

In the Matter Of

1:20-cv-08390-RA

KRAGULJ

v.

CORTES, D.D.S., et al.

Deposition of Steve Galella, D.D.S.

Wednesday, July 7, 2021



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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BOJA KRAGULJ,

Plaintiff,

vs.

Case No.:
1:20-cv-08390-RA

MARTHA CORTES, D.D.S., STEVE
GALELLA, D.D.S., ORTHOMATRIX
CORP., INC., FACIAL BEAUTY
INSTITUTE, and JOHNS DENTAL
LABORATORY, INC.,

Defendants.

July 7, 2021
9:09 a.m.

Remote video-teleconference deposition of STEVE
GALELLA, D.D.S., taken by Plaintiff, held at the
offices of Fumuso, Kelly, Swart, Farrell, Polin &
Christesen, LLP, 110 Marcus Boulevard, Suite 500,
Hauppauge, New York 11788, pursuant to notice,
before Elizabeth F. Tobin, a Registered Professional
Reporter and Notary Public of the State of New
York.

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A P P E A R A N C E S:

On behalf of the Plaintiff:

CHARNAS LAW FIRM, P.C.
455 East 51st Street
New York, New York 10022
212.980.6800
BY: SCOTT E. CHARNAS, ESQ.
scharnas@charnaslawfirm.com
(via video-teleconference)

On behalf of the Defendant Martha Cortes, D.D.S.:

LAW OFFICES OF HENRY SCHWARTZ
32 Court Street, Suite 908
Brooklyn, New York 11201
718.222.3118
BY: HENRY R. SCHWARTZ, ESQ.
hschwartz@henryschwartzlaw.com
(via video-teleconference)

On behalf of the Defendant Steve Galella, D.D.S.:

FUMUSO, KELLY, SWART,
FARRELL, POLIN & CHRISTESEN, LLP
110 Marcus Boulevard, Suite 500
Hauppauge, New York 11788
631.232.0200
BY: ALAN J. FUMUSO, ESQ.
afumuso@110-law.com
(via video-teleconference)

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A P P E A R A N C E S: (Continued)

On behalf of the Defendants OrthoMatrix Corp., Inc.
and Facial Beauty Institute:

RIVKIN RADLER, LLP
926 RXR Plaza
Uniondale, New York 11566
516.357.3000
BY: KENNETH C. MURPHY, ESQ.
(via video-teleconference)

On behalf of the Defendant John's Dental Laboratory,
Inc.:

FRENCH & CASEY, LLP
29 Broadway, 27th Floor
New York, New York 10006
212.797.3544
BY: SCOTT J. LAIRD, ESQ.
slaird@frenchcasey.com
(via video-teleconference)

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IT IS HEREBY STIPULATED AND AGREED
by and between the attorneys for the
respective parties herein, that filing and
sealing be and the same are hereby waived.

IT IS FURTHER STIPULATED AND AGREED
that all objections, except as to the form
of the question, shall be reserved to the
time of the trial.

IT IS FURTHER STIPULATED AND AGREED
that the within deposition may be sworn to
and signed before any officer authorized to
administer an oath, with the same force and
effect as if signed and sworn to before the
Court.

- oOo -

1 S. Galella

2 COURT REPORTER: Mr. Murphy, are you
3 ordering a copy of the transcript?

4 MR. MURPHY: Yes.

5 COURT REPORTER: Mr. Laird, are you
6 ordering a copy of the transcript as well?

7 MR. LAIRD: Yes, I am.

8 COURT REPORTER: Mr. Schwartz, are you
9 ordering a copy of the transcript?

10 MR. SCHWARTZ: Yes.

11 COURT REPORTER: Good morning. My name
12 is Elizabeth Tobin. I am a New York State
13 stenographic reporter and a registered
14 professional reporter. Today's date is
15 July 7, 2021 and the time is approximately
16 9:09 a.m. This is the deposition of Steve
17 Galella, D.D.S. in the matter of Kragulj versus
18 Cortes, et al. This case is venued in the
19 United States District Court, Southern District
20 of New York. The case number is
21 1:20-cv-08390-RA.

22 At this time I will ask counsel to
23 identify yourself, state whom you represent and
24 agree on the record that there is no objection
25 to this deposition officer administering a

1 S. Galella

2 binding oath to the witness remotely via
3 video-teleconference.

4 MR. CHARNAS: No objection.

5 MR. FUMUSO: Alan Fumuso, no objection.

6 MR. SCHWARTZ: Henry Schwartz, no
7 objection.

8 MR. LAIRD: Scott Laird, no objection.

9 MR. MURPHY: Kenneth Murphy, no
10 objection.

11 S T E V E G A L E L L A,

12 of lawful age, called by the Plaintiff for
13 examination pursuant to the Federal Rules of Civil
14 Procedure, stating an address of 875 Poplar Avenue,
15 Suite 16, Collierville, Tennessee 38017, having been
16 first duly sworn remotely upon agreement of all
17 counsel, as hereinafter certified, was examined and
18 testified as follows:

19 EXAMINATION OF STEVE GALELLA, D.D.S.

20 BY MR. CHARNAS:

21 Q. Good morning. Good morning, Dr. Galella.
22 It's my understanding that you're here as an
23 individual and also as a representative for a
24 30(b)(6) deposition simultaneously held with your
25 deposition. That 30(b)(6) deposition is of

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S. Galella

defendants OrthoMatrix and Facial Beauty Institute.

Is that your understanding as well?

A. Yes.

Q. I've marked 17 deposition exhibits all of which I've given to counsel just before this deposition.

I'm going to show you Exhibit 1, Dr. Galella.

(Exhibit 1, 30(b)(6) notice, marked for identification.)

Q. Can you see that, Doctor, Exhibit 1?

A. Yes.

Q. I can scroll through the whole thing, but I think your counsel will agree, this is the deposition notice that you're here to testify as a witness for; is that right?

A. That's correct.

Q. And there are also four exhibits to that notice which I'm going to show you, Exhibit A -- 1A, I'm sorry.

(Exhibit 1A, medical record; 00356-62, marked for identification.)

Q. That's 1A.

Do you see that, Doctor?

1 S. Galella

2 A. Yes.

3 Q. Sorry. Zoom makes it a little unwieldy.

4 This is 1B.

5 (Exhibit 1B, MX appliance documents;
6 00333-37, marked for identification.)

7 Q. Can you see that, Doctor?

8 A. Yes.

9 Q. Then we have 1C.

10 (Exhibit 1C, November FBI newsletter; 15
11 pages, marked for identification.)

12 Q. Can you see that, Doctor?

13 A. Yes.

14 Q. And 1D.

15 (Exhibit 1D, FBI Kragulj medical record;
16 4 pages, marked for identification.)

17 Q. Can you see that, Doctor?

18 A. Yes.

19 Q. Those are the four sub-exhibits, if you
20 will, to Exhibit 1.

21 Doctor, have you ever been deposed
22 before?

23 A. Yes.

24 Q. Were any of those depositions in
25 connection with an anterior growth guidance

1 S. Galella

2 appliance?

3 A. No.

4 Q. I'm going to ask you a series of
5 questions, as I've been doing, to which you're
6 expected to respond audibly. Shrugs of the
7 shoulder, shakes of the head, don't show up very
8 well on the transcript.

9 If at any time I ask a question which you
10 don't fully hear or understand, please let me know
11 and I'll attempt to repeat or rephrase it for you.
12 If you don't let me know, I'll assume you heard and
13 understood the question.

14 Is that fair?

15 A. That's fair.

16 Q. If at any time you want to take a break
17 for whatever reason, whether to confer with counsel,
18 use the facilities, you just let us know and I'll be
19 glad to accommodate you.

20 I may ask you to answer any pending
21 question before you take that break. Okay?

22 A. Okay.

23 Q. Now, sir, did you talk to anyone in
24 preparation for this deposition other than
25 attorneys?

1 S. Galella

2 A. No.

3 Q. Did you receive any substantive
4 information from anyone about the subject matter of
5 this deposition in preparation for this deposition?

6 A. Repeat the question.

7 Q. Sure. In preparation for this
8 deposition, did you receive any substantive
9 information about the subject matter of the
10 deposition from anyone?

11 A. No.

12 Q. Doctor, I'm going to show you a document
13 which has been marked as Exhibit 2. And I want to
14 represent that this document was produced in
15 discovery by your counsel.

16 (Exhibit 2, Galella curriculum viae; 16
17 pages, marked for identification.)

18 Q. Can you see this, Exhibit 2?

19 A. Yes.

20 Q. Does this appear to be your curriculum
21 vitae, Doctor?

22 A. Yes, it does.

23 Q. I want to ask you a few questions about
24 that.

25 Are you a D.D.S., Dr. Galella?

1 S. Galella

2 A. Yes.

3 Q. Is it fair to say that you have never
4 been licensed to practice dentistry in the state of
5 New York?

6 A. Yes.

7 Q. Is it fair to say that the only states
8 that you are licensed and have ever been licensed to
9 practice dentistry are Arkansas and Tennessee?

10 A. That's correct.

11 Q. Are you an orthodontist?

12 A. No. I'm a general dentist.

13 Q. Are you an oral surgeon?

14 A. I do oral surgery, but I'm not a
15 specialist, no.

16 Q. Did you complete a four- or a six-year
17 residency beyond dental school in the field of oral
18 surgery?

19 A. No.

20 Q. Are you a craniomaxillary surgeon?

21 A. No.

22 Q. Are you a medical doctor?

23 A. No.

24 Q. Now, Doctor, at the top of your CV it
25 says practice limited to orthopedics/orthodontics

1 S. Galella

2 TMD/craniofacial pain.

3 Where did you receive the training in
4 orthopedics with?

5 A. Orthopedics in dentistry is a term used
6 for appliances that affect the hard tissue of the
7 oral cavity. So just various continuing education
8 events and working with other doctors.

9 Q. Can you tell us what continuing education
10 events you're talking about?

11 A. They're listed on the CV.

12 Q. Thank you. Now, you graduated from
13 University of Tennessee dental school in December of
14 1978 and you started at Methodist --

15 A. 1977.

16 Q. 1977. I'm sorry. And what was your
17 first job in the field of dentistry after that? Was
18 it at Methodist Hospital?

19 A. My first job?

20 Q. Physician, in the field of dentistry.

21 A. I think I was in a rented part of a
22 practice at night, worked at night when I got
23 started, and then eventually transitioned into
24 private practice.

25 Q. From 1983 to 1989, you were chief

1 S. Galella

2 surgeon/director of education for the Oral-Facial
3 Rehabilitation Group at Methodist Hospital in
4 Memphis?

5 A. I don't think it says chief surgeon on
6 the CV. If you'll scroll to that part, I'd like to
7 see that.

8 Q. Sure. Hang on one second, if you would.

9 Can you see, it's on page 3 of Exhibit 2.
10 It says "Oral-Facial Rehabilitation Group-chief
11 surgeon/director of education, 1983 to 1989." It
12 also says just below that, "Cleft Palate
13 Reconstruction Team, chief surgeon 1983 through
14 1989."

15 Did I read that correctly?

16 A. Yes, that's correct.

17 Q. Were you chief surgeon of the Oral-Facial
18 Rehabilitation Group?

19 A. That was a group comprised of
20 otolaryngologists, an orthodontist, myself and I
21 think that's all that was on the team.

22 Q. Did you, in fact, carry the title of
23 chief surgeon?

24 A. Yeah, I was chief surgeon, occasionally,
25 but not every operation.

1 S. Galella

2 Q. That was your title, Doctor, chief
3 surgeon?

4 A. In the oral rehabilitation group which
5 was -- yeah, it was a corporation. So I was the
6 chief surgeon of that corporation.

7 Q. What, if any, degree other than your
8 D.D.S. qualified you to carry the title of surgeon?

9 A. Doctor of dental surgery, that's what
10 D.D.S. stands for.

11 Q. Did you have a direct supervisor at
12 either of those positions, Doctor?

13 A. Worked with otolaryngologists. They were
14 pretty much supervising all the hospital surgeries.

15 (Simultaneous speakers.)

16 Q. I'm sorry. I didn't mean to interrupt
17 you. Go ahead.

18 A. We also traveled and did cleft palate
19 surgery in third world countries.

20 Q. Can you name one of your supervisors in
21 either of those positions of chief surgeon?

22 A. Dr. John Hodges, M.D. and Dr. Charlie
23 Gross, M.D.

24 Q. Do you know if either of those two
25 gentlemen are still alive?

1 S. Galella

2 A. I know Dr. Hodges is still alive. I'm
3 not quite sure about Dr. Gross.

4 Q. Have you ever been appointed to the
5 faculty of any college or university?

6 A. No.

7 MR. CHARNAS: Off the record.

8 (Discussion held off the record.)

9 Q. Doctor, you've lectured on something
10 called ControlledArch, correct?

11 A. That's correct.

12 Q. What is ControlledArch, generally
13 speaking?

14 A. It's an orthodontic technique.

15 Q. Can you be more specific, sir?

16 A. I'm not quite sure what you're trying to
17 ask.

18 Q. Is ControlledArch a system of some kind?

19 A. It's a technique that -- it's a system or
20 technique that allows you to move the crowns and
21 move the teeth simultaneously instead of as in
22 traditional orthodontics where you move the crown
23 first and then the root.

24 Q. Does ControlledArch include
25 ControlledArch braces, as well as -- generally

1 S. Galella

2 speaking now -- controlled arch braces as well as an
3 anterior growth guidance appliance?

4 A. I'm not sure what you mean by
5 ControlledArch braces. The brackets were developed
6 by Larry Andrews in 1969, 1971 and we used the
7 straight-wire bracket system. But we don't have a
8 ControlledArch brace.

9 Is that what you're asking?

10 Q. Thank you for your answer.

11 Have you ever heard the term anterior
12 growth guidance appliance?

13 A. Yes.

14 Q. What is that, generally speaking?

15 A. That is an appliance that's used -- for
16 non-growers it's used to remodel the maxilla which
17 in turn remodels the nasomaxillary complex, et
18 cetera.

19 (Simultaneous speakers.)

20 Q. Sorry. I thought you were finished. I
21 apologize. Go ahead.

22 A. It changes the craniofacial architecture.

23 Q. Let me show you a document -- hang on one
24 sec.

25 Do you see this document, which is

1 S. Galella

2 Exhibit 1B which we looked at a few moments ago?

3 A. No.

4 Q. How about now?

5 A. Yes.

6 Q. So it says "MX" which I assume stands for
7 maxilla, "fixed anterior growth guidance appliance
8 facial version" and then right under that it says
9 "MX fixed Osseo-Restoration Appliance facial
10 version."

11 Are those two different devices?

12 A. Yes.

13 Q. Can you tell us the difference?

14 A. The facial version has the spring
15 assembly and the lock stops on the facial side of
16 the maxillary teeth. The lingual version has them
17 on the lingual side or palatal side of the maxillary
18 teeth.

19 Q. Have you ever reviewed Dr. Martha Cortes'
20 record in regard to the care and treatment of Boja
21 Kragulj, the plaintiff in this case?

22 A. Let me just be clear. You had said the
23 records?

24 Q. Yes. The office records?

25 A. No.

1 S. Galella

2 Q. Doctor, are you aware that at some point
3 you had approved two anterior growth guidance
4 appliances through Johns Dental for use by
5 Dr. Cortes on Boja Kragulj?

6 MR. FUMUSO: I'll object to that. Please
7 rephrase that.

8 Q. Doctor, as part of your duties from time
9 to time you approved anterior growth guidance
10 appliances manufactured by Johns Dental for
11 particular patients; is that correct?

12 MR. FUMUSO: I have a problem with the
13 word approved. Approved implies he was
14 involved with the care and treatment.

15 MR. CHARNAS: Your objection is noted.

16 Q. Doctor, can you answer that?

17 A. John will send me photographs of the
18 appliance made on models. I have no history or
19 knowledge of the patient other than it's on a model,
20 did they make the appliance correctly. So that's
21 what I look at, make sure it's made within the
22 parameters of the way the appliance should be made.

23 Q. Is it fair to say that you judged two of
24 those appliances as appropriate or "looks good" for
25 Boja?

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S. Galella

A. For Dr. Cortes?

Q. For Dr. Cortes' use on Boja Kragulj.

A. Yes.

Q. Were those particular -- let me strike that.

MR. CHARNAS: I'm going to show you Exhibit 10.

(Exhibit 10, email communication with attached photographs; 0001-0031, marked for identification.)

Q. Can you see that Exhibit 10 sticker there, Doctor?

A. Yes.

Q. I'm going to represent to you that this was a record that was produced by Johns Dental in discovery in this case. I'm going to show you on the second page an email which appears to be from you to MotionView 3D which appears to be an email address at Johns Dental.

Do you see that there, Doctor?

A. Yes.

Q. That's dated January 2nd, 2018. And you said "looks great," right?

A. That's what it says.

1 S. Galella

2 Q. And then on page 3 -- by the way, I've
3 paginated these pages to make it -- for ease of
4 reference on the bottom left.

5 And on page 3, Doctor, there's another
6 email from you to the same email address at Johns
7 Dental dated November 29, 2018, and you say they're
8 great. You see that, right?

9 A. Yes.

10 Q. Let me show you --

11 MR. LAIRD: Scott, it's time for me to
12 take my break now. I will send an email when
13 I'm done which I hope will be less than ten
14 minutes.

15 MR. CHARNAS: Thank you, Scott.

16 MR. LAIRD: Thank you all.

17 (A recess was taken from 9:28 a.m. to
18 9:38 a.m.)

19 BY MR. CHARNAS:

20 Q. Can you see that, Doctor? Back on
21 Exhibit 10.

22 A. Okay.

23 Q. I'm going to turn to the 13th page of
24 Exhibit 10. Again, Doctor, this is the Johns Dental
25 record that was produced in discovery.

1 S. Galella

2 Can you tell us, we're looking at a mold
3 of teeth, obviously, correct?

4 A. Yes. Correct.

5 Q. What is the device on the teeth, Doctor?

6 A. That's the Osseo-Restore appliance, the
7 facial version.

8 Q. Is that sometimes called FAGGA,
9 F-A-G-G-A?

10 A. Well, not by me. That's a term that was
11 made by bloggers.

12 Q. Is there a shorthand way of referring to
13 this device?

14 A. O-S S-E-O hyphen Restore.

15 Q. Osteo-Restore.

16 A. Not osteo. Osseo -- O-S-S-E-O.

17 Q. Osseo. Thank you. I was thinking bone.
18 Thank you.

19 Is this the device that you said looks
20 great?

21 A. I would have to see the whole document.

22 Q. Sure. Let me withdraw that question.
23 Let me ask a different question.

24 Let me show you on the 23rd page,
25 obviously we're looking at a model of teeth again,

1 S. Galella

2 correct, Doctor?

