numbers you have here. When you say that this is -- it only includes the first five months of the year -- is that right? For Drs. Ruan and Couch?

A No. The data is collected for the entire year.

Q Okay. But the data that's reflected here for Drs. Ruan and Couch comes from the first five months only of the year; is that right?

A I'm unable to tell you whether or not it was only the first five months. That would require inspection of the data itself.

Q Okay. And you didn't inspect the data?

A I did not inspect the data, no.

Q And when we say inspect, does that entail asking questions about the data?

A No, it does not.

Q At some point in time -- well let me back up a little bit

and ask you -- you've talked about this, about this project. Would you agree that the work of your company, NBI MEDIC, is to identify, investigate, and proactively prevent potential fraud, waste, and abuse in Medicare's prescription drug programs?

A I would.

Q And there's three words: identify, investigate, proactively prevent; is that right?

A Yes.

Q Now, this project, the doctor -- I'm sorry, I forgot the name of it. The project we're talking about here is a -- it identifies prescribers from all specialties; right?

A This is correct.

Q Okay. With an aggregated risk score above the established thresholds; is that accurate?

A Yes.

Q Okay. So this just identifies; is that right?

A Yes.

Q In other words, we talked about those three steps of what your company does. This is just the first step, identifying?

A That is correct.

Q And when you used the word "anomaly" with Mr. Bodnar, an anomaly means an abnormality; right?

A That is correct.

Q But according to this project and the process you used to

get your numbers here and your list, it wouldn't matter, would it, what the actual numbers are; it's just going to take essentially the top of the list in the country and that's going to be the result; is that right?

A Not entirely, no.

Q Okay. Well, let's look at some of these, some of these factors. I'd like to ask you about a few of them. We might come back to that question.

Would you agree, Dr. McCash -- let's see if I can get it all in there -- that the project here, in this project, prescribers were considered as high risk if the number of beneficiaries prescribed controlled II substances, which is -- well, let me just go through the list -- the number of beneficiaries prescribed controlled II substances, the number of beneficiaries prescribed controlled -- substances of schedule III, and the number of 30-day equivalent PDE records for controlled substances II through IV were all above the 75 percentile among the potential prescribers. Is that -- is that right?

A In order to be considered high risk, yes, that is the threshold.

Q Okay. So it looks like there are just a handful of these 17 that make a high-risk prescriber. And I'll go through them again because I bumbled a couple of the terms.

The number of beneficiaries prescribed controlled

substance schedule II drugs. That's one; right?
A Yes.
Q The number of beneficiaries prescribed controlled substance III medications. That's two; right?
A Yes.
Q And the number of 30-day equivalent PDE records for controlled substances II through IV. That's the third?
A Yes.
Q And if all of those are above the 75th percentile, you're high risk?
A As long as you were also above the 95th percentile in the nation for all of the 17 risk factors combined.
Q Okay. And about how many are there of those? Are you talking about -- it sounds like there's kind of an initial stage and then subsequent stage. But you just referred to "as long as you're above the 95th percentile." How many providers does that yield?
A It's usually between 1,000 and 800.
Q Okay. So if you're in the upper 75th percentile of that bunch with those three factors, you're high risk?
A The 75th percentile applies to the entire -- the entire population of prescribers that are included in the project that can receive scores, those meeting the minimum thresholds.
Q Okay. I think I got that, Dr. McCash. Basically if you're big, if you prescribe a lot of medications, controlled

medications, you're likely to be high risk according to your project analysis?
A Not necessarily.
Q Okay. But you would agree that it's just those three. So it's the number of beneficiaries, the number of beneficiaries prescribed controlled substance III, and the number of 30-day equivalents. That's the set that gives you the benchmark, and above that benchmark you're high risk; is that fair?
A As long as you're above the 95th percentile in the combination of all of the risk factors, yes.
Q Okay. And that comes first?
A That comes first.
Q The first thing you do is you take a whole set of 60 to 70,000 -- and we're not talking about pain management physicians; we're talking about physicians in the United States, 60 to 70,000 physicians?
A Yes. That are prescribing controlled substances, yes.
Q Okay. And you do that first piece, above the 95th percentile; right? And then you get --
A Yes.
Q Okay. Let's assume then. So assuming that, if you are above the 75th percentile on those three factors I listed, you are high risk; is that accurate?
A Yes.
Q Thank you. Now, being big, Dr. McCash, is that the basis