3 A. Yes.

4 Q. What's the device on that?

5 A. That's the Osseo-Restore facial version.

6 Q. Is that device on page 23 the same device
7 as we looked at on page 13 in terms of modeling
8 type?

9 A. Yes. It's on a different set of models,
10 different circumstances, but it's the same design.

11 Q. So they're both Osseo-Restore devices?

12 A. Osseo-Restore and that's it.

13 Q. From now on throughout this deposition,
14 Doctor, when I say Osseo-Restore device, or
15 appliance, this is what I'm referring to, that type
16 of model of device.

17 Do you understand?

18 A. Unless it's a lingual one, yes. That's
19 the facial version.

20 Q. Yes. I'm talking about this particular
21 device. If I'm talking about a different device,
22 I'll try to make that clear.

23 A. Thank you.

24 Q. When was this Osseo-Restore device first
25 in use, Doctor? I'm talking about this particular

1 S. Galella

2 model or type, again.

3 A. Well, it's gone through changes over the
4 years. The first one was used probably in early
5 nineties. And this particular version was used
6 until about 2020, 2021. 2020, probably.

7 Q. When was this particular device first
8 used, approximately, Doctor?

9 MR. FUMUSO: This model.

10 A. This model would have been the nineties,
11 early nineties.

12 Q. Has this device ever been referred to as
13 Generation 7, this particular model, device?

14 A. I'd have to see more the size. I think
15 it's probably Generation 5 or 6.

16 Q. Let me show you some other photos, if
17 this helps you, Doctor.

18 I'm going to scroll through this.

19 A. You have to remember I'm from Tennessee,
20 so I don't see as fast as you do.

21 Q. Sorry, Doctor. Us New Yorkers, we're a
22 little rapid?

23 A. It looks like a Generation 5 or 6. Could
24 be a 7. I think 7 had an eyelet on it and this just
25 had a bent over hook. So that would be 5 or 6.

1 S. Galella

2 Q. Current in use there's a Generation 8; is
3 that correct?

4 A. There is a Generation 8, but it looks
5 different.

6 Q. Right. Thank you.

7 Doctor, do you have a patent on the
8 Osseo-Restore device?

9 A. It's pending. Patent pending.

10 Q. When did you first apply for this patent?

11 A. Probably about a year, year-and-a-half
12 ago.

13 Q. Is it fair to say that you've personally
14 installed these Osseo-Restore devices on patients?

15 A. Install is an odd word for a dentist. We
16 don't install things. Placed would be -- is that
17 what you mean, placed?

18 Q. If that's a word you prefer, Doctor,
19 that's fine with me.

20 A. Okay. Well, yes. Now what was the
21 question again?

22 Q. Is it fair to say that you've placed
23 these Osseo-Restore devices in patients?

24 A. Yes.

25 Q. By the way, getting back to that

1 S. Galella

2 Exhibit 10 for a moment, when you said looks great
3 in January of 2018 in that email and you said great
4 in the November 2018 email, what were you trying to
5 convey?

6 A. Well, my job is to look at the -- the
7 appliance on the model and look at the way it was
8 designed, the way it was put together and make sure
9 that acrylic pad was the right size and the right
10 place and the wire that abuts the cingulums of the
11 anterior teeth is in the right place and the spring
12 is in the right place, all the components are
13 properly assembled by the laboratory. I have no
14 knowledge of the patient, the patient's history or
15 even the doctors other than they're just names to
16 me.

17 I'm just looking at physical -- the
18 physical appliance. And is it going to work. I'm
19 looking for parallelism and the sliding arms, et
20 cetera.

21 Q. Doctor, one of the components of the
22 Osseo-Restore device is an acrylic piece that's
23 pressing the mucosa of the anterior hard palate; is
24 that fair to say?

25 A. Yes.

1 S. Galella

2 Q. What's the purpose of that device, that
3 portion of the device?

4 A. It puts a calculated amount of pressure
5 on the soft palate which pushes on the bone and it
6 effectively works with Wolff's Law which says if you
7 put pressure in a situation like this, the body will
8 react by remodeling the bone because of the pressure
9 it puts.

10 Q. Is the pressure being put on the
11 nasopalatine nerve?

12 A. Part of the pressure is on the branch of
13 the trigeminal nerve that comes out of the incisal
14 canal. But it's just a minor pressure there. And
15 it's also pressure on the attached gingiva of the
16 hard palate which is mostly water so it conveys the
17 pressure directly to the bone and the bone reacts.
18 Yes.

19 Q. So there's pressure on the nasopalatine
20 nerve; is that right?

21 A. Yes.

22 Q. Now, there's a wire attached to the
23 lingual surfaces of the anterior six teeth of this
24 device; is that correct?

25 A. That's correct.

1 S. Galella

2 Q. What's the purpose of that device?

3 A. The wire body is bonded to the cingulums
4 of the -- in this model to the cingulums of the six
5 anterior teeth to keep the acrylic pad from sliding
6 down the incline plane of the palate.

7 Q. There are also bands for the posterior
8 teeth on this Osseo-Restore Device?

9 A. That's correct.

10 Q. What's the purpose of that, those bands?

11 A. Well, A, they hold the device in. B, the
12 components are attached which is a stop lock and a
13 spring and a sliding arm.

14 Q. What's the purpose of a stop lock?

15 A. It's to compress the spring --

16 (Indiscernible noise.)

17 (Court reporter requested clarification.)

18 Q. Doctor, what's the purpose of the stop
19 lock or stop locks?

20 A. The stop lock on each side compress the
21 spring which delivers the force to the sliding arm
22 that the pressure is exerted on the acrylic pad.
23 When you compress the springs, the arm slides and
24 the pressure is put on the acrylic pad.

25 Q. What's the purpose of the sliding arm?

1 S. Galella

2 A. To put the pressure on the acrylic pad.

3 Q. What's the length of the sliding arm in
4 the Osseo-Restore Device?

5 A. Show me a picture of the one that we're
6 talking about and it just varies between the
7 generation.

8 Q. Hang on. Can you see that, Doctor?

9 A. Okay. So you want the length of the
10 sliding arm?

11 Q. Yes.

12 A. Well, the -- in the standard design, you
13 see those little tubes, you see the spring and then
14 there's a tube that the wire slides into. The tubes
15 are 13 and a half millimeters long so the length of
16 the sliding arm, it varies depending on the model
17 that you're working on, the patient that you're
18 working on.

19 Q. Have you ever heard the term facial
20 orthopedics?

21 A. Yes.

22 Q. What's facial orthopedics?

23 A. That's the general term. That could be
24 use of any appliance to effectively change the bone
25 of the teeth and the orofacial structure.

1 S. Galella

2 Q. Earlier you used the term non-grower and
3 I want to make sure we've got it defined.

4 How do you define non-grower?

5 A. A non-grower is somebody that is not
6 growing. So, growth is defined by two things,
7 displacement and remodeling. So in a grower,
8 mid-face grows up and back, it's displaced down and
9 forward. As it's displaced, it has to be remodeled
10 to accommodate the structures and the functions.

11 Q. Would you agree that generally by the age
12 of 18 a person is a non-grower?

13 A. Well, now you're getting into the
14 science. There is some speculation in the
15 literature that women it's 22, men it's 27. And
16 there's some in the literature that says it's 14 and
17 16.

18 But what is probably the -- generally
19 assumed from the literature is by age 12, 80 percent
20 of all displacement is complete. So I guess by 18
21 you could say that most likely they're finishing up
22 their growth displacement. Growth has to have
23 displacement remodeling. It doesn't mean that you
24 can't remodel after the displacement is gone. It
25 just means by definition they're not growing.

1 S. Galella

2 Q. Is it fair to say that it's generally
3 accepted in dentistry and orthodontics that people
4 stop growing by the age of 18 in terms of facial
5 growth?

6 A. You're making a generalization and you
7 want me to agree. I'm sort of --

8 MR. FUMUSO: If you can't answer the
9 question, just tell him.

10 A. Rephrase the question, please. I don't
11 know exactly what you want me to answer.

12 Q. Do you have any sort of age limit in
13 terms of when a person becomes a non-grower? In
14 other words, if a person is 50 years old, you would
15 agree that they're probably not a grower, right?

16 A. Yes. 50, yes. Well, the general --
17 because there's a difference between what general
18 dentists think and what orthodontists think.
19 Generally 18 -- let's just give it a range. You
20 could say, depending on the individual, somewhere
21 between 18 and, say, 25. That could be varying
22 because we do have people that are in their twenties
23 that are still growing and we have people that, you
24 know, as young as 14 years old that stopped growing.

25 Q. Is it fair to say that generally speaking

1 S. Galella

2 a non-grower would be over the age of 25?

3 A. Yes.

4 Q. And have you ever said that a non-grower
5 is over the age of 18?

6 A. I'm sorry. I didn't hear the question.

7 Q. Have you ever written anything to the
8 effect that non-growers are people who are over the
9 age of approximately 18?

10 A. I may have, yes. I may have.

11 Q. I asked you this earlier and I'm not
12 quite sure I understood your answer, so let me ask
13 it a different way.

14 Have you ever lectured on something
15 called a ControlledArch brace?

16 A. No. ControlledArch is a system or a
17 technique but there's no ControlledArch brace.
18 That's a term that is -- the LVI, Las Vegas
19 Institute, uses. CAB or ControlledArch brace,
20 that's their term, not mine.

21 MR. CHARNAS: I'm going to show you a
22 document which has been marked as Exhibit 3A.

23 (Exhibit 3A, article part 1; 49 pages,
24 marked for identification.)

25 Q. Can you see, that, Doctor?

1 S. Galella

2 A. Yes.

3 Q. And the title is "Guiding Atypical Facial
4 Growth Back To Normal; Part 1, Understanding Facial
5 Growth."

6 Did I read that correctly?

7 A. Yes.

8 Q. There's also a Part 2 which I represent
9 to you I've marked as 3B and we'll get to in a
10 moment.

11 This was written -- co-authored by you
12 and Donald Enlow as well as others, correct?

13 A. That's correct.

14 Q. Now let me show you 3B.

15 (Exhibit 3B, article part 2; 23 pages,
16 marked for identification.)

17 Q. Do you see that, Doctor, Exhibit 3B?

18 A. Yes.

19 Q. That says "Guiding Atypical Facial Growth
20 Back To Normal; Part 2, Causative Factors, Patient
21 Assessment and Treatment Planning."

22 Did I read that correctly?

23 A. Yes.

24 Q. That was also co-authored by you, Donald
25 Enlow and others, right?

1 S. Galella

2 A. That's correct.

3 Q. These articles were written in 2011 and
4 2012, approximately?

5 A. I have no idea. I have to see the dates.
6 That's a long time ago.

7 Q. Do you agree that these two articles
8 provide a description of theories related to the
9 process of normal and atypical facial growth and
10 development through the teenage years?

11 A. I'm sorry. Read that question a little
12 bit slower.

13 Q. I'm sorry. Do you agree that these two
14 articles provide a description of theories related
15 to the process of normal and atypical human facial
16 growth and development through the teenage years?

17 A. Through the teenage years? These are
18 pretty much papers concerning the removable growth
19 appliance. So it would be the younger -- a younger
20 audience. It would be -- the causes of atypical
21 growth would be epigenetics, we get into that. It's
22 mainly the work of Donald Enlow from "Essentials of
23 Facial Growth."

24 Q. Is it fair to say that these articles, 3A
25 and 3B, essentially apply to non-growers?

1 S. Galella

2 A. No. They're mainly applying to people
3 that are actually growing.

4 Q. So these two articles apply to growers,
5 essentially, correct?

6 A. Pretty much. The first article may
7 include some non-grower information. But the part
8 two is pretty much the treatment planning using
9 removable appliances which is growers.

10 Q. Do you agree that neither part one or
11 part two were intended by you to apply to
12 non-growers?

13 A. Rephrase that question.

14 Q. Sure.

15 A. I'm sorry.

16 Q. Do you agree that neither of those two
17 articles were intended by you, at least, to apply to
18 non-growers?

19 A. Well, some of the information in regards
20 to the remodeling would apply to non-growers. But,
21 as a rule, it's growers because their displacement
22 is involved. So remodeling and displacement which
23 is the growth, a grower. So if it's non-grower, it
24 would apply to the remodeling portion such as the
25 mandible or parts of the nasomaxillary complex.

1 S. Galella

2 Q. Isn't it true that you've just
3 extrapolated beyond these articles?

4 MR. FUMUSO: Objection. Argumentative.
5 Please rephrase the question.

6 MR. CHARNAS: You have your objection. I
7 don't intend to rephrase the question. I note
8 your objection.

9 MR. FUMUSO: Well, I object and I ask
10 that you rephrase the question.

11 MR. CHARNAS: I don't think the question
12 needs rephrasing. You've objected. Now I'm
13 going to move forward. If you're right, the
14 question and answer will be stricken.

15 MR. FUMUSO: If there is an answer.

16 A. Ask me the question again, please.

17 MR. CHARNAS: Could the court reporter
18 read back the question.

19 (Record read.)

20 A. All right. So I'm sorry. I'm from
21 Tennessee. So we need to -- if you could just break
22 that down to little simple words.

23 Q. Sure. Doctor, these two articles,
24 Exhibit 3A and 3B, you've already told us deal with
25 principles concerning growers, correct?

1 S. Galella

2 MR. FUMUSO: I'm sorry. What was that
3 question?

4 Q. Doctor, you've just told us that articles
5 3A and 3B deal with growers, correct?

6 MR. FUMUSO: No. You're misconstruing
7 his testimony.

8 MR. CHARNAS: You don't get a chance to
9 make coaching answers -- coaching objections.
10 So if you want to object, object.

11 MR. FUMUSO: Hold on a second.
12 Counselor, I'm going to object the way that I
13 want to object. If I feel your question is
14 objectionable, I'm going to state the reason
15 why. There's nothing that you're going to say
16 or do which is going to prevent me from doing
17 that. I'll tell you that right now.

18 I am not coaching the witness. I am
19 pointing out the inconsistency and the
20 objectionable aspect of your question. Okay.

21 MR. CHARNAS: Speaking objections are
22 inappropriate.

23 MR. FUMUSO: Counselor, your question is
24 inappropriate.

25 MR. CHARNAS: If you continue to make

1 S. Galella

2 them, then we'll take it up with the court.

3 MR. FUMUSO: Well, we'll take it up the
4 with the court. Fine. You want to take it up
5 with the court, we'll take it up with the
6 court. I'm indicating the basis of my
7 objection and I can do so. I can state the
8 basis of my objection.

9 MR. CHARNAS: Actually, you're not
10 supposed to.

11 MR. FUMUSO: I disagree with you on that.

12 MR. CHARNAS: If we keep wasting this
13 time, I don't think we're going to finish
14 Dr. Galella in one day.

15 MR. FUMUSO: If we don't finish him
16 because you're doing something improper, then
17 we don't finish him. I'm not going to
18 compromise my client's defense because you're
19 trying to instruct me how to defend my client.
20 I'm not going to do that.

21 Q. Dr. Galella, is it fair to say that these
22 two articles were co-written by you and Enlow and
23 others in regard to growing people, correct?

24 A. To the best of my recollection, I'd have
25 to read the article. It's been a while since I read

1 S. Galella

2 these articles.

3 Q. Is it fair to say that as of
4 January 25th, 2018, these two articles, Exhibit 3A
5 and 3B, including their references in the articles,
6 encompass your basis for the development and proof
7 of efficacy of Osseo-Restore devices in non-growers?

8 A. I have to -- let me read the article.
9 Could we take a minute and let me read them? I
10 don't want to say what I don't remember is in the
11 article. We have a copy of them, don't we?

12 Q. Yeah. You have a copy. Let's take a few
13 minutes. You can read the articles, Doctor.

14 MR. CHARNAS: You've got them, Alan?

15 MR. FUMUSO: He's going to read them over
16 here. I'm muting.

17 MR. CHARNAS: You want to take a
18 five-minute break?

19 MR. FUMUSO: Sure. We'll take a
20 five-minute break.

21 (A recess was taken from 10:02 a.m. to
22 10:12 a.m.)

23 Q. Dr. Galella, while we were off the
24 record, you had a chance to read Exhibit 3A and 3B,
25 correct?

1 S. Galella

2 A. That's correct.

3 Q. By the way, Doctor, is it fair to say
4 that you developed the Osseo-Restore Device?

5 A. Well, not by myself.

6 Q. Were you part of a team that developed
7 this device?

8 A. Yes. There's -- it's a long story, but
9 yes.

10 Q. Can you tell me the names of the people
11 on that team?

12 A. Well, the removable has been around for a
13 long time. It's a variant of the sagittal appliance
14 made popular by Dr. John Witzig in the eighties.
15 The fixed one was developed by Joe Sim and myself.
16 He was the head of orthodontics and pediatric at
17 Southern Illinois University. And the original
18 version was developed, I guess, probably in the
19 nineties, sometime in the early nineties.

20 Q. By you among others -- or with others, I
21 should just say?

22 A. Well, I just told you. Dr. Sim and
23 myself developed the fixed. And then the various
24 generations after that with contributions from other
25 people.

1 S. Galella

2 Q. Would it be fair to call you a
3 co-inventor of the Osseo-Restore Device?

4 A. Well, "co-" implies two. There's
5 probably several over the years that have added
6 ideas that helped us develop it even better.

7 Q. Doctor, is it fair to say that as of
8 January 25th, 2018, those two articles, Exhibits 3A
9 and 3B, including their references encompassed your
10 basis for the development and proof of efficacy of
11 the Osseo-Restore Device for non-growers?

12 A. Rephrase that question so I could -- it's
13 a little complex.

14 Q. You participated in the development of
15 this Osseo-Restore Device, correct?

16 A. Correct.

17 Q. And you believe that the Osseo-Restore
18 Device has certain efficacy, correct?

19 A. Yes.

20 Q. And you believed that as of January 25th,
21 2018, correct?

22 A. Yes.

23 Q. And what do you -- what's your
24 understanding or claim as to what the Osseo-Restore
25 Device does, generally speaking?

1 S. Galella

2 A. Depends on which appliance. There's a
3 removable and a fixed.

4 Q. I think I mentioned earlier that when I
5 say Osseo-Restore Device, I'm talking about the
6 device that was pictured in Exhibit 10 that you said
7 looks great or great. That's the device I'm talking
8 about. So it's the fixed device.

9 A. The fixed device. Ask me one more time
10 so I'll try to get the exact question you're asking.

11 MR. CHARNAS: Could the court reporter
12 please read the question back?

13 (Record read.)

14 MR. CHARNAS: I'll ask it again.

15 Q. Is it fair to say that as of
16 January 25th, 2018, your basis for the development
17 and proof of efficacy of the Osseo-Restore Device
18 was encompassed by those two articles including the
19 references in those articles?

20 A. Well, there was -- the references are the
21 key part. The basis of the fixed appliance which is
22 for non-growers, those papers were generally written
23 for growing patients. But the fixed Osseo-Restore
24 was from the work of Don Enlow, "Essentials of
25 Facial Growth"; from New York University, Tim

1 S. Galella

2 Bromage, "Hard Tissue Research"; and various
3 paleontologists, physiologists, anthropologists and
4 anatomists, but the basis is remodeling of bone.
5 You put a certain amount of force on bones and it
6 remodels and it remodels in a three-dimensional way.

7 Q. Is it fair to say your basis for the
8 belief in the efficacy of the Osseo-Restore devices
9 for non-growers as of January 2018 was based on
10 those two articles and the references in them?

11 MR. FUMUSO: Objection. He just answered
12 the question. Next.

13 MR. CHARNAS: I don't think so.

14 MR. FUMUSO: He just gave you an answer
15 to that question. Next question.

16 Q. Doctor, tell us, what beyond that article
17 and the references in that article specifically did
18 you rely upon as of January 2018 for the proof of
19 efficacy of the Osseo-Restore Device?

20 MR. FUMUSO: Other than what he just told
21 you?

22 MR. CHARNAS: I asked him specifically
23 what.

24 MR. FUMUSO: He just gave you an answer.

25 MR. CHARNAS: No, he didn't.

1 S. Galella

2 MR. FUMUSO: Sure, he did. He talked
3 about --

4 MR. CHARNAS: I'm not going to debate --

5 MR. FUMUSO: I'm not going to debate the
6 issue either. He just gave you a long answer
7 explaining the basis and so that's it. He gave
8 you a long answer explaining the basis.

9 MR. CHARNAS: I'm asking for specific
10 documents or articles. He did not give me
11 specific documents or articles.

12 MR. FUMUSO: Sure, he did. Dr. Enlow.
13 He gave you a specific article. He gave you --

14 MR. CHARNAS: Dr. Enlow is not a specific
15 article. Dr. Enlow is a person.

16 MR. FUMUSO: He gave you the name of the
17 book that he wrote.

18 MR. CHARNAS: I'm asking for all
19 documents, treatises, et cetera, specifically,
20 other than what's referenced in those two
21 articles or the two articles themselves. Now
22 if you're refusing to let him answer...

23 MR. FUMUSO: I'm not refusing to let him
24 answer at all.

25 Q. Then please answer the question, Doctor.

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S. Galella

MR. FUMUSO: Doctor, answer the question. If you -- if you restate what you've already testified to, restate it. Answer the question to the best of your ability.

MR. CHARNAS: Don't coach him.

Q. Answer the question, please.

MR. FUMUSO: Counselor, he answered the question. You're asking him the same question. You don't like his answer so I'm telling him answer the question.

MR. CHARNAS: His answer was incomplete. I'm not going to be debating this with you for the rest of this deposition. I'm getting a little tired of it.

MR. FUMUSO: You're growing tired of it? I'm growing tired of it.

Q. I'll ask you one more time, Doctor, beyond what's in -- strike that.

Beyond the terms of the two articles, what's in the two articles, including the references, what specifically did you rely upon as of January of 2018 for your proof of efficacy of the Osseo-Restore Devices in non-growers?

MR. FUMUSO: Objection. Asked and

1 S. Galella

2 answered. But you can answer the question. Go
3 ahead.

4 A. The articles are really directed at
5 growing patients, not non-growers. But the work of
6 Enlow. There's the work of -- the work of Bromage.
7 The work of various authors in the literature. I
8 can't quote you the documents. But there's a whole
9 library that I can give you a list of papers if you
10 would like that and then you could read through and
11 see what I used.

12 I can't remember off the top of my head.
13 Otherwise I'd be a genius.

14 Q. Other than the work of Bromage and Enlow,
15 can you name any specific individuals whose work you
16 relied upon in this regard?

17 A. No. You're asking me for names and I'm
18 drawing a blank. I have a library -- I think we
19 already furnished the library to you. But I'd be
20 happy to furnish it again.

21 Q. Would you agree that Dr. Enlow's work was
22 primarily in regard to growers?

23 A. No. It was both growers and non-growers.
24 Those two articles I wrote were directed primarily
25 at growers. I didn't get to the non-growers. I

1 S. Galella

2 haven't written those papers yet.

3 Q. Dr. Bromage, what's his full name?

4 A. Bromage. Timothy Bromage, New York
5 University.

6 Q. What's his area of specialty?

7 A. He's a paleontologist by his degree.
8 He's hard tissue research.

9 Q. Doctor, you're familiar with a scientific
10 method, are you not?

11 A. What method are you talking about?

12 Q. Have you ever heard of a scientific
13 method?

14 A. I don't understand your question.

15 Q. Did you ever attend any course or lecture
16 or in college or dental school in which, as you
17 recall, they discuss something called the scientific
18 method?

19 A. Not in those specific terms but --

20 MR. FUMUSO: No, no. You answered the
21 question.

22 Q. You've told us that much of your work in
23 the field of facial orthopedics relies on the work
24 of Dr. Donald Enlow; is that correct?

25 MR. FUMUSO: He said and others. So I'll

1 S. Galella

2 object to that.

3 Q. Much of your work relies on Donald Enlow;
4 is that fair to say?

5 A. Yes, he was considered the authority.

6 Q. Is it fair to say that Enlow's
7 publications generally indicate that he believed
8 facial growth ended in the teenage years; is that
9 correct?

10 A. I have to reread his work to give you
11 that specific answer. I'd be guessing.

12 Q. Is it fair to say that you believe that
13 Enlow's theories on facial growth in children can
14 apply to adults as well?

15 A. There's a different basis between growers
16 and non-growers. Growers, the changes that used is
17 based on displacement. Non-growers, there's no
18 displacement. It's pure remodeling.

19 Q. When you say displacement, Doctor, are
20 you talking about bone forming in the posterior
21 maxillary tuberosity and working to push the maxilla
22 forward?

23 A. Well, that's not exactly the way it
24 happens. It's the --

25 MR. FUMUSO: You answered it.

1 S. Galella

2 Q. Let's go back to that article, Doctor.
3 This is Exhibit 3A that you co-wrote with Donald
4 Enlow and others. On the page which is 51 in the
5 article, that says table 1, growth stages changes.

6 Do you see that, Doctor?

7 A. Yes.

8 Q. And can you read the first stages into
9 the record, Stage 1, Stage 2, please?

10 A. Stage I, bony maxillary arch lengthens --
11 (Court reporter requested clarification.)

12 A. Bony maxillary arch lengthens
13 horizontally in posterior direction. Bone deposited
14 on posterior-facing cortical surface of maxillary
15 tuberosity. Resorption occurs on opposite side of
16 same cortical plane.

17 Q. And then Stage 2?

18 A. Stage 2, maxillary tuberosity grows and
19 lengthens posteriorly. Entire maxilla displaced
20 anteriorly.

21 Q. Now, is it --

22 A. I'm not through with that.

23 Q. I just wanted you to read the first two
24 pages.

25 A. Well, I'm not through.

1 S. Galella

2 Q. I'm sorry.

3 A. Forward displacement exactly equals an
4 amount of posterior lengthening in Stage 1.

5 Q. Is it fair to say that's what Dr. Enlow
6 believed in regard to growers?

7 A. Yes.

8 Q. At some point in your career, Doctor, did
9 you believe that that applied to non-growers as well
10 in terms of the way the maxilla moves forward?

11 A. No. Non-growers, we're talking about --

12 MR. FUMUSO: That's it. The answer to
13 the question was no.

14 Q. Did you want to expound on your answer?

15 A. No.

16 MR. FUMUSO: Just answer the question.
17 Don't volunteer beyond that.

18 Q. Would you agree that Enlow's theory was
19 that maxillary growth in growers occurs through a
20 process of new bone deposition and resorption,
21 generally speaking?

22 A. What you're describing is remodeling, not
23 displacement.

24 Q. Well, remodeling --

25 A. That's -- growth is displacement and

1 S. Galella

2 remodeling. You described remodeling.

3 Q. When you say remodeling, Doctor, what do
4 you mean?

5 A. Change of shape.

6 Q. Are you talking about a process that you
7 claim occurs where bone is deposited at the front of
8 the alveolar and resorbed behind it, the resorption
9 occurs behind it? Is that what you mean by
10 remodeling?

11 A. I'm not sure. Some of the terms you're
12 using are not medical terms.

13 Q. What do you mean by remodeling in the
14 context of the growth or forward advancement of the
15 maxilla?

16 A. The maxilla in a non-grower does not
17 move. In a grower, it's displaced. The whole
18 nasomaxillary complex is displaced. In a
19 non-grower, it changes its shape, it remodels.

20 Q. Would you agree that Enlow believed that
21 new bone forming in the tuberosity causes the
22 maxilla to advance forward?

23 A. In a grower.

24 Q. In children?

25 A. Yes.

1 S. Galella

2 Q. Is that --

3 A. But it's not just the maxilla. There's a
4 whole complex. You can't say just the maxilla.

5 Q. I understand there may be other changes.
6 But that was Enlow's theory in terms of how the
7 maxilla advanced in growers, correct?

8 A. No. His theory was that the
9 nasomaxillary complex grew up and back and it was
10 displaced down and forward.

11 Q. Forward was part of the advancement,
12 correct?

13 A. In a child, in a grower.

14 Q. Yes. We're talking about a child now.

15 A. Yes.

16 Q. So it's fair to say that Enlow believed
17 that new bone forming in the tuberosity caused the
18 maxilla, among other things, to advance forward,
19 correct?

20 A. No.

21 Q. What's wrong with that statement?

22 A. It's not just the tuberosity. One bone
23 changes in the craniofacial architecture, they all
24 have to change simultaneously. So it would be the
25 middle cranial fossa, the tuberosity, middle cranial

1 S. Galella

2 fossa, the perpendicular plate of ethmoid. I mean,
3 you could go on and on and name all the bones. But
4 as they grow, they're displaced. As they add bone,
5 parts are displaced. But it's all a uniform thing.
6 That's the way Enlow describes it.

7 Q. Why don't you tell us your theory as to
8 how the Osseo-Restore Device functions?

9 A. Just to clarify, you're referring to the
10 fixed device in a non-grower?

11 Q. Unless I tell you otherwise, when I say
12 Osseo-Restore Device, that's what I mean, Doctor.

13 A. Okay. The pressure put on the palatal
14 vault by the acrylic plate causes the maxilla to
15 begin a remodeling process in a three-dimensional
16 way; lateral, transverse, up, down, oblique, any way
17 you can think of. And as that changes, the other
18 bones in the cranium have to change also which
19 includes the naso-complex, the nasomaxillary
20 complex, the sphenoid bone, the occipital, et
21 cetera, et cetera. Temporo bones. Everything
22 changes when it remodels. But it begins with that
23 pressure on the maxilla.

24 Q. Pressure on the maxilla or pressure on
25 the nasopalatine nerve?

1 S. Galella

2 A. On the maxilla and the pressure on the
3 trigeminal nerve probably has an effect. That's
4 debatable. That's in the literature there's pros
5 and cons.

6 Q. I'm not clear what you're saying, Doctor,
7 in terms of how the Osseo-Restore Device creates
8 this three-dimensional change.

9 What specifically happens as a result of
10 using this device that causes this three-dimensional
11 change?

12 A. The pressure of the acrylic plate on the
13 palatal tissue which translates to the bone and the
14 few nerve endings of the trigeminal nerves creates
15 the reaction that the body changes the shape.

16 Q. What is that reaction and how does the
17 body change the shape?

18 A. I'll refer you to Enlow's "Essentials of
19 Facial Growth" and you've got edition 1 and edition
20 2.

21 Q. I'm asking you, Doctor.

22 A. Explains how it happens.

23 Q. Enlow is dead so I can't ask Enlow. So
24 I'm asking you.

25 A. Well, his book explains it pretty well.

1 S. Galella

2 I could spend days educating you on this. I'm not
3 sure what you want me to answer you.

4 Q. I want you to tell us what the
5 physiological -- the precise physiological process
6 is which causes this three-dimensional change in the
7 nasomaxillary complex?

8 MR. FUMUSO: Objection. I thought he
9 just did.

10 MR. CHARNAS: No.

11 A. Are you familiar with Wolff's Law?

12 Q. A little bit. Is that in regard to
13 remodeling, Doctor?

14 A. Yeah.

15 Q. Yeah. Tell us. Put it object record for
16 us.

17 A. Wolff's Law states that if the pressure
18 on a bone is within the realm of adaptability, the
19 bone will adapt to that pressure. And that's
20 precisely what the appliance does.

21 Q. Doctor, are you saying that the
22 Osseo-Restore Device causes bone deposition at the
23 front of the alveolar ridge or the alveolar bone?

24 A. Okay. I guess we need to use the same
25 terms here. The front, are you talking about the

1 S. Galella

2 anterior?

3 Q. Yes, Doctor. The anterior.

4 A. According to Enlow, the alveolar bone
5 is -- there's a resorption on the facial of the
6 plate and it's added to the posterior of the plate
7 on the facial cortical plate. On the palatal plate
8 it's added to the back and taken -- I mean, added to
9 the back taken away from the front. So you've got
10 resorption. But the body keeps everything exactly
11 the same width no matter what. And it's called
12 cortical drift.

13 Q. So are you saying that Enlow talked about
14 resorption behind the alveolar bone and deposition
15 of bone, new bone, in front of the alveolar?

16 A. No, it's the opposite. He said it was
17 resorptive on the front, taken away on the front,
18 and apposition on the back side of that cortical
19 plate.

20 Q. What you just described is the generally
21 accepted -- strike that.

22 Have you ever stated that remodeling
23 occurs through the use of Osseo-Restore devices
24 through deposition of bone at the anterior of the
25 alveolar and resorption behind it?

1 S. Galella

2 A. Not that I recall.

3 Q. By the way, Doctor, whenever you want to
4 take a break, just let me know.

5 I'm going to show you Exhibit 4A, 4B and
6 4C.

7 (Exhibit 4A, introduction to the white
8 papers; 2 pages, marked for identification.)

9 (Exhibit 4B, white paper; 11 pages,
10 marked for identification.)

11 (Exhibit 4C, functional matrix hypothesis
12 revisited; 15 pages, marked for
13 identification.)

14 Q. First we're going to start with Exhibit
15 4A. What are we looking at here, Doctor? Can you
16 see it?

17 A. Yes.

18 Q. What is this?

19 A. "Introduction to the White Papers" is
20 what it says.

21 Q. This is a document that you co-wrote with
22 others from the Facial Beauty Institute, correct?

23 A. No. The white paper was written by
24 Dr. Timothy Bromage.

25 Q. I'm sorry. I'm only talking about the

1 S. Galella

2 introduction which is Exhibit 4A.

3 A. That was written by Dr. Timothy Bromage.

4 Q. When it says the Facial Beauty team, at
5 the end there, it says Facial Beauty Institute team,
6 that's Dr. Bromage alone?

7 A. No. He's part of the team. But that's
8 just the way that I guess the IT guy put it up on
9 the website.

10 Q. Did you have any input into the writing
11 of this document, Exhibit 4A?

12 A. No.

13 Q. Did you approve this document in any way?

14 A. No.

15 Q. Do you know why Dr. Bromage wrote that
16 article?

17 A. He wrote it to explain what was happening
18 with our growth appliances.

19 Q. Was it because of this lawsuit that you
20 asked Dr. Bromage to write this article?

21 A. No.

22 Q. Now I'm going to show you Exhibit 4B.

23 Do you see that, Doctor?

24 A. Yes.

25 Q. You co-authored this document, correct,

1 S. Galella

2 which is called "White Paper on the Efficacy of
3 Osseo-Restore Appliance to Effect Skeletal Patency
4 and Growth in the Anterior Maxilla"? You co-wrote
5 that, right?

6 A. Well, my name is on it, but Dr. Bromage
7 was the author.

8 Q. You had no input into this article?

9 A. No, he's the hard tissue expert.

10 Q. Did you read this document over before it
11 was published to make --

12 A. Yes.

13 Q. -- to make sure it comported with your
14 ideas and concepts?

15 A. Yes.

16 Q. Is there any part of this document you
17 didn't approve of?

18 A. I don't recall. I'd have to reread it.

19 Q. If you disapproved of part of the
20 article, would you have put your name on it?

21 A. I would have discussed it with
22 Dr. Bromage. He would either correct me that I was
23 wrong, prove to me that I was wrong or I wouldn't
24 put my name on it. Correct.

25 Q. I'm going to show you 4C. This is an

1 S. Galella

2 article that was written by Dr. Bromage, correct?

3 A. I don't know. I don't see it.

4 Q. Do you see it now?

5 A. It's written by Dr. Bromage, right.

6 Q. Did you read this before it was
7 published?

8 A. No.

9 Q. 4A, 4B and C, where were they published,
10 what periodical?

11 A. I have no idea. He's published in these
12 papers. I don't know where he submitted them.
13 They're probably in peer review. But they haven't
14 been published in a journal yet.

15 Q. They have not been published in a journal
16 yet; is that what you said?

17 A. I'm not sure where he submitted them.
18 But they're probably in peer review.

19 Q. Let's go back to 4A. That's 4A again.
20 Now, the introduction, it talks about on
21 the fifth line, ControlledArch/Osseo-Restore.

22 What does that refer to?

23 A. I have to read it to see what the context
24 is.

25 Q. Okay. Do you want to read the whole

1 S. Galella

2 article to figure out what the ControlledArch
3 Osseo-Restore means?

4 A. Just let me read for a minute and then
5 we'll go from there.

6 Q. Sure.

7 A. Fair enough?

8 Q. Sure.

9 MR. FUMUSO: He's just asking you what
10 these words mean. That's all.

11 THE WITNESS: I want to see what context
12 he's trying to do now.

13 MR. FUMUSO: I'm going to leave the room
14 for a moment while the doctor is reading that.
15 I'll be right back.

16 (Mr. Fumuso left the
17 video-teleconference.)

18 THE WITNESS: Can you scroll up for me a
19 little bit on that?

20 MR. CHARNAS: Sure.

21 THE WITNESS: Little bit more. That's
22 good right there. Scroll up a little bit,
23 please. Okay. Up a little bit. Up a little
24 bit.

25 MR. CHARNAS: Ready for the next page?

1 S. Galella

2 THE WITNESS: Yep. Okay.

3 (Mr. Fumuso returned to the
4 video-teleconference.)

5 Q. Doctor, now can you tell us what the
6 ControlledArch Osseo-Restore reference is?

7 A. In this introduction written by
8 Dr. Bromage, he talks about the use of the
9 ControlledArch technique and the Osseo-Restore
10 appliance in tandem.

11 Q. What is the ControlledArch in this
12 context?

13 A. It's a technique, an orthodontic
14 technique. ControlledArch is an orthodontic
15 technique and the Osseo-Restore is an appliance.

16 Q. Now, I'm going to read a section on the
17 first page. Take a look and make sure I read it
18 right, Doctor. It says the ControlledArch
19 Osseo-Restore Growth Appliance -- strike that.
20 Before I do that.

21 The reference to Osseo-Restore, that's
22 the Osseo-Restore we've been talking about in this
23 deposition, right?

24 A. They could be the removable. It could be
25 the fixed or removable. You have to say. There's

1 S. Galella

2 the maxillary fixed which is facial or lingual and
3 there's a maxillary removable.