of any determination of fraud, waste, and abuse at NBI MEDIC?
A The determination of fraud, waste, and abuse is outside of the scope of my work.
Q Okay. So you didn't do any examination of anything further beyond those factors?
A My job is to assign the risk score and to produce that result.
Q Sure. And I want to ask you -- I'm not going to go through them all, Doctor. But I do want to ask you about just a couple -- a few of these. Would you agree that most of these are quantitative? In other words, number of schedule II controlled substance beneficiaries, that's a number; right?
A Yes.
Q Okay. And the same with number two; right?
A Yes.
Q And let's just say three as well. And then four through six, there's some analysis there. But essentially it's just a number; right?
A Yes.
Q Okay. Now, this travel threshold business right here, you said, I believe, that for beneficiaries who are in rural environments, it's 120 miles?
A That's correct.
Q And for beneficiaries who are in urban environments, it's more like 30 miles; right?

A Yes.
Q And you didn't -- did you look at a map of the regional area here to determine how many ZIP codes are rural and how many are urban?
A No. We used the Federal Information Processing Standards, FIPS county codes.
Q Sure. And if you're doing an actual analysis -- in other words, if you're doing that second piece, identifying -- and then the second piece is what? Investigate; right?
A Yes.
Q If you're doing that investigating, you're going to ask questions, aren't you, about the number of schedule II controlled substance beneficiaries; right?
A That is out of the scope of my work.
Q Okay. Are there folks at Health Integrity that do that kind of work?
A Yes, there are.
Q Okay. And they make an assessment. In fact, they engage their reason, do they not, to determine whether or not, for example, a pain management clinic is going to be a high risk, according to your project, a high-risk prescriber?
A I cannot speak to the methods and techniques that they use.
MR. WILLSON: Okay. Just a moment.
THE COURT: All right.
Q Just a couple more, Doctor. The threshold of travel,

that's just simple mileage; right? It's a number?
A Yes.
Q Okay. It has nothing to do -- in terms of what you do, it has nothing to do and you didn't look at, for example, how many other providers there are in the regional area?
A No.
Q That has nothing to do with how many practitioners there are who have a full sweep of treatment options in their facility?
A No.

MR. WILLSON: Okay. I believe that's all I have.

THE COURT: Mr. Knizley?

MR. KNIZLEY: We don't have any questions, Your Honor.

THE COURT: Any redirect?

MR. BODNAR: Briefly, Your Honor.

REDIRECT EXAMINATION

BY MR. BODNAR:
Q Mr. McCash, do you recall the defense attorney going over with you that the first thing that's done is look for -- or examine which doctors are in the 95th percentile based on all 17 factors?
A Yes.
Q So that's the top 5 percent; is that correct?
A That is correct.
Q Of anomalies?

A They would be the anomalies.
Q And then of that 5 percent, then you look at what's the top 25 percent of that as well?
A It's not of that particular group, it's of the group as a whole.
Q Of the group as a whole? And when you said that yields the high-risk number, is that the 951 to 1,000?
A The 951 to 1,000 is determined by the 95th percentile. The 75th percentile is used to determine whether or not they are high risk.
Q So if Dr. Ruan and Dr. Couch scored at 1,000 then, does that put them at the highest level you can be of high risk?
A Yes.
Q I just want to scroll over to -- let me find it here.

MR. BODNAR: No further questions, Your Honor.

THE COURT: All right. May this witness be excused?

MR. BODNAR: Yes, Your Honor.

THE COURT: All right. Thank you Dr. McCash. You may be excused.

* * *

C E R T I F I C A T E

STATE OF ALABAMA)

COUNTY OF BALDWIN)

I do hereby certify that the foregoing proceedings were taken down by me and transcribed using computer-aided transcription and that the foregoing is a true and correct transcript of said proceedings.

I further certify that I am neither of counsel nor of kin to any of the parties, nor am I in anywise interested in the result of said cause.

I further certify that I am duly licensed by the Alabama board of Court Reporting as a Certified Court Reporter as evidenced by the ACCR number following my name found below.

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