4 Q. The ControlledArch/Osseo-Restore Growth
5 Appliance System has been successfully utilized in
6 clinical practice for over 14 years. Clinicians
7 trained by the Facial Beauty Institute and certified
8 instructors have successfully completed over 8,000
9 ControlledArch/Osseo-Restore appliance cases of
10 record without any reported adverse effects. The
11 safety and efficacy of the Osseo-Restore Appliance
12 is well established.

13 Did I read that correctly?

14 A. Yes.

15 Q. Do you agree with that statement?

16 A. Well, probably there's more cases than
17 indicated, than 8,000, but yes.

18 Q. You would agree that the Osseo-Restore
19 would include the type of Osseo-Restore fixed device
20 we've been talking about, right, in this context?

21 A. Yes.

22 Q. Now, how would you define successfully
23 utilized?

24 A. Did you have good results? You remodeled
25 and created what you needed, the remodeling process

1 S. Galella

2 based on the non-grower.

3 Q. Can you point to any peer-reviewed
4 publication that supports the fact that over 8,000
5 of these ControlledArch/Osseo-Restore Appliance
6 cases have been successful?

7 MR. FUMUSO: Objection to that question.

8 But you can answer over objection, if you can.

9 A. No.

10 Q. Can you point to any peer-reviewed
11 articles that support -- that any of the
12 ControlledArch Osseo-Restore Appliance cases have
13 been successful?

14 MR. FUMUSO: You can answer over
15 objection.

16 A. The article part 2 that I wrote, that was
17 Exhibit 3 something. 3B maybe.

18 Q. We'll get back to that.

19 Other than what you --

20 A. I know. But I was telling you, there is
21 a peer review journal that said it's successful and
22 it showed a case.

23 Q. You're talking about the one case of one
24 adult, correct?

25 A. You asked for a peer-reviewed journal.

1 S. Galella

2 Q. Yes. You answered it. Now I'm asking
3 another question.

4 A. Okay.

5 Q. That article was one written by you,
6 correct?

7 A. And Enlow and others.

8 Q. Let's make sure we know what article
9 we're talking about.

10 A. 3B.

11 Q. That was an article not about growers,
12 correct?

13 A. It was about growers.

14 Q. Right. Is there any reviewed article
15 that supports the statement that ControlledArch
16 Osseo-Restore Growth Appliance System has been
17 successfully utilized in clinical practice in regard
18 to non-growers?

19 MR. FUMUSO: Over objection you can
20 answer.

21 A. Not that I'm aware of.

22 Q. Are there any clinical studies or
23 clinical trials that support the proposition that
24 ControlledArch Osseo-Restore Growth Appliances have
25 been successfully used?

1 S. Galella

2 MR. FUMUSO: Read that question back.

3 MR. CHARNAS: Let me withdraw that
4 question.

5 Q. Are you aware of any clinical trials or
6 studies that support that ControlledArch
7 Osseo-Restore Appliances work or function as claimed
8 by you in non-growers?

9 MR. FUMUSO: Clinical trials or studies.

10 A. Well, clinical trials would be cases. I
11 can present cases, but not published.

12 Q. You understand a case is not a clinical
13 trial?

14 A. Well, clinical trials are cases, but not
15 published, no.

16 Q. Is it your position that one case
17 constitutes a clinical trial?

18 A. No. It's not.

19 Q. Do you understand how clinical trials
20 work?

21 A. Yes.

22 Q. Tell us how clinical trials work,
23 generally speaking.

24 A. You have a series of a controlled group
25 and a test group and you run them through trials.

1 S. Galella

2 It's a basic principle. I understand that.

3 Q. Are you aware of any clinical trials that
4 support that the ControlledArch Osseo-Restore
5 appliance system functions as you claim in
6 non-growers?

7 A. No.

8 Q. Now, that statement says at the end, the
9 safety -- and this is in bold. Quote, The safety
10 and efficacy of the Osseo-Restore Appliance is well
11 established, close quote.

12 Did I read that right?

13 A. Yes.

14 Q. You agree with that statement?

15 A. Yeah, I think it's true.

16 Q. What clinical trials or studies exist to
17 this date which demonstrate the safety or efficacy
18 of the Osseo-Restore Appliance?

19 A. That's been published?

20 Q. Published -- let's start with published,
21 yes.

22 A. Not to my knowledge.

23 Q. And unpublished?

24 A. There are several in the works, but they
25 haven't been published.

1 S. Galella

2 Q. Any written or about to be written by
3 anyone other than you?

4 A. I'm sure they're out there.

5 Q. Can you name any?

6 A. They're not complete yet.

7 Q. Who's working on it?

8 A. I don't recall the names.

9 Q. Is there any peer-reviewed article or
10 publication to this day which supports the safety of
11 the Osseo-Restore Appliance?

12 MR. FUMUSO: Object to the form of the
13 question. Can you answer the way it's phrased.

14 A. If you could ask that a different way, it
15 would help my mind work better.

16 Q. Let me try. Is there any peer-reviewed
17 publication out there to this day that supports or
18 concludes that the Osseo-Restore Appliance is safe?

19 A. I'm not aware.

20 Q. When this introduction was written -- I'm
21 sorry. When this article was -- no. I was right
22 the first time. Strike that.

23 When this introduction 4A was written, is
24 it fair to say that it was either late 2020 or early
25 2021?

1 S. Galella

2 A. I don't recall the dates.

3 Q. It was written by the year 2020, wasn't
4 it?

5 A. Yes, it could be.

6 MR. CHARNAS: Let me strike that
7 question.

8 Q. When this introduction came out, were you
9 aware of the current lawsuit by Boja Kragulj against
10 yourself and others?

11 A. I don't recall.

12 Q. Do you stand by this statement that there
13 have been no reported adverse effects from the use
14 of a ControlledArch/Osseo-Restore Appliance System?

15 A. Well, I guess I do because there was
16 no -- at the time he wrote that, we were not aware
17 of any complaints.

18 Q. Are you sure about that, Doctor?

19 A. No. I don't recall when this was put up.
20 You know, this is all -- I don't have dates so it
21 doesn't help me.

22 MR. MURPHY: Scott, can you just remind
23 me what exhibit this is up on the screen?

24 MR. CHARNAS: Yes, Alan, this is 4A.

25 MR. MURPHY: That was Murphy.

1 S. Galella

2 MR. CHARNAS: Sorry. All the voices
3 sound the same at this point. I'm going to
4 show you another document, Doctor.

5 Q. Can you see Exhibit 1B, Doctor? We
6 looked at it earlier.

7 A. Yes. Yes.

8 Q. Now that first sentence, Doctor, under
9 description, the MX, could you read that first
10 sentence to yourself, please.

11 A. Yeah.

12 Q. Do you agree that one of the purposes or
13 functions of the Osseo-Restore Device is to develop
14 a nasomaxillary complex in adults?

15 A. Say that one more time. I'm hard of
16 hearing and sometimes it sort of drifts out on me.
17 I'm sorry.

18 Q. No problem. Again, Doctor, any time you
19 don't hear or understand a question of mine you just
20 let me know.

21 Is it fair to say that this device, the
22 Osseo-Restore Device that we've been talking about,
23 one of its functions is to develop a nasomaxillary
24 complex in adults?

25 A. Yes. When you say develop, that

1 S. Galella

2 translates to remodels which means changes the shape
3 to me. Yes.

4 Q. Well, I'm just kind of reading what it --
5 we're taking exactly what it says in 1B. Develop
6 the nasomaxillary complex. You would agree --

7 A. That's true. I'm just saying, that's
8 what I'm translating in my head.

9 Q. Did you write this document or have a
10 part in writing or drafting this document?

11 A. Yes.

12 Q. Would you agree that one of the functions
13 of the Osseo-Restore Device is to develop a maxilla
14 three dimensionally through remodeling in an adult?

15 A. Yes.

16 Q. Would you agree also that the
17 Osseo-Restore Device is designed to also create a
18 positive effect on the nasopharyngeal airway in an
19 adult?

20 A. Yes.

21 Q. Can you point to any clinical studies,
22 clinical trials or peer-reviewed articles or
23 publications which support the claim that the
24 Osseo-Restoration Device develops the nasomaxillary
25 complex in adults in three dimensions for

1 S. Galella

2 remodeling?

3 A. Well, not the fixed. The removable, yes.
4 The one in the works now by Simmons and Deal, but
5 not for the fixed. They haven't got to that one
6 yet.

7 Q. When you say they, who do you mean?

8 A. I just said Simmons and Deal.

9 Q. What are Simmons and Deal's first names?

10 A. Dr. Chris Simmons, S-I-M-M-O-N-S.
11 Dr. Steven Deal, D-E-A-L.

12 Q. Are they affiliated with the Facial
13 Beauty Institute or Las Vegas Institute?

14 A. They're affiliated with the Facial Beauty
15 Institute.

16 Q. We referenced a development of a maxilla
17 three-dimensionally through modelling. Just to be
18 clear, you're talking about sagittally, vertically
19 and transversely?

20 A. Yes.

21 Q. By the way, do you ever refer to this
22 Osseo-Restore Device as AGGA or Anterior Growth
23 Guidance Device?

24 A. I've never used the term FAGGA.

25 Q. No. AGGA.

1 S. Galella

2 A. But the early name for it was Anterior
3 Growth Guidance Appliance. And the name was changed
4 to Osseo-Restore/Restoration. This one is just --

5 Q. I'm sorry. I didn't mean to step on you.
6 Did you finish your answer?

7 A. The name was changed to Osseo-Restoration
8 Appliance because the initial name was not clear to
9 some people what it did.

10 Q. Is it fair to say that you at some point
11 in your career called it Anterior Growth Guidance
12 Appliance?

13 A. Yeah. And I just said that.

14 Q. I'm going to go back to 4B.

15 THE WITNESS: While you're bringing that
16 up, can I take a quick break?

17 MR. CHARNAS: Sure. You all want to take
18 a five-minute break?

19 MR. FUMUSO: Five minutes is good.

20 Thanks.

21 (A recess was taken from 11:02 a.m. to
22 11:09 a.m.)

23 Q. Doctor, let's go back to Exhibit 4B.

24 Can you see that, Doctor, Exhibit 4B?

25 A. Right.

1 S. Galella

2 Q. In the abstract section under results, do
3 you see it there, Doctor?

4 A. Yes.

5 Q. I'm going to read that into the record.
6 Quote, Mechanical forces elicited by an orthopedic
7 appliance in the biological range will stimulate
8 normal growth remodeling in the growing child and
9 compensatory remodeling in the adult non-grower.

10 Did I read that correctly?

11 A. Yes.

12 Q. Now, those mechanical -- strike that.
13 Before we get to that, what is compensatory
14 remodeling?

15 A. We talked about Wolff's Law. That's
16 compensatory remodeling.

17 Q. Just so I understand, which side of the
18 alveolar is the new bone deposited during
19 compensatory remodeling, the posterior or the
20 anterior?

21 A. You're oversimplifying a complex system.
22 In Enlow it shows resorption of bone on the anterior
23 surface of the alveolar process but that's a
24 cortical plate. And on the backside, you add
25 bone -- I mean, you add bone. And on the palatal

1 S. Galella

2 side, you add bone but on the opposite side of that
3 plate you take away bone. It's called cortical
4 drift.

5 Q. Just --

6 A. Does that make sense to you?

7 Q. Well, not to make it too simple, but is
8 it fair to say that what you just stated includes
9 deposition of new bone at the anterior of the
10 alveolar?

11 A. No.

12 Q. Now, those mechanical forces elicited by
13 the orthopedic appliance, that's what you say
14 develops the nasomaxillary complex of adults,
15 develops the maxilla in three dimensions through
16 remodeling and creates a positive effect on the
17 nasopharyngeal airway in adults, correct?

18 A. Well, it's when one bone remodels, every
19 other bone has to remodel or change in some form or
20 fashion to have the equilibrium of function. So if
21 that's what you're asking, that's the answer.

22 Q. What you've just stated starts with the
23 mechanical forces that are elicited by the
24 Osseo-Restore Device, correct?

25 A. Yes.

1 S. Galella

2 Q. In the conclusion section, Doctor, of the
3 same document, it says, quote, Anterior alveolar
4 remodeling may be specifically targeted to treat
5 maxillary deficiencies provided that treatment
6 forces do not exceed the biological range, close
7 quote.

8 Did I read that correctly?

9 A. Yes.

10 Q. What is the anterior alveolar remodeling
11 that's referred to? Strike that.

12 Let me ask it again.

13 What's the anterior alveolar remodeling
14 referred to there?

15 A. Specifically you're talking about -- or
16 in general. It can be in general. Generally it's
17 the remodeling of the anterior alveolar process.
18 The whole thing changes.

19 Q. And that's in the context of -- or
20 includes the context of the Osseo-Restore Device,
21 correct?

22 A. Yeah. Yes.

23 Q. Is it your testimony that that was
24 Enlow's theory, that that was part of Enlow's
25 theory?

1 S. Galella

2 A. Well, he didn't -- his theory didn't
3 include how to treat mid -- he didn't do treatment.
4 It was just theory of how the bone grows and how the
5 bone develops.

6 Q. So is it fair to say that this anterior
7 alveolar remodeling idea that you just told us about
8 was not something espoused by Enlow; is that
9 correct?

10 A. No, that's not correct.

11 Q. So -- I'm sorry. Go ahead.

12 A. No. I'm fine.

13 Q. Can you point to a publication in which
14 Enlow indicates his approval of the idea of anterior
15 alveolar remodeling?

16 A. Read those two articles in 3A, 3 B.

17 Q. Those --

18 A. He co-authored those articles.

19 Q. And that pertains to growers, correct?

20 A. Yes.

21 Q. Has the concept of anterior alveolar
22 remodeling been confirmed by clinical trials or
23 peer-reviewed articles in non-growers?

24 A. Rephrase it or ask it where I can
25 understand what you're saying.

1 S. Galella

2 Q. Has the concept of anterior alveolar
3 remodeling in the context of appliances, like we've
4 been talking about, been confirmed as a viable
5 theory by clinical trials or by peer-reviewed
6 articles or publications?

7 A. Of course. In the John Witzig, the --
8 the -- give me a minute. I have to think of all
9 these authors.

10 Q. Take your time.

11 A. There's been several things. Witzig
12 comes to mind back in the eighties. He was treating
13 non-growers with the removable appliance. Same
14 principle.

15 Q. Dr. Galella, would you agree that it's
16 widely accepted in orthodontics today and has been
17 since at least 2017 that when teeth move through the
18 alveolar there is resorption through the front of
19 the alveolar and deposition at the back of the
20 alveolar?

21 A. I'm not sure what terms you're using.
22 Could you rephrase it. Alveolar doesn't make sense
23 to me.

24 Q. You never heard of -- what's the alveolar
25 in that sentence in conclusions, anterior alveolar

S. Galella

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remodeling?

A. That's the housing of the teeth.

Q. The bone, right?

A. Yes. Alveolar bone.

Q. Would you agree that it's widely accepted in orthodontics and has been since at least 2017 that when teeth move through that alveolar bone there is resorption at the front of the alveolar and deposition at the back of the alveolar?

A. That's -- teeth moving through bone has nothing to do with the front -- the anterior part of the alveolar bone or the posterior part of the alveolar bone. I don't understand what you're trying to say. I'm sorry.

Q. During the process of orthodontics generally speaking, teeth move through the alveolar bone as a result of forces applied by an appliance, correct?

A. Appliance referring to braces?

Q. For example, yep.

A. Okay. Yes.

Q. So isn't it widely accepted in orthodontics that when the teeth move through the alveolar bone there is resorption at the front of

1 S. Galella

2 the -- of that bone and deposition of bone at the
3 back of the alveolar? Isn't that generally
4 accepted?

5 A. As teeth move through the bone there's a
6 process that -- of teeth moving through the bone.
7 If the bone is stable and not remodeling, then
8 there's no -- there's nothing that occurs on the
9 front or the backside.

10 You're talking about moving teeth in the
11 alveolar bone, you're talking about deposition and
12 resorption and it's not the same. I'm sorry. It's
13 out of context.

14 Q. Just so it's clear, I wasn't talking
15 about the phenomenon with regard to the
16 Osseo-Restore Appliance.

17 A. I know. You're talking about moving
18 teeth.

19 Q. Let me go on to something else. Is it
20 fair to say that one of the reasons you participated
21 in the writing of the article 4B was to show proof
22 of concept and function of the Osseo-Restore
23 Appliances, correct?

24 MR. FUMUSO: Do you understand the
25 question?

1 S. Galella

2 A. Not really. Say that one more time.

3 Q. One of the reasons you participated in
4 the writing of this article, Exhibit 4B, was to show
5 that the Osseo-Restore Appliance System or appliance
6 works, right?

7 MR. FUMUSO: Are you telling him or
8 asking him? Objection to form. Objection to
9 form.

10 MR. CHARNAS: It's leading? Is that your
11 objection?

12 MR. FUMUSO: Yeah. It's leading.

13 MR. CHARNAS: Okay. Okay. Thanks.

14 Q. Can you answer that, Doctor?

15 A. One more time. I've got to hear it.

16 Q. Okay. I'm sorry. Maybe I'm going too
17 fast. I'm trying to figure out at least one of the
18 reasons that you wrote or co-wrote this article, 4B,
19 Doctor.

20 Is it fair to say that one of the reasons
21 was to show that the Osseo-Restore system or
22 removable -- strike that.

23 That the Osseo-Restore system works?

24 A. Yes.

25 Q. Does this article pertain to fixed

1 S. Galella

2 Osseo-Restore devices or just removable ones?

3 A. Both.

4 Q. Is it fair to say that in your attempt to
5 show that the Osseo-Restore Appliance works, you
6 pointed to two examples, two cases, if you will, one
7 is the growing child, nine years and four months and
8 the other is an adult; is that correct?

9 A. That's correct.

10 Q. Why did you limit your proof in the
11 article to only one child and one adult?

12 A. Because it was a white paper.

13 Q. I'm sorry. What does that mean exactly?

14 A. A white paper is an explanation of the
15 function of the appliance. That's basically all it
16 was. It was not published. And if it was
17 published, they probably would have done just one
18 paper. This was Dr. Bromage's choice. He
19 publishes -- he writes a lot of papers, so we let
20 him decide what to put in there.

21 Q. Is it fair to say that the growth in the
22 adult, that is the forward advancement of the
23 maxilla in the one adult was between one and three
24 centimeters?

25 A. You're saying for forward advancement,

1 S. Galella

2 you mean the remodeling of the maxilla?

3 Q. We can call it that, sir. The remodeling
4 created a forward advancement of the maxilla of one
5 to three centimeters, correct?

6 A. The maxilla didn't really move. It just
7 remodeled. So as long as we're clear on that,
8 then -- if that's what the paper says, then that's
9 what the paper says.

10 Q. How old was the adult in this example
11 used?

12 A. I don't recall.

13 Q. Doctor, are you aware of any nongrowing
14 individuals in whom an Osseo-Restore Device --
15 again, that means fixed in this case, as I said
16 earlier -- in whom an Osseo-Restore Device has
17 caused an inferior and outward relocation of the
18 maxillary alveolus by as much as 8 to 10
19 millimeters.

20 A. I'm sorry. Rephrase that. It was a
21 little confusing.

22 Q. Sure, you've told us that the maxilla
23 remodels in three dimensions, correct?

24 A. Yes.

25 Q. Using an Osseo-Restore Device, correct?

1 S. Galella

2 A. Yes.

3 Q. And one of those directions is sagittal,
4 right? On the sagittal plane?

5 A. Yes. It's three-dimensional, all at the
6 same time.

7 Q. Yes. Yes. In terms of sagittal
8 advancement of the maxilla, are you aware of any
9 nongrowing individuals in whom an Osseo-Restore
10 Device has caused an advancement in the sagittal
11 plane of the maxilla by as much as 8 to 10
12 millimeters?

13 A. Only the sagittal plane? Is that the
14 question?

15 Q. Yes.

16 A. No. No.

17 Q. What's the --

18 A. It's three dimensional. Keep that in
19 mind. Three dimensional.

20 Q. Let me make sure my question is clear.
21 I'm not saying that the other dimensions didn't
22 change. I'm just trying to focus on the sagittal
23 dimension.

24 A. Okay.

25 Q. You understand? So, have you encountered

1 S. Galella

2 in your practice or are you aware of any nongrowing
3 individuals who has experienced 8 to 10 millimeters
4 of advancement of the maxilla in the sagittal plane
5 with an Osseo-Restore Device?

6 A. Yes.

7 Q. Can you estimate for us how many such
8 individuals have experienced, in your experience or
9 knowledge, that much advancement?

10 A. I can't give you a number.

11 Q. Would it be at least 100 of the 8,000
12 Osseo-Restore devices sold?

13 A. I have no idea.

14 Q. Would you say it's more than ten?

15 A. I have no idea. I mean, I really don't
16 recall the exact numbers. The average is probably 5
17 to 6 millimeters.

18 Q. Have you ever -- are you aware, I should
19 say, of anyone who's experienced as much as 12 or 13
20 millimeters of advancement of the maxilla using the
21 Osseo-Restore Device?

22 A. I think I'm aware of a couple of people
23 that got that much.

24 Q. Can you name them? I don't mean the
25 patients. I mean the dentists.

1 S. Galella

2 A. No.

3 Q. Do you have any objective evidence of
4 this advancement of the maxilla in a sagittal plane
5 forward of as much as 8 to 10 millimeters as a
6 result of the use of an Osseo-Restore Device?

7 A. Say that one more time, please, sir.

8 Q. Do you have any objective evidence of 8
9 to 10 millimeters of movement or the 5 or 6
10 millimeters of movement that you've just talked
11 about, in regard to the maxilla advancing in the
12 sagittal plane?

13 A. What do you mean by objective?

14 Q. Have you ever heard the term objective
15 evidence in medicine or science?

16 MR. FUMUSO: He just told you. Object to
17 the form of the question. He just gave you
18 answers to that question. He said his clinical
19 experience. He just gave you an answer to that
20 question.

21 MR. CHARNAS: Could you read his answer
22 back, please. Never mind. Don't bother.

23 Q. In terms of scans or films, CBCT scans,
24 panorex, x-rays, do you have any such evidence of
25 either 8 to 10 millimeters of advancement of the

1 S. Galella

2 maxilla or even 5 to 6 millimeters of advancement of
3 the maxilla as a result of the use of an
4 Osseo-Restore Device?

5 A. Yes.

6 Q. Have you published your findings in
7 regard to that proof that you've just discussed?

8 A. No.

9 Q. Can you tell us why not?

10 A. I haven't had time to.

11 Q. What method or methods did you use to
12 determine using that -- the objective evidence that
13 I just enumerated for you --

14 A. Well --

15 Q. Let me just finish. What method or
16 methods did you use to determine that amount of
17 growth?

18 A. In non-growers there is no growth.
19 You've used the term growth and you're talking about
20 non-growers?

21 Q. Let me see if I can get this back on the
22 right track.

23 A. Okay.

24 Q. I'm only talking about non-growers now.

25 A. Okay.

1 S. Galella

2 Q. I believe you've told us that you've seen
3 5 to 6 as a norm average or normal amount and as
4 much as 8 to 10 or more of millimeters of
5 advancement of maxillas in the sagittal plane among
6 other dimensions as a result of Osseo-Restore Device
7 use, correct?

8 A. Yes.

9 Q. And you've told me, if I understood what
10 you said, that you have objective evidence of same
11 in the form of either x-rays, CBCTs, scans or films,
12 correct?

13 A. Well, among other things. Clinical
14 measurements, et cetera, yes.

15 Q. You took clinical measurements of models
16 or of patients?

17 A. Both.

18 Q. Both. So in terms of your confirming
19 that advancement of the maxilla in non-growers using
20 scans or films or CBCTs, what methodology did you
21 use to determine or confirm the growth that you're
22 talking about?

23 A. We're talking about non-growers. There
24 is no growth. You keep saying growth.

25 Q. Advancement rather than growth.

1 S. Galella

2 A. That's the same as remodeling. Just so
3 we're clear.

4 Q. Let me rephrase the question so there's
5 no doubt about it.

6 A. Okay.

7 Q. In terms of non-growers, what methods or
8 method have you used to confirm advancement of the
9 maxilla in the sagittal plane as a result of the use
10 of Osseo-Restore Appliances?

11 A. All right. So the maxilla does not
12 advance. It's remodeled. That being said, when the
13 appliance is used, a space is developed at the
14 distal, which is the backside, of the cuspid and
15 the -- and the anterior, front side of whatever
16 bicuspid in the mouth. And you measure each
17 side -- because one side is usually more than the
18 other -- each side, divide by two, and that gives
19 you the millimeters of remodeling. And that's the
20 basis, the way we discuss it.

21 So if it was 6 millimeters on one side
22 and 4 millimeters of space on the other side, you
23 add them together and that's 10 and divide by two,
24 that's five. So the maxillary remodeling in the
25 sagittal direction would be 5 millimeters.

1 S. Galella

2 Q. That's remodeling, not advancement,
3 correct?

4 A. That's correct.

5 MR. CHARNAS: Let me show you another
6 document which is Exhibit 5.

7 (Exhibit 5, ControlledArch Flow Sheet; 37
8 pages, marked for identification.)

9 Q. And it says ControlledArch at the top.
10 Then it says ControlledArch flow sheet by Steve
11 Galella and the copyright is 2000 to 2017.

12 By the way --

13 A. I have to see it.

14 Q. I'm sorry. That will help. Here's
15 Exhibit 5, ControlledArch. You see what I just
16 talked about?

17 A. Yes.

18 Q. It says copyright 2000 to 2017, Inside
19 Dentistry, Inc., the Facial Beauty Institute.

20 First of all, Doctor, what is Inside
21 Dentistry, Inc.?

22 A. Inside Dentistry, Inc. is a corporation
23 that differentiates my practice income from my
24 teaching income.

25 Q. Did you draft or author this document?

1 S. Galella

2 A. I did.

3 Q. Let's take a look at the third page.

4 This document includes a reference to the
5 Osseo-Restore Device, correct?

6 A. I don't think so.

7 Q. Here on the third page, Doctor, it says
8 "maxillary sagittal expansion."

9 Do you see that there?

10 A. Yes.

11 Q. It says "for anterior expansion or
12 advancement."

13 What did you mean by advancement there,
14 Doctor?

15 A. Advancement is remodeling in this
16 context.

17 Q. So when I said advancement before, I was
18 using the proper term, wasn't I?

19 A. Well, in this context. But in the
20 context of using the appliance alone, it's -- it
21 could be misconstrued.

22 I just wanted to be clear.

23 Q. Now, it says in that same section: A, if
24 sagittal correction is over 4 millimeters, use a
25 maxillary fixed Anterior Growth Guidance Appliance.

1 S. Galella

2 That is a maxillary fixed Osseo-Restoration
3 Appliance.

4 Is what you were trying to convey in that
5 section that if you needed anterior expansion or
6 advancement of the maxilla, you needed to use an
7 Osseo-Restore Device?

8 A. Say that one more time. I'm trying to
9 get -- grasp what your question is.

10 Q. Sure. By making this statement, did you
11 mean to state that if a patient needs advancement of
12 the maxilla over 4 millimeters an Osseo-Restore
13 Device should be used?

14 A. Yeah. But it's -- the context is, the
15 number up above, it talks about molar and cuspid
16 expansion which is transverse. And this one is
17 talking about sagittal expansion. It's taking each
18 of the three-dimensional aspects one at a time.
19 But -- does that make sense to you?

20 Q. Well, we'll see. Would you agree that
21 you represented to dentists prior to January 2018
22 that more than 4 millimeters of maxillary
23 advancement can be obtained by use of an odd?

24 A. Remodeling. Sagittal plane, if you
25 measured it, yes.

1 S. Galella

2 Q. In fact, would you agree that you
3 represented to dentists prior to January 2018 that
4 as much as 8 to 10 millimeters, if not more, of
5 advancement of the maxilla in the sagittal plane can
6 be obtained through the use of an Osseo-Restore
7 Device?

8 A. Under certain circumstances, yes.

9 Q. What circumstances?

10 A. The amount of deficiency. The amount of
11 bone. The closeness of the anterior teeth to the
12 facial cortical plate. The angulation of the teeth,
13 et cetera. There's a lot of factors.

14 Q. It depends on the patient, in other
15 words?

16 A. That's what I just said.

17 Q. Right. Is it your position that the
18 Osseo-Restore Device is an alternative to jaw
19 surgery?

20 A. It can be in certain circumstances,
21 depending on the patient.

22 Q. And that was your position since at least
23 2015, right?

24 A. Yes. I assume so.

25 MR. CHARNAS: I'm going to show you

1 S. Galella

2 another exhibit. This is Exhibit 6.

3 (Exhibit 6, November 2017 FBI newsletter;
4 15 pages, marked for identification.)

5 Q. I'm going to represent to you this was
6 produced in discovery, I believe, by your attorneys.
7 I apologize, but the way I received it, part of the
8 title was cut off but it does refer to facial or
9 fascia something, and it says newsletter
10 November 2017. Let me scroll through it for you a
11 little bit. "Should you have any questions," it
12 says, "please contact Dr. Galella," on the third
13 page.

14 And then I think your name appears again,
15 if I'm not mistaken -- I don't want to waste too
16 much of your time.

17 Do you recognize this document, generally
18 speaking, Doctor?

19 A. Yes, I've looked at it.

20 Q. Tell us, generally speaking, what is this
21 document?

22 A. It's a newsletter that was put together
23 by Dr. Deal and it was, I think, put on the website
24 at some point in 2018.

25 Q. This was created by the Facial Beauty

1 S. Galella

2 Institute?

3 A. Dr. Deal wrote it.

4 Q. It's a Facial Beauty Institute document;
5 isn't it?

6 A. Well, yeah. It's -- the newsletter was
7 done by Dr. Deal. It says November '17. But I
8 think it was put up whenever the website went live
9 which was 2000 whenever. Or maybe it was sent out
10 through his supply company, Essential Orthodontics.
11 I'm not quite sure.

12 Q. Would you agree that this document was
13 created in or near November 2017?

14 A. Well, it was -- that was the first draft.
15 I think the final draft was probably 2018.

16 Q. Did you have any role in creating this
17 document?

18 A. Just to read it over.

19 Q. What was the purpose of this document?

20 A. Just to enlighten the doctors that had
21 already taken courses on this particular appliance
22 and ControlledArch. It was a newsletter.

23 Q. I think you mentioned, was it circulated
24 on the internet?

25 A. I don't recall how it was done.

1 S. Galella

2 Dr. Deal -- Essential Orthodontics, he may
3 distribute it through his supply company.

4 MR. FUMUSO: Do you know one way or the
5 other?

6 THE WITNESS: I don't know one way or the
7 other. I don't know exactly what happened.

8 Q. If you don't know, Doctor, please don't
9 guess.

10 MR. FUMUSO: Don't speculate.

11 THE WITNESS: Okay.

12 Q. Now, I'm going to read a section to you
13 that starts on page 2 and I'll try to read it slowly
14 and you tell me if I read it incorrectly.

15 Call for research. As many of you know,
16 the Facial Beauty Institute is currently conducting
17 research on the many aspects of the
18 Osseo-Restoration Appliances, parenthesis, growth
19 appliances, close parenthesis.

20 Let me stop there for a moment. Did you
21 refer to the Osseo-Restore Device being referred to
22 as growth appliances?

23 A. That's a general term that dentists use.

24 Q. Going back to reading it.

25 Currently we need before and after 3-D

1 S. Galella

2 CBCTs of patients who have undergone both the fixed
3 and removable versions. The Criteria for the fixed
4 growth appliance are, one, a pretreatment 3-D CBCT
5 should be completed.

6 If you have already -- then it goes on to
7 the third page -- submitted the before 3-D CBCT
8 through OrthoMatrix/OrthoAssist Diagnostics, you can
9 upload the postop zipped 3-D CBCT to the same
10 patient's folder. Just indicate when choosing the
11 type of file that the DICOM (.dcm) files are postop.
12 We will be automatically notified when your postop
13 uploads are completed.

14 Two, the pre and postop files will be
15 overlaid to show the osseous changes that have
16 occurred. The overlays will be completed using a
17 protocol developed by Dr. Bromage.

18 Three, screenshots of the completed
19 overlays will be available to you when they are
20 completed.

21 Four, you will be recognized for your
22 contributions to this part of the research.

23 Five, should you have any questions,
24 please contact Dr. Galella. It gives your email
25 address. Future newsletters will provide more

1 S. Galella

2 information regarding the other areas of research.

3 Did I read that basically correct,
4 Doctor?

5 A. You did. Very good.

6 Q. What research were you calling for here?

7 A. Basically, we wanted to look at the cone
8 beams and look at the changes. Because they were
9 cone beams, we could look at them in
10 three-dimensional aspects, we could make
11 measurements. We could determine how the remodeling
12 was occurring not only in the maxilla but the
13 nasomaxillary complex and the entire cranium.

14 Q. Is it fair to say that you were calling
15 for research to be done on the efficacy of the
16 Osseo-Restoration Appliance?

17 A. On the efficacy? We just wanted to do
18 some comparisons and maybe do a case study or a
19 report that could be published.

20 Q. Is it fair to say that you were looking
21 for research to prove that the Osseo-Restoration
22 Appliance functioned as you claimed it functioned,
23 correct?

24 MR. FUMUSO: Object to the form of the
25 question. Can you answer it the way it's

1 S. Galella

2 phrased.

3 A. It doesn't make sense to me.

4 Q. All right. You claimed, did you not,
5 before this newsletter was put out that the
6 Osseo-Restoration Appliance or Osseo-Restore
7 Appliance, created changes in the three dimensions
8 and nasomaxillary complex, correct?

9 A. That's correct.

10 Q. Is it fair to say you were calling for
11 research to try to prove whether, in fact, that was
12 correct?

13 A. Not really. We were just -- wanted to
14 see what -- we wanted to have a library of cases.

15 (Technical difficulty.)

16 A. So Dr. Bromage could compare results.

17 MR. CHARNAS: Did the court reporter get
18 that?

19 (Record read.)

20 Q. Is it fair to say that one of the
21 purposes of creating that library for Dr. Bromage
22 was to prove or try to prove that the
23 Osseo-Restoration Appliance worked to make three
24 intentional changes in the nasomaxillary complex?

25 A. We already knew it worked. We were just

1 S. Galella

2 trying to get a large number of cases so we can
3 publish.

4 Q. Before you put out this call for research
5 how many such cases had you identified?

6 A. I have no idea. I can't recall the
7 numbers. But we wanted to have a lot of numbers.

8 Q. Do you still have those cases? That is,
9 the films or other documents upon which you relied
10 on for proof of efficacy of the Osseo-Restore or
11 Restoration Appliance before this newsletter came
12 out.

13 A. Sure.

14 Q. Where do you have those?

15 A. They would be in Ortho -- my cases and
16 Dr. Simmons, Dr. Deal, Dr. Prabhu (phonetic) and the
17 OrthoAssist/OrthoLogic portal. And then the after
18 ones are there as well. Not in the portal but in
19 the doctors' possession.

20 Q. And so these cases before November 2017,
21 approximately, in your opinion proved the efficacy
22 of the Osseo-Restore system in terms of the
23 three-dimensional development of the nasomaxillary
24 system, correct?

25 A. Well -- and others. And other areas as

1 S. Galella

2 well, yes.

3 Q. Did you ever publish that research --

4 A. No.

5 Q. -- of these cases?

6 A. No. I already told you that.

7 Q. As a result of putting out this call for
8 research, did you receive additional proof of the
9 efficacy of the Osseo-Restore or Osseo-Restoration
10 Appliance?

11 A. We did.

12 Q. And do you still have that proof?

13 A. I'm sure we do. It's probably in the
14 database.

15 Q. And generally speaking, what does that
16 proof consist of?

17 A. The cone beams that we asked for and some
18 people submitted pictures as well. And some people
19 submitted finished cases.

20 Q. What method or methods did you use to
21 determine whether the system, the appliance, worked
22 in regard to the CBCT scans?

23 A. Well, that's the overlay system that
24 Dr. Bromage developed. When you try to overlay like
25 they used to do Ceph's, it didn't show -- it only

1 S. Galella

2 showed movement of teeth, not the changes in bone.
3 So Dr. Bromage developed a 3-D system that you can
4 overlay. That's in the white paper, his examples,
5 that you can actually see the remodeling changes.

6 Q. Has the -- I'm sorry. Go ahead.

7 A. I'm done.

8 Q. Has Dr. Bromage's overlay system been
9 peer-reviewed?

10 A. It hasn't been published yet. We just
11 started with the white paper and we're fine-tuning.

12 Q. Did you have --

13 A. I think he's got it out for journal, but
14 I don't recall what journal it's in for publication.

15 Q. Did Dr. Bromage conduct any clinical
16 trials in regard to this overlay system?

17 A. Well, it doesn't lend itself to clinical
18 trials. It lends itself to -- it's like an analysis
19 of all the cone beams before and afters, treatment.

20 Q. That was probably a poor use of words.
21 Clinical studies. Has Dr. Bromage subjected his
22 overlay system to any clinical studies?

23 A. We're in the process. It's a relatively
24 new thing and we're trying to fine-tune it.

25 Q. How does that system, his overlay system,

1 S. Galella

2 differ from the system that you used before November
3 of 2017 to use CBCTs to prove the efficacy of the
4 Osseo-Restore Appliance?

5 A. Try that again so I can understand it,
6 please.

7 Q. Sure. Let me ask you this: Did
8 Dr. Bromage have this overlay system in use before
9 November of 2017?

10 A. No.

11 Q. What system or method did you use before
12 November of 2017 with the CBCT scans to determine
13 proof of efficacy of the Osseo-Restore Appliance in
14 terms of development of a nasomaxillary complex in
15 three dimensions?

16 A. We would have to take screenshots of the
17 before and after, size them up exactly, and then we
18 would use the mammalian boundary lines and try to
19 correct the differences and put them side by side.
20 There was no overlay.

21 Q. Let's call that the early system. And
22 Dr. Bromage's is the overlay system.

23 Did you see a need for the overlay system
24 because of deficiencies in the accuracy of the first
25 system?

1 S. Galella

2 A. Well, yes.

3 Q. What were those deficiencies?

4 A. They were just minute angles and
5 measurements trying to reproduce on two separate
6 scans without the same -- we were using planes that
7 were not easily obtained until we developed a new
8 system.

9 Q. Did you find that that interfered or
10 compromised the accuracy of the --

11 A. No. It was just a minor. It was minor
12 inaccuracies, but enough that if you published it,
13 it would be considered to be a variant.

14 Q. It's still not published, correct?

15 A. We're still making the fine-tuning of it,
16 yes.

17 Q. Let's turn to the fifth page of
18 Exhibit 6. And you'll see it says: Facial growth
19 and growth appliances. Tip: Read and study the
20 appliance instructions provided by Johns Laboratory
21 with each case. These instructions are critical to
22 your success using Osseo-Restoration Appliance.

23 Now, that reference to Johns Laboratory,
24 is that the same entity, to your knowledge, as Johns
25 Dental Laboratory, Incorporated?

1 S. Galella

2 A. Yes.

3 Q. What instructions are you referring to?

4 A. The instructions on how to use the
5 appliance, how to fit and use the appliance, how to
6 monitor the progress, et cetera.

7 Q. Were those instructions intended --
8 strike that.

9 Who developed those instructions?

10 A. I did. I authored it.

11 Q. Were those instructions intended to be a
12 form of treatment plan?

13 A. No. They were intended for the use and
14 maintenance of the appliance.

15 Q. Did you intend those instructions to be
16 used as a guide by a treating dentist in creating a
17 treatment plan for a patient in regard to the
18 Osseo-Restore Appliance?

19 A. No. They were used to instruct the
20 dentist on how to insert the appliance and how to
21 monitor its progress and to look for anything that
22 may be out of whack or may be going wrong.

23 Q. Those instructions are not the same as
24 Exhibit 1B, are they? Do you remember that
25 document?

1 S. Galella

2 A. I don't remember 1B.

3 Q. I was hoping you did. Hang on one
4 second. Do you see it now, Doctor, 1B?

5 A. That was the instructions at the time of
6 around 2017, 2018.

7 Q. Those are the Johns Dental instructions
8 essentially we were just reading about?

9 A. You know, they've changed.

10 Q. Understood.

11 A. But at the time of this insertion by
12 Dr. Cortes, this was an appliance that was at the
13 time.

14 Q. Let's go back to 6.

15 Can you see that now, Doctor, Exhibit 6?

16 A. Yes.

17 Q. Now there's a section on the sixth page
18 of Exhibit 6. It says: MX fixed Osseo-Restoration
19 Appliance, tip of the month.

20 To minimize the time in a maxillary fixed
21 Osseo-Restoration Appliance special care should be
22 taken while compressing the springs. Several
23 doctors have reported that their patients have worn
24 the maxillary fixed Osseo-Restoration Appliance in
25 excess of six months. The normal wear time is three

1 S. Galella

2 to four -- going on page 7 -- months for 8 to 10
3 millimeters of development. Let me stop there.

4 What do you mean by development there?

5 A. I explained earlier, you take the space
6 that's created distal of the cuspids to the mesial
7 of the first bicuspid, measure each space on each
8 side, divide it by two -- add them together, divide
9 it by two.

10 That's how we referenced the development.
11 Those that have been instructed on how to use the
12 appliance, they know that's how you measure it.

13 Q. So 8 to 10 millimeters doesn't refer to 8
14 to 10 millimeters of maxillary advancement in the
15 sagittal plane?

16 A. It could. Generally three to four months
17 can get you up to 8 to 10 millimeters on some
18 patients. That's been reported.

19 Q. In the advancement of the maxilla in the
20 sagittal plane, you mean?

21 A. Yes.

22 Q. Then you say patients who are over 50 may
23 require four to five months. Again reading from
24 this document: In most cases the springs were only
25 partially compressed by the doctor or the assistant.

1 S. Galella

2 Then it goes on.

3 Now, would you consider 10 months of
4 Osseo-Restore use in a nongrowing adult to be
5 necessarily excessive?

6 A. I would say that's probably excessive.
7 Generally two things can happen.

8 MR. FUMUSO: No, no. He asked whether it
9 would be excessive and you answered the
10 question. Next question.

11 Q. What's the basis of your answer?

12 A. Well, normally it's four to five months.

13 Q. What's the your basis of your answer that
14 10 months would be necessarily excessive?

15 A. Sometimes the springs are not compressed
16 all the way so the force placed on the bone to the
17 acrylic pad is not adequate to create the
18 remodelling process. Sometimes the doctors don't
19 compress the springs for two or three months and
20 sometimes they don't notice that they've loosened
21 the stop lock and the spring isn't compressed when
22 they get through thinking they've compressed it.

23 Q. I'm trying to make sure I understand what
24 you said.

25 Is it that the use of an Osseo-Restore

1 S. Galella

2 Appliance in a patient for 10 months would
3 necessarily be the result of an error made by the
4 dentist?

5 A. Yes.

6 MR. FUMUSO: Note my objection to the
7 form.

8 Q. I'm sorry. I didn't hear your answer,
9 Doctor? Did you say yes?

10 MR. FUMUSO: Object to the form of the
11 question. You can answer over objection.

12 MR. CHARNAS: I think he answered it
13 already. Can you read his answer back, Court
14 Reporter.

15 (Record read.)

16 MR. CHARNAS: Now would be a good time to
17 take a 10-minute break if that's all right with
18 everyone.

19 (A recess was taken from 12:01 p.m. to
20 12:16 p.m.)

21 Q. Before we broke, Dr. Galella, you said
22 that 10 months of Osseo-Restore Appliance use would
23 be excessive. What are the risks of using an
24 Osseo-Restore Appliance for 10 to 13 months?

25 MR. SCHWARTZ: Note my objection to the

1 S. Galella

2 form.

3 MR. FUMUSO: You can answer over
4 objection, Doctor.

5 A. The risks are really not that bad because
6 there's mammalian boundaries that have been
7 established for hundreds of years -- hundred years
8 at least, that when the body reaches these
9 boundaries, it just quits responding or quits
10 remodeling. That's been our experience.

11 So the doctors that say, well, they wear
12 the appliance themselves. I've worn this appliance
13 for 10 months and nothing is happening. Well,
14 that's all they're going to get, so it's time to
15 take it off. That's pretty much the risk involved.
16 You're not going to damage anything else. You're
17 not going to push the teeth out of the bone. You're
18 not going to do any major harm. It's just wasting
19 time, if that makes sense.

20 Q. I believe you said mammalian response
21 that protects the patient?

22 A. No. No, that's not what I said. We have
23 mammalian boundaries that our body is programmed to
24 go to these extremes in the DNA in the bone. That's
25 the boundaries. If you try to violate the

1 S. Galella

2 boundaries, then the body tends to resist that.

3 So we're guiding the growth, guiding the
4 remodelling to the boundaries. And then when it
5 reaches the boundaries, it's different in every
6 patient, then the appliance just quits working.

7 Q. Dr. Galella, has the Osseo-Restore or
8 Osseo-Restore Device or Appliance ever been
9 submitted to the FDA for approval?

10 A. It's based on the construct --

11 MR. FUMUSO: He asked whether the
12 appliance had been submitted for FDA approval.

13 A. No.

14 Q. Is it your understanding that the FDA
15 does not have jurisdiction over this device?

16 A. That's my understanding.

17 Q. Doctor, I'm going to refer to sections of
18 Dr. Cortes' office records on Boja. They were
19 marked in her deposition as Exhibits 1, 2 and 3.
20 I'm not going to make them a separate exhibit in
21 this deposition. But I may refer to certain
22 portions of it from time to time.

23 I understand that you told us you have
24 not reviewed it. Dr. Galella, prior to 2020, did
25 you ever consult with Dr. Cortes concerning the care

1 S. Galella

2 or treatment of the plaintiff in this case, Boja
3 Kragulj?

4 A. Not to my knowledge.

5 Q. Is it fair to say that prior to 2020 you
6 never provided Dr. Cortes your opinion about Boja's
7 condition, her progress or lack thereof with an
8 Osseo-Restore Device or recommended any continued or
9 additional treatment for Boja?

10 A. Prior to when?

11 MR. FUMUSO: 2020.

12 Q. 2020.

13 A. No. We did a --

14 MR. FUMUSO: No, no. You answered the
15 question.

16 A. Please repeat the question.

17 MR. CHARNAS: Sure, sure.

18 Q. Is it fair to say that prior to 2020 you
19 never consulted with Dr. Cortes about Boja's care or
20 treatment, you never provided Dr. Cortes your
21 opinion about Boja's condition or her progress or
22 lack thereof with an Osseo-Restore or Restoration
23 Device?

24 A. No.

25 Q. You never did, correct?

1 S. Galella

2 A. As far as I recall.

3 MR. FUMUSO: The answer -- is that
4 correct, yes.

5 A. Yes.

6 Q. I want to show you another document.

7 MR. CHARNAS: This is Exhibit 7. I'm
8 going to represent to you that it's a page from
9 Dr. Cortes' deposition Exhibit 2 and that page
10 was Bates-stamp 38.

11 (Exhibit 7, color photographs; 00380,
12 marked for identification.)

13 Q. I'm going to represent to you further
14 that these were intraoral photographs taken of Boja
15 at Dr. Cortes' office on October 23rd, 2018.

16 Can you see these photos, Doctor?

17 A. Yes.

18 Q. Now, take a look at this photograph which
19 is on the right here, it's IMG_0079.JPG.

20 Do you see this photo?

21 A. Yes.

22 Q. Would you describe those anterior
23 maxillary teeth as slightly angulated?

24 MR. FUMUSO: You know, I have an
25 objection to this line of inquiry. We've

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S. Galella

indicated the doctor didn't see these. These are not part of his office records; am I correct about that?

MR. CHARNAS: They're not part of his office records. I'm showing him a photograph and I'm asking him to comment on it. I made it clear he hasn't seen it before.

MR. FUMUSO: This is the problem I have. In a federal case, I mean, the jurisdiction is New York. And it's my understanding that the New York law would apply and we have a case here in New York called Carvalho versus New Rochelle Hospital which stands for the proposition that one defendant in a case cannot be asked to give what amounts to expert testimony about another defendant in a case.

And by showing him records and photographs that he's never seen before, that's exactly what you're asking him to do. So this is not a form objection. This is a legal objection that I don't think that you're entitled to do this.

MR. SCHWARTZ: I agree. It's specific to one defendant having to testify against another

1 S. Galella

2 defendant. That's really specific to the case
3 law.

4 MR. CHARNAS: Well, first of all, this is
5 a product liability case. But let me quote for
6 you from the Carvalho case: In an action for
7 malpractice brought against more than one
8 physician, one defendant may not be examined
9 before trial about the professional quality of
10 the services rendered by a codefendant
11 physician if the questions bear solely on the
12 alleged negligence of the codefendant and not
13 on the practice of the witness.

14 First of all, this is a product liability
15 case and the efficacy of this device in terms
16 of what it does to the flaring of teeth is part
17 of the case.

18 Second of all, I intend to prove that
19 Dr. Galella did, in fact, treat my client. So
20 this question bears on Dr. Galella, it bears on
21 the device, it bears on the product liability
22 issues in the case. It is not solely in regard
23 to Dr. Cortes.

24 MR. SCHWARTZ: The response -- instead of
25 laying down a foundation to ask the questions

1 S. Galella

2 as to Dr. Galella, instead you laid down a
3 foundation against Dr. Cortes and her alleged
4 malpractice by asking questions specific to the
5 time frame that she employed the device. So
6 you actually laid a foundation specific to the
7 objection that codefendant counsel has raised
8 and I agree.

9 You've already tried to obtain testimony
10 from one codefendant against another and now
11 you're proceeding to continue that line of
12 questioning against my client. I seriously
13 object to this. And I want the answers to
14 Dr. Galella's prior questions that are also
15 covered by Carvalho stricken. I'll make that
16 motion for the time of trial and motion in
17 limine.

18 MR. FUMUSO: I agree with that. Carvalho
19 only makes an exception if the treatment of the
20 defendant who's being questioned is intimately
21 intertwined with the treatment of the
22 codefendant he or she is being questioned
23 about.

24 Here you established that this is not
25 part of his record. Dr. Cortes indicated that

1 S. Galella

2 Dr. Galella was not involved in this patient's
3 care and treatment. So I don't think you have
4 a basis to ask him these questions. This is
5 not a form objection. This is a substance
6 objection and I'm going to stand by that
7 objection.

8 I'm not going to allow Dr. Galella to be
9 asked to give commentary that could be
10 construed as critical of another codefendant in
11 this case based upon the Carvalho versus New
12 Rochelle decision.

13 MR. CHARNAS: First of all --

14 MR. SCHWARTZ: I also pointed out,
15 Mr. Charnas, it's already been occurring.
16 You've been setting up my doctor with this
17 doctor for several questions. You can have it
18 read back. I know that you have your outline
19 in front of you. His objection is correct. My
20 motion to strike those answers from
21 Dr. Galella, the questions that should not have
22 been permitted in the first place, will be
23 raised at trial.

24 MR. CHARNAS: Gentlemen, part of this
25 case is a malpractice case against Dr. Galella.

1 S. Galella

2 And I'm going to show that Dr. Galella saw
3 images of my client during the same time
4 period. I mentioned Dr. Cortes solely for the
5 purpose of demonstrating this is a photograph
6 taken during Dr. Cortes' treatment on
7 October 23rd, 2018.

8 So this is about Dr. Galella's
9 malpractice. Let me make that clear. And it
10 will be even clearer when you listen to the
11 additional questions in this deposition.

12 MR. SCHWARTZ: Counsel, he --

13 MR. CHARNAS: I'm sorry. I didn't
14 finish. It is also about the function of the
15 product. This is a product liability case.
16 Now if you want to object and move to strike
17 later on, that's your right. But you do not
18 have a right to tell me I can't ask these
19 questions.

20 MR. FUMUSO: What do you mean I don't
21 have a right? I certainly have a right as this
22 doctor's attorney to make a substantive
23 objection. Don't tell me I don't have a right
24 to make an objection on behalf of my client.

25 MR. CHARNAS: This is about his

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S. Galella

malpractice, not Cortes'.

MR. FUMUSO: What was that?

MR. CHARNAS: This is about his malpractice, not Cortes'.

MR. SCHWARTZ: Counsel, why did you ask him about the 10- to 13-month time frame and then follow that up with the risks associated with that time frame when you know it's my doctor's time frame? It was very specific, Mr. Charnas, that you've been trying to do this with one witness against another, one codefendant against another. You did that on the record.

MR. FUMUSO: You established that he never even saw these photographs.

MR. CHARNAS: I have established that he hasn't seen the photographs. I'm going to establish that he saw either photographs or film of her in this condition in October 2018. So just hang on and you'll see this.

MR. FUMUSO: Well, you're going to have to get there. You can't go through the back door without going through the front door.

MR. CHARNAS: So you're telling him not

1 S. Galella

2 to answer this question; is that right?

3 MR. FUMUSO: I'm telling you --

4 MR. CHARNAS: You're instructing him not
5 to answer?

6 MR. FUMUSO: -- substantively you cannot
7 ask him a question that bears upon the
8 negligence potentially of a codefendant.

9 MR. CHARNAS: The only basis to instruct
10 a witness not to answer is privilege.

11 MR. FUMUSO: No. I can also make an
12 objection on the substantive law, not just on
13 privilege.

14 MR. CHARNAS: You can make an objection,
15 but you can't instruct him not to answer.

16 MR. FUMUSO: I disagree. I disagree.
17 Okay. This is not a form objection. It's a
18 substance objection.

19 MR. CHARNAS: You're instructing the
20 witness not to answer this question?

21 MR. FUMUSO: That's correct. I'm
22 objecting to any question which could
23 inferentially or directly call him to testify
24 about the negligence, implicit negligence, of a
25 codefendant, yes.

1 S. Galella

2 MR. CHARNAS: That's not the Carvalho
3 standard. The Carvalho standard was solely in
4 regard to another practitioner's negligence.
5 I'm telling you that this is about his
6 negligence.

7 MR. FUMUSO: He never treated the
8 patient. How could he be negligent when he
9 never treated the patient? Come on.
10 Dr. Cortes said he never treated the patient.

11 MR. CHARNAS: I'm going to go about this
12 a different way.

13 Q. Dr. Galella, do you recall meeting with
14 Dr. Cortes in person in a coffee shop or restaurant
15 in Memphis, Tennessee in October 2018?

16 A. You mean Collierville, Tennessee?

17 Q. I'm sorry. I'm not too familiar with
18 Tennessee jurisdiction and geography.

19 Was it Collierville, Tennessee?

20 A. Yes. We had breakfast.

21 Q. Do you recall discussing various patients
22 of Dr. Cortes with her?

23 A. Is this the recorded thing that she
24 submitted?

25 Q. We'll get to that, Doctor.

1 S. Galella

2 Do you recall during that breakfast
3 conversation discovering certain patients of
4 Dr. Cortes with her?

5 A. I don't recall if it was patients. It
6 was concepts of -- mainly was about
7 temporomandibular joint patients and different
8 concepts.

9 Q. Did Dr. Cortes tell you that she was
10 recording the conversation when she was recording
11 it?

12 A. No.

13 Q. Did you tell -- strike that.

14 MR. CHARNAS: Before we get to that
15 conversation or the details thereof, let's go
16 to Exhibit 8.

17 (Exhibit 8, text messages; 3 pages,
18 marked for identification.)

19 Q. Do you see Exhibit 8 on the screen there?
20 Can you see it, Doctor?

21 A. Yes. Yes.

22 Q. I'm going to represent to you that these
23 are, according to my client, text messages that were
24 sent between her and Dr. Cortes. Blue is my client
25 and the gray is Dr. Cortes.

1 S. Galella

2 A. Slow down. I can't read --

3 Q. Don't worry. I'm going to get to the
4 appointment.

5 A. Okay.

6 Q. Yeah. Yeah. Hang on. Just bear with
7 me.

8 Your dental office was in Collier,
9 Tennessee in 2018; is that correct?

10 A. Collierville, yes.

11 Q. Collierville. I'm sorry. I'm going to
12 ask you, and I'll scroll for you, Doctor:

13 Do you see on the third page, it says:
14 Hello Boja. Yes, I'm thinking of you. How are you?

15 Do you see that?

16 A. Yes.

17 Q. I'm going to ask you to read to yourself
18 from that one text up to get to the text, I'll
19 scroll up to you again, of 10/12/2018. You just
20 start reading there and tell me when to scroll to
21 the next page.

22 A. Okay. Scroll. Go up.

23 Q. This is the next -- I'm sorry.

24 A. Keep going -- go down, I'm sorry. You
25 went too fast.

1 S. Galella

2 Q. That's the page you started on. Okay?

3 A. All right.

4 Q. And then that's the next page. You tell
5 me when to scroll up further.

6 A. Okay. Hold on. Okay. Why don't we read
7 this backwards?

8 Q. You want it backwards?

9 A. No, you're scrolling backwards.

10 (Simultaneous speakers.)

11 Q. Sorry. I don't mean to step on you. I'm
12 starting at an earlier date so the chronology is
13 appropriate. I'll start again.

14 A. Just remember. I can't read minds.
15 Okay. Okay. Okay. Okay. Okay.

16 Q. Just read up to including the 10/12/18
17 text.

18 A. Okay.

19 Q. Have you finished reading it?

20 A. Yes.

21 Q. I'm going to read the 10/12/18 text into
22 the record of Dr. Cortes.

23 Hello Boja, Dr. Galella loved your case.
24 And that slight angulation, he said that was
25 nothing. He and I have similar opinions. He

1 S. Galella

2 thought your case had the most pronounced changes.

3 Smiles. Yeah. See you soon.

4 Is that a true statement that Dr. Galella
5 made --

6 MR. FUMUSO: Wait.

7 MR. CHARNAS: Strike that.

8 Q. To the best of your knowledge, is that a
9 true statement that you loved her case?

10 A. I don't --

11 MR. FUMUSO: Wait. Object to the form of
12 the question. You can answer it if you can the
13 way it's phrased. Is that a true statement in
14 there?

15 A. I don't recall ever saying that because I
16 don't recall discussing her case.

17 MR. FUMUSO: Did you get the last part of
18 that answer.

19 (Record read.)

20 MR. SCHWARTZ: I object to the question
21 anyway.

22 MR. CHARNAS: I didn't hear you.

23 MR. SCHWARTZ: I have an objection.

24 You're asking if it's a true statement and the
25 statement is not written by him.

1 S. Galella

2 Q. Is that a true statement that you loved
3 Boja's case?

4 (Simultaneous speakers.)

5 MR. SCHWARTZ: Let me finish my
6 objection. Mr. Charnas, that was an objection
7 for the record. He obviously asked and
8 answered it already.

9 MR. FUMUSO: My objection is he asked and
10 answered it already. Number two, this is not
11 anything that Dr. Galella authored. That's
12 another objection I have.

13 MR. CHARNAS: I didn't ask whether he
14 wrote it. I asked him if the statement in
15 there that Dr. Cortes made is true.

16 Q. You've told us you don't remember that.
17 Do you remember telling Dr. Cortes that a slight
18 angulation of Boja's was nothing?

19 MR. FUMUSO: I'm going to object to the
20 form of the question. If you want to change
21 that to did he tell her as opposed to
22 remember -- remembering implies that such a
23 conversation took place. Okay. And you
24 haven't established that such a conversation
25 took place with this witness. So I'm going to

1 S. Galella

2 object to the form of the question and I'm
3 going to stand by that objection.

4 Q. Can you answer the question?

5 MR. FUMUSO: No. Not in that form.

6 MR. CHARNAS: You're instructing him not
7 to answer based on form?

8 MR. FUMUSO: Not in that form.

9 MR. CHARNAS: Could you read the question
10 back, please.

11 (Record read.)

12 MR. FUMUSO: I'm going to object to the
13 form of that question unless you establish a
14 foundation that he had -- that he recalls a
15 conversation. Which he already indicated that
16 he didn't. The way your question is phrased
17 implies that such a conversation took place and
18 he can't remember it. That's my objection.

19 Q. Dr. Galella, did you ever tell Dr. Cortes
20 in October 2018 that a slight angulation -- strike
21 that.

22 Excuse me.

23 Did you ever tell Dr. Cortes at that
24 meeting in October of 2018 or at any time that Boja
25 had a slight angulation of her teeth and that it was

1 S. Galella

2 nothing?

3 MR. SCHWARTZ: I'm going to object.

4 MR. FUMUSO: The doctor can answer.

5 A. I don't recall ever telling Dr. Cortes
6 that.

7 MR. SCHWARTZ: For the record, I have an
8 objection to the entire line of questioning.
9 My client was deposed several weeks ago. These
10 emails were not read to her for the purpose of
11 attempting to refresh her recollection and now
12 they're being used with the codefendant for the
13 purpose of attacking the credibility of my
14 client who simply couldn't recall that there
15 was anything specific as with regard to any
16 patient she had a discussion with Dr. Galella
17 at that time.

18 Now he's taking out these emails from
19 years ago and suggesting through this witness
20 that my client wasn't being totally credible at
21 her deposition because he simply chose for a
22 strategy not to refresh her recollection with
23 these emails with which he obviously had. So I
24 have a problem with all of this questioning
25 from that perspective and that may be also part

1 S. Galella

2 of a motion in limine.

3 MR. FUMUSO: I join in that objection for
4 the reasons enumerated by Mr. Schwartz. Also,
5 I join in that objection because Dr. Cortes
6 testified that she had no recollection of ever
7 discussing this patient with Dr. Galella during
8 that breakfast meeting.

9 MR. MURPHY: Also join as well.

10 Q. Let me ask you some additional questions,
11 Doctor.

12 During that coffee shop meeting, do you
13 remember Dr. Cortes telling you that one of her
14 patients commuted from Florida?

15 MR. FUMUSO: Do you recall that one way
16 or the other?

17 A. Yes. I think she said something about
18 some patient from Florida. But she has a lot of
19 patients from Florida from what she tells me.

20 Q. Doctor, do you recall that during that
21 coffee shop meeting Dr. Cortes played a videotape
22 for you of that patient from Florida?

23 A. No, I don't recall that. I don't recall
24 seeing a videotape.

25 Q. Do you recall anyone stating -- strike

1 S. Galella

2 that.

3 MR. CHARNAS: I think what we're going to
4 do is. I'm going to attempt to play portions
5 of this tape. For the record, this tape was
6 produced by Dr. Cortes in discovery.

7 And I'm going to play the tape for a
8 little bit, Doctor. I'm going to ask you if
9 you can tell us who the male voice is and who
10 the female voice is. Okay.

11 (Exhibit 9, audio recording, deemed
12 marked for identification.)

13 (Audio recording played.)

14 Q. Doctor, did you hear that tape? I just
15 want to make sure.

16 A. Yes.

17 Q. I'm going to ask you who the male voice
18 is and who the female voice is.

19 (Audio recording played.)

20 Q. Doctor, is it fair to say that the male
21 voice is yours?

22 A. The male voice is mine.

23 Q. Is it fair to say that the female voice
24 is Dr. Cortes?

25 A. I'm assuming so. I don't recall her

1 S. Galella

2 voice in my head.

3 Q. Now, I'm going to shift to a point that
4 is an hour and 17 minutes and approximately 49
5 seconds into the tape. I'm going to ask you to
6 listen from that point until an hour 24 minutes and
7 35 seconds. It's about seven minutes.

8 (Audio recording played.)

9 Q. All right. I want to play one very brief
10 section again. It's at 1:22:49, approximately.

11 (Audio recording played.)

12 MR. CHARNAS: Now I'm stating for the
13 record that that recording of the coffee shop
14 meeting in October of 2018 has a video
15 recording played on it which is my client's
16 voice and then Dr. Cortes says at one hour 22
17 minutes and 49 seconds, Boja, which is a
18 mispronunciation of my client's name, which is
19 commonly done, Boja, where is it. That and for
20 other reasons I think has established enough of
21 a foundation that I am going to ask questions
22 to Dr. Galella about certain aspects of
23 treatment that he was involved in. And that's
24 my intention.

25 MR. SCHWARTZ: Mr. Charnas, I did not

1 S. Galella

2 hear what you said you heard. I don't know
3 what you heard. I heard a lot of garble. The
4 things you said about your client on that
5 recording, I didn't hear them.

6 MR. FUMUSO: And I did not hear them
7 either.

8 MR. CHARNAS: I don't have to prove my
9 case to you to get to ask questions.

10 MR. SCHWARTZ: No. You don't have to
11 prove your case. Mr. Charnas, you have to put
12 evidence on the record to lay a foundation.
13 You have not done that. You've testified,
14 Mr. Charnas. You've testified.

15 MR. FUMUSO: I didn't hear anything about
16 Boja on that type.

17 (Simultaneous speakers.)

18 MR. SCHWARTZ: Who told you that that was
19 her voice, Mr. Charnas, your client? Are you
20 testifying at trial now? Because your
21 rendition requires your testimony as to whose
22 voice that was and that is your client telling
23 you it was her voice. I don't know any of
24 this.

25 We're not on trial now but if you're your

1 S. Galella

2 star witness, we've got a problem.

3 MR. FUMUSO: As far as I'm concerned,
4 there is absolutely no foundation that your
5 client was discussed during that breakfast
6 meeting and, in fact, Dr. Cortes has taken the
7 position she has no recollection of ever
8 discussing this patient during that meeting
9 with Dr. Galella. And I didn't hear anything
10 about Boja. I didn't hear anything about your
11 client's voice. I think it's your imagination
12 as opposed to evidence.

13 MR. CHARNAS: Are you telling us that you
14 don't recognize my client's voice on that --

15 MR. FUMUSO: Absolutely. I didn't hear
16 your client's voice. I didn't hear the word
17 Boja. I'm not going to allow this. Objection.

18 MR. CHARNAS: The judge will make the --
19 I'm going to ask the questions. If you
20 instruct the witness not to answer, you do so
21 at your peril. I intend to make a motion and
22 have this witness brought back.

23 MR. FUMUSO: I don't do it at my peril.
24 I do it in representing my client. Okay. It's
25 not my peril.

1 S. Galella

2 MR. CHARNAS: And I'm going to ask for
3 costs, by the way.

4 MR. FUMUSO: Okay. Good.

5 Q. Dr. Galella, I'm showing you Exhibit 7.
6 I'm representing to you, as I have before, that this
7 is a photograph taken October 23rd, 2018, and is
8 part of Dr. Cortes' records in regard to my client.

9 Do you detect any angulation in the
10 anterior maxillary teeth?

11 MR. FUMUSO: Objection for the reasons I
12 set forth previously. The doctor has never
13 seen this document. I don't believe this
14 document was exchanged prior to this morning
15 with me. And under the Carvalho rule, as far
16 as I'm concerned, Carvalho holding, you're
17 implicitly asking him to give expert testimony
18 about a codefendant in this case and I will --
19 certainly was not -- he was not involved with
20 the care and treatment of the patient and
21 certainly not at this particular time and I'm
22 going to stand on my objection.

23 MR. SCHWARTZ: I join in that objection.

24 MR. CHARNAS: You're instructing him not
25 to answer; is that correct?

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S. Galella

MR. FUMUSO: It's a substantive objection and I'm directing him not to answer.

MR. CHARNAS: Just for the record. I have a claim of malpractice in this case against Dr. Galella. And it is my position that Dr. Galella was shown records of Boja during the October 2018 coffee shop meeting and that he made comments, including she needs another 2 millimeters more of growth. I intend to ask a series of questions in regard to his observations of my client and I will ask them. And if you instruct the witness not to answer, we will take it up with the court.

It's my intention to seek costs in regard to the necessity of reconvening this deposition.

MR. FUMUSO: Okay.

MR. CHARNAS: Now, it is 12:57. It's probably a good time to break right now. So why don't we resume at 1:30?

MR. FUMUSO: Okay. That sounds fine. Thank you.

(A recess was taken from 12:57 p.m. to 1:31 p.m.)

1 S. Galella

2 MR. CHARNAS: Before continuing with the
3 questioning, I want to make a statement for the
4 record. I've spoken to my client who has
5 listened to Exhibit 9 which is the tape of the
6 breakfast conversation. She will be submitting
7 an affidavit in connection with a motion to
8 compel further questions with regard to the
9 areas I have been precluded from questioning
10 about. She will identify in that affidavit
11 that it is her voice on the tape that
12 Dr. Cortes showed to Dr. Galella at that
13 meeting.

14 Further, I seriously doubt that either
15 one of you is going to be submitting an
16 affidavit to the effect it is not her voice on
17 the tape. And Dr. Galella is clearly on the
18 tape mentioning an additional 2 millimeters of
19 growth in regard to that patient.

20 So I believe further that the appropriate
21 way of handling this is not an instruction not
22 to answer but it is to allow the question and
23 answer and to move to strike later on.

24 So I ask counsel whether they will
25 reconsider based on this information. Sorry,

1 S. Galella

2 let me add one other thing. The questioning is
3 also relevant in regard to the product
4 liability claim against Dr. Galella and Johns
5 Dental.

6 MR. FUMUSO: First of all, I don't think
7 it's relevant to the product liability claim.
8 Your claim is that this is a defective device
9 here. This has to do with specific treatment
10 given to this particular patient. I think the
11 two are different and you're trying to bring in
12 a product liability as a way to avoid Carvalho
13 and I don't think that that's appropriate under
14 the circumstances. That's number one.

15 Number two, I didn't hear anybody's voice
16 on that tape other than Dr. Cortes and
17 Dr. Galella. I didn't hear anybody, to tell
18 you the truth. And I certainly didn't hear
19 anybody make reference to the name Boja.

20 Number three, if this was your
21 presentation and position, then, you know,
22 maybe you should have had your client testify
23 to that at her deposition. Maybe you should
24 have presented Dr. Cortes with this at her
25 deposition. But you did not.

1 S. Galella

2 I'm not going to allow my witness to
3 answer questions based upon a representation on
4 something I can't even hear myself on the tape.
5 So I always find it's best when I'm making a
6 substantive objection to protect my client and
7 I'm going to do that at this particular point.
8 I want to hear the questions. And if I think
9 it has to do with treatment rendered by
10 Dr. Cortes, I'm going to object.

11 My client is very clear that he did not
12 treat this patient, certainly prior to her
13 coming to him in March of 2020. And that was
14 also the testimony of Dr. Cortes.

15 So that's the basis of my objection.
16 That's my position at this point.

17 MR. SCHWARTZ: If I could, I would just
18 like to add for the record, that, in fact, my
19 client did appear. She was asked questions
20 about this specific part of the tape but you
21 didn't play her part of the tape. We didn't
22 get that in depth with it. And she couldn't
23 recall.

24 Had she seen the emails, had you played
25 the tape, we might have been able to clarify

1 S. Galella

2 this. And it would have assisted my client in
3 responding, so it wouldn't look as if she was
4 trying not to respond which is what I think
5 you're trying to do today asking these
6 questions of this witness and not my witness
7 who was the person who recorded it.

8 She did testify that she spoke about a
9 lot of patients that day. And the idea that
10 this specific one is your client as opposed to
11 the other ones, that's where my objection lies.

12 I don't know if she mentioned this
13 particular plaintiff on that tape. She said
14 she spoke to him about 40 of them. You know,
15 if that's the case, I think that you should
16 have -- really should have tried to clarify
17 that, instead of now basically testifying for
18 your client in order to lay a foundation and
19 asking us to accept her affidavit when I'm
20 pretty sure my client is going to say she
21 doesn't hear her voice either. I don't know
22 what she'll say. I didn't hear her voice.

23 This really should have been handled at
24 your client's deposition or my client's
25 deposition, not now.

1 S. Galella

2 MR. LAIRD: I join in the objections made
3 by Henry and Alan.

4 Q. Okay, Doctor. Let's proceed. Does the
5 Osseo-Restore or Osseo-Restoration Device cause
6 flaring anterior maxillary teeth?

7 MR. FUMUSO: I'm sorry. May I hear the
8 question back, please?

9 MR. CHARNAS: Let me repeat it.

10 Q. Does the Osseo-Restore or
11 Osseo-Restoration Device, either way you want to
12 call it, cause flaring of the anterior maxillary
13 teeth?

14 MR. FUMUSO: Can you answer that question
15 the way it's phrased?

16 THE WITNESS: I can answer that.

17 A. If it's inserted and applied and
18 monitored properly, you should get minimal flaring.
19 By minimal, I mean not noticeable.

20 Q. Let me show you Exhibit 7, image 0079.
21 Do you have that on the screen, Doctor?

22 A. Yes.

23 Q. Now, take a look at that image and tell
24 me if what you see is consistent with the design
25 goals of the Osseo-Restore or Osseo-Restoration

1 S. Galella

2 Device?

3 MR. FUMUSO: I'm going to object to this.
4 Once again, we've established this was
5 apparently a picture taken while the patient
6 was under the care and treatment of Dr. Cortes.
7 He could give answers that could implicate
8 Dr. Cortes. The doctor never saw this exhibit
9 before this morning. It's not part of his
10 office record. I'm going to object and make a
11 substantive objection on Carvalho and direct
12 him not to answer.

13 MR. SCHWARTZ: I'm going to state that
14 this is precisely what Carvalho is about. You
15 asked the doctor to indicate -- if he were to
16 say this is not the design objectives, you're
17 then getting testimony against my client.

18 MR. CHARNAS: I'm not going to belabor
19 the point. This is a product liability action.
20 Among other things, one of the issues is the
21 functions and effects of the device that's at
22 the heart of this matter and asking him whether
23 this picture shows a condition which is
24 consistent with the design objectives of that
25 device. You're refusing to let him answer,

1 S. Galella

2 Alan; is that correct?

3 MR. FUMUSO: That's correct.

4 Q. Let me show you another photograph from
5 the same Exhibit 0082. I ask you, again, for the
6 record, this is a page from Boja's -- strike that.

7 This is a page from Dr. Cortes' record,
8 Exhibit 2 from that deposition, page 380. I'll ask
9 you in regard to 0082 whether you see anything
10 that's inconsistent with the design goals of the
11 Osseo-Restore Device?

12 MR. FUMUSO: Same objection.

13 MR. SCHWARTZ: Same objection. Also, I'd
14 like to add, there's no foundation for these
15 questions. Are we looking at a photograph?
16 There's no measurements connected with it. We
17 don't know what she looked like beforehand, how
18 long she wore the device. You could phrase it
19 as a hypothetical, but it would still be
20 objectionable because it is my client's photos.

21 MR. CHARNAS: Just so it's clear, Alan,
22 you're instructing the witness not to answer?

23 MR. FUMUSO: That's correct.

24 MR. CHARNAS: Let me show you another
25 document which was marked as Exhibit 11.

1 S. Galella

2 (Exhibit 11, emails containing color
3 photographs; 00498-500, marked for
4 identification.)

5 Q. Can you see that, Dr. Galella?

6 A. Yes.

7 Q. It consists of three pages. Again, these
8 are from Dr. Cortes' record, for the reported. And
9 they are Bates-stamped 498, 499 and 500.

10 Do you see that the email list is Steve?

11 A. Yes.

12 Q. And it's dated 8/23 of '19. Do you see
13 that at the top there?

14 A. No.

15 Q. Can you see that, to the right of the
16 exhibit sticker?

17 A. I see it. I can see that. It's behind
18 the picture.

19 Q. Doctor, are you the Steve?

20 A. I have no idea. I've never seen this
21 before.

22 Q. Just so it's clear, you've never seen
23 these photographs which are part of that document?

24 A. Not to my recollection.

25 Q. For the record, I did want to ask you one

1 S. Galella

2 more question about that document.

3 Do you see anything inconsistent in the
4 four photographs on the first page of the document
5 in terms of being inconsistent with the design goals
6 of the Osseo-Restore Device?

7 MR. FUMUSO: I'm going to object under
8 Carvalho.

9 MR. SCHWARTZ: Same objection.

10 MR. CHARNAS: You're refusing to let him
11 answer?

12 MR. FUMUSO: That's correct.

13 MR. CHARNAS: I wish you would state
14 that. It would just make it easier.

15 MR. FUMUSO: Okay.

16 MR. CHARNAS: Thank you.

17 Q. Doctor, we're going to get back to
18 Exhibit 1A which we looked at earlier.

19 Can you see that, Doctor?

20 A. Yes.

21 Q. I'm going to scroll through it solely for
22 the purpose of you identifying what the document is.
23 If and when you recognize what it is, just stop me.

24 A. It looks like the report from
25 OrthoAssist/OrthoLogic Diagnostics.

1 S. Galella

2 Q. I'm sorry. You said
3 OrthoAssist/OrthoLogic?

4 A. It used to be OrthoAssist and at some
5 point it switched to OrthoLogic because of a
6 trademark issue.

7 Q. Are they divisions of the defendant
8 OrthoMatrix?

9 A. Yes.

10 Q. Were they divisions of the defendant
11 OrthoMatrix from 2016 to 2020?

12 A. Yes.

13 Q. When is the last time you saw this
14 document?

15 A. Several weeks ago.

16 Q. Did you read it in preparation for this
17 deposition?

18 A. No.

19 Q. In what context did you read this
20 document?

21 A. Just to review. But I didn't read it in
22 detail.

23 Q. Did you have any part in drafting this
24 document?

25 A. Yes.

1 S. Galella

2 Q. What is this document intended to be?

3 A. It's a suggested treatment plan for the
4 patient that was submitted to the diagnostic system.

5 Q. And that treatment would be Boja Kragulj,
6 right?

7 A. That's what it says.

8 Q. Did you have a role in creating a
9 treatment plan for -- at some point for Boja
10 Kragulj -- let me strike that. Let me rephrase
11 that.

12 Did you have a role in creating a
13 treatment plan for Dr. Cortes to use in regard to
14 Boja Kragulj?

15 A. Suggested treatment plan, yes.

16 Q. Was this done as part -- strike that.

17 Did you do this for FBI, for Facial
18 Beauty Institute, or the two ortho companies you
19 mentioned or did you do it on your own or something
20 else?

21 A. It's OrthoMatrix. It's OrthoMatrix
22 diagnostic system. They just name it --
23 (Simultaneous speakers.)

24 Q. Sorry. We're going to get into this a
25 little bit more later.

1 S. Galella

2 Are you an officer of OrthoMatrix?

3 A. I'm a principal.

4 Q. Is OrthoMatrix a corporation?

5 A. Yes.

6 Q. Do you hold an office in that
7 corporation?

8 A. Board member. I know I'm a board member.

9 Q. Are you president, vice-president or
10 something else?

11 A. I don't think so.

12 Q. When you drafted this treatment plan,
13 were you a board member of OrthoMatrix?

14 A. Yes.

15 Q. There's black writing and there's red
16 writing on this document.

17 Did you write the black writing and the
18 red writing?

19 A. This was compiled by several people and
20 the final version was edited by me. And, yes, black
21 and red.

22 Q. So the black -- both the black and the
23 red were written by you; is that fair to say?

24 A. They were edited by me.

25 Q. Let me rephrase it then.

1 S. Galella

2 The black and the red were approved by
3 you, correct?

4 A. I guess approved would be a good word,
5 yeah.

6 Q. And the red, were you the only one who
7 wrote the red?

8 A. No.

9 Q. Who participated in the creation of this
10 document besides yourself?

11 A. Dr. Andy Abernathy, Anatomage
12 Diagnostics. I think this particular one -- what
13 was the date of this one, was the one provided for
14 Dr. Cortes?

15 Q. Yes.

16 A. That would have been BeamReaders, I
17 think, did the radiology report and some of the
18 language on this report is also copied from the
19 radiology report.

20 Q. Is BeamReaders affiliated with
21 OrthoMatrix or any of its divisions?

22 A. No. It's a radiology company. It's Oral
23 Maxillofacial Radiology. I think they're a
24 corporation.

25 Q. And you mentioned Dr. Abernathy.

1 S. Galella

2 A. Yes.

3 Q. Is Dr. Abernathy affiliated with
4 OrthoMatrix?

5 A. Yes.

6 Q. What was his affiliation in --

7 A. He gathers the data and sends it off to
8 the various areas so it will be processed. Sends it
9 to the radiologist. Sends it to Anatomage and
10 checks the tracings from Anatomage and the accuracy
11 of the radiology report.

12 Q. Is Dr. Abernathy a dental professional?

13 A. He holds a D.D.S. license in Tennessee.

14 Q. Is he licensed in New York?

15 A. Licensed in Tennessee.

16 Q. And the radiologist, who is the
17 radiologist who reviewed films for purposes of
18 creating this treatment plan?

19 A. Well, I'd have to look at the radiology
20 report because there were various ones that rendered
21 opinions.

22 Q. Would this be part of this seven-page
23 document?

24 A. It would be the radiology report.

25 Q. Would it be part of the treatment plan?

1 S. Galella

2 A. No. It would be on the radiology report,
3 his signature.

4 Q. Can you --

5 A. Or her.

6 Q. Are you talking about the FBI radiology
7 report dated 11/26/18?

8 A. Yes. It would be on the signature, him
9 or her, whoever read the cone beam, et cetera.
10 Their signature is on that page.

11 Q. This treatment report, is it fair to say
12 it was created in approximately November of 2018?

13 A. Yes.

14 Q. What was your understanding as to, if
15 any, of what use Dr. Cortes intended to make of this
16 treatment plan?

17 A. I don't understand the question.

18 Q. When you were creating a treatment plan
19 for Dr. Cortes in terms of her use of the
20 Osseo-Restoration Appliance on Boja, correct?

21 A. No. Orthodontic treatment plan which
22 could or could not include Osseo-Restoration
23 Appliance and ControlledArch technique. It
24 depends -- it depends on the patient. So this
25 particular patient was Dr. Cortes and she submitted

1 S. Galella

2 a cone beam and a series of pictures and asked for
3 an evaluation and treatment plan. And part of that
4 was the tracings and loads and loads of information
5 on the download section. And this report was a
6 final result which was a suggested treatment plan
7 for this patient.

8 Q. What was the information -- strike that.

9 The information that you reviewed in your
10 coming up with this treatment plan, was any of it
11 for the year 2018?

12 A. I'm sorry. I don't understand the
13 question.

14 Q. That was a poor question. I'm sorry.

15 I'm trying to get at what specifically
16 you reviewed in order to come up with this treatment
17 plan, you personally reviewed.

18 And more specifically, I want to know
19 whether anything you reviewed in terms of films or
20 photographs was from the year 2018.

21 A. Well, from my recollection, the cone beam
22 that was submitted was from 2016. The pictures were
23 from 2016. And there was no medical history
24 provided other than what was on the checklist of
25 symptoms and signs that they saw. And then I

1 S. Galella

2 reviewed -- from that I reviewed the tracings from
3 Anatomage, which is the American Board of
4 Orthodontics diagnostics. And then the mammalian
5 boundary growth page developed by Bromage and
6 others.

7 Then there was an interpretation of the
8 tracing, the numbers. Things are based on numbers.
9 We interpreted so we could make easy statements such
10 as prognathic mandible, retrognathic maxilla, et
11 cetera, and then it was all put together.

12 Some of this report was copied and pasted
13 from the radiology report. Some of it was
14 interpretation of the numbers and some of it was a
15 basic treatment plan rendered in a step-by-step way
16 and the doctor gets to pick and choose what they
17 wanted to do.

18 Q. Was it your understanding when you were
19 drafting this treatment plan that Anatomage had
20 reviewed any scans, films, radiographic documents of
21 any kind from the year 2018?

22 A. They were only provided what we were
23 provided which was 2016.

24 Q. So is it fair to say that you were coming
25 up with a treatment plan for Dr. Cortes in the year

1 S. Galella

2 2018 based on data you received from 2016; is that
3 fair to say?

4 A. Yes. Well, the information in the
5 portal. I don't know what it was from. But in the
6 portal when she submitted the -- before you submit
7 the case, you give case values and you say is it
8 various -- questions are asked and she answered
9 them.

10 But I'm not sure what her time frame was
11 on those things.

12 Q. When you come up with a treatment plan
13 for future treatment in the year 2018, do you think
14 it's a good idea to rely on data that's current?

15 MR. FUMUSO: Objection to the form of the
16 question.

17 A. Yeah. Could you rephrase it, please.

18 Q. Yeah. I take it that it was acceptable
19 to you to draft a treatment plan for future
20 treatment of Boja in 2018 or thereafter based upon
21 data that dated back to 2016 or earlier?

22 MR. FUMUSO: Or later. I'll object to
23 that.

24 Q. What's your answer, Doctor?

25 A. You have to ask it again. You were

1 S. Galella

2 talking sort of fast. I'm sorry.

3 Q. Doctor, you created this treatment plan
4 for Dr. Cortes for her treating of Boja around
5 November of 2018, correct?

6 A. Yes.

7 Q. And the films that you were relying on
8 and/or that Anatomage company reviewed, they were
9 films, to your knowledge, from 2016; is that
10 correct?

11 A. That's correct.

12 Q. And you can't tell us as you sit here
13 whether any of that data that was inputted by
14 Dr. Cortes for you to come up with this treatment
15 plan was current in terms of the year 2018; correct?

16 A. That's correct.

17 Q. Before you came up with a treatment plan
18 in 2018 for future treatment of Boja, would you not
19 have wanted to know whether you were basing your
20 opinions and your suggestions on current data?

21 MR. SCHWARTZ: Objection.

22 MR. FUMUSO: You can answer over
23 objection.

24 A. That's the data we were provided.
25 Generally this older data we usually ask. But

1 S. Galella

2 currently we ask if they have an updated one. But
3 at the time we just took the data that they provided
4 because the instructions in the portal said current.

5 Q. What did OrthoMatrix charge for this
6 treatment plan?

7 A. \$467 is the normal fee.

8 Q. So I'm reading down a little bit towards
9 the bottom of the first page of this exhibit and it
10 says, "Airway is severely constricted."

11 Do you see that there, Doctor?

12 A. Yes.

13 Q. That statement, "Airway is severely
14 constricted on the document," to the best of your
15 knowledge, is that based on films from 2016?

16 A. Yes. The radiology report used the same
17 cone beam.

18 Q. Now, on the second page of that same
19 exhibit, it says, "Noted, before beginning
20 treatment, discuss with the patient the generalized
21 gingival resection that is present."

22 So is it fair to say that you're talking
23 about generalized gingival recession that was
24 present in 2016?

25 A. Yes.

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2 Q. Then you say, "There is a significant
3 possibility that gingival grafting and/or osseous
4 drafting will be necessary at the completion of
5 treatment."

6 What is the basis of your statement?

7 A. Because they had gingival recession and
8 the oral hygiene may change at any time. If they
9 don't keep their teeth clean, it could get a whole
10 lot worse and you could get extra bone loss.

11 MR. CHARNAS: Could the court reporter
12 read back the answer.

13 (Record read.)

14 Q. When you wrote that, did you understand
15 that the patient had been using an Osseo-Restore or
16 Restoration Device since January of 2018?

17 A. No, we did not know that.

18 Q. Were you concerned not only about
19 improper oral hygiene, but also about whether an
20 Osseo-Restore Device placed on this patient could
21 cause there to be gingival grafting and/or osseous
22 grafting?

23 A. No. It's pretty much a disclaimer saying
24 you need to take good care of your teeth. If you
25 have gingival recession, it may continue with

1 S. Galella

2 whatever treatment is rendered. That's a given. We
3 weren't concerned about the appliance. We thought
4 we were starting from ground zero.

5 Q. When you say you thought you were
6 starting from ground zero, what do you mean?

7 A. That means this patient had never had
8 anything done other than what information was given
9 to us which was minimal, which was pretty much
10 nothing.

11 Q. When you created this treatment plan, was
12 it your understanding that Dr. Cortes intended to
13 use or place an Osseo-Restoration Device in the
14 patient?

15 A. Rephrase that, please.

16 Q. When you created this treatment plan or
17 approved this treatment plan, was it your
18 understanding that Dr. Cortes intended to place the
19 Osseo-Restoration Device on the patient?

20 A. She could choose to or choose not to.
21 Part of the treatment plan, in an ideal situation,
22 this is what this patient needs, this specific
23 patient.

24 Q. Was the data that was inputted that you
25 referred to here earlier, was that inputted into the

1 S. Galella

2 Total Diagnostics portal?

3 A. I don't remember the submit date. But it
4 was -- yeah. It was within several weeks of when we
5 finished it at the end of November.

6 Q. Tell us, what is the Total Diagnostics
7 portal?

8 A. That's where you submit the cone beams,
9 the pictures, patient information, et cetera.

10 Q. For what purpose?

11 A. For a diagnostic workup. What is the
12 diagnosis? What is the suggested treatment plan and
13 what's the suggested retention?

14 Q. Is the Total Diagnostics portal just for
15 dentists or other dental professionals who are
16 considering use of Osseo-Restoration Appliances?

17 A. No. It could be just for orthodontics,
18 removable. It could be for anything. It's an
19 orthodontic diagnostic system. And the appliances
20 would fit the particular patient, not the patient
21 fit the appliances.

22 Q. On the second page under note it says:
23 Before treatment discuss with the patient those
24 teeth involved with root resorption and the
25 possibility that the resorption may continue with

1 S. Galella

2 eventual loss of those teeth.

3 Let me stop there for a moment. Are you
4 saying in that sentence that you saw root resorption
5 in the films or photographs that you were furnished?

6 A. The radiologist made a comment that there
7 was root resorption. So this statement says: You
8 need to have a discussion with the patient that
9 they've had root resorption. Root resorption can
10 iatrogenically or for any reason return and finish
11 taking the roots away. It's a reaction of the body
12 that sees the roots as a foreign body.

13 So it's just -- discuss it with the
14 patient and certainly let them know that there's
15 consequences if you decide to treat this patient.

16 Q. Consequences if you decide to treat this
17 patient generally or consequences if you decide to
18 treat this patient a particular way?

19 A. Generally. Just root resorption is -- it
20 doesn't have a specific cause. It can recur. It's
21 already occurred, it can recur. Had the patient
22 been treated orthodontically before is a good reason
23 they may have it or the some other treatment we
24 didn't know about or trauma. Anything can cause it.
25 But when you start treating with an appliance or

1 S. Galella

2 orthodontically, it can recur and go to the worst
3 case scenario which is loss of teeth.

4 Q. You say further here: The patient should
5 be informed of the periodontal bone loss and the
6 consequences during orthodontic treatment. This
7 along with other concerns presented in an informed
8 concept paper should be well documented.

9 What other concerns were you thinking
10 about that should be presented in the informed
11 consent papers?

12 A. Well, most practitioners have informed
13 consent papers they have their patients sign that
14 explain all the consequences of whatever treatment
15 they're having.

16 We provided two examples in our download
17 section that they could use. It covers root
18 resorption, bone damage, gingival recession.
19 Anything is always covered. It's just legalese for
20 we need to make sure we cover everything with the
21 patient so they understand the consequences of any
22 kind of treatment that they have.

23 Q. Thank you. Now on the third page,
24 Doctor, it says under 4: Special note, correction
25 of Class III skeletal patients with neutral growth

1 S. Galella

2 patterns presents certain special considerations.
3 Occasionally, additional maxillary anterior
4 development is necessary to prevent the mandible
5 from outgrowing or out-remodeling the maxilla and
6 returning to a skeletal Class III relation.

7 Did you yourself determine either
8 yourself or from looking in that report that you
9 referenced earlier that the patient had a Class III
10 skeletal with neutral growth patterns?

11 A. If you scroll up to the diagnosis, I'm
12 sure it's in there. Dental Class III, division two,
13 there's your diagnosis.

14 Q. And that's not obviously a general
15 diagnosis. That's a general diagnosis in regard to
16 the patient Boja, right?

17 A. Yes. It's specific to her.

18 Q. Do you recall suggesting anywhere that
19 before any appliances be used on Boja that a full
20 periodontal assessment be made?

21 A. I would have to read the report. I don't
22 recall.

23 Q. Is that something you generally do when
24 you do these treatment plans; you suggest a full
25 periodontal assessment?

1 S. Galella

2 A. Currently we do.

3 MR. FUMUSO: He's not asking you
4 currently. He's asking back then in 2018.

5 A. If it's not on there, we didn't put it
6 down.

7 There was a note about the gingival
8 recession. And that generally signals the doctor to
9 reevaluate.

10 Q. When did you start suggesting periodontal
11 specimens when doing these treatment plans?

12 A. Oh, probably in 2020.

13 Q. Why did you start doing that?

14 A. Because we -- as we evolved in our thing,
15 we wanted to make sure we covered everything on
16 behalf of the doctor. It's just part of the growth
17 process.

18 MR. CHARNAS: Let me show you another
19 document in a moment.

20 Q. Do you see that, Doctor, that's
21 Exhibit 7? Can you see it?

22 A. Yes.

23 Q. Just making sure. Let me ask another
24 question your lawyer is probably not going to let
25 you answer, but I need to ask it.

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2 Do you agree that the gingival recession
3 and root exposure seen in Exhibit 7 indicate that
4 new bone is not being deposited at the interior of
5 the alveolar bone?

6 MR. FUMUSO: Objection as previous. This
7 doctor was not involved in the treatment of
8 this patient. He's never seen these
9 photographs before today and I have a Carvalho
10 objection and I'm directing him not to answer.

11 MR. SCHWARTZ: I join.

12 MR. CHARNAS: I would state for the
13 record that those points are irrelevant to the
14 question that's being asked which is relevant,
15 among other things, to the product liability
16 case as well as the malpractice case against
17 Dr. Cortes.

18 MR. FUMUSO: I will comment this has
19 nothing to do with the products liability case,
20 in my opinion.

21 Q. Now, I'm going to pose to you a
22 hypothetical and I'm going to suggest that the
23 person who is depicted in photograph 0082 was
24 wearing an Osseo-Restore Device from January 25th,
25 2018, until at least the date of this picture,

1 S. Galella

2 October 23rd, 2018.

3 Is there anything that you see in this
4 photograph which is inconsistent with the design
5 goals of the Osseo-Restoration Device?

6 MR. FUMUSO: Same objection as
7 previously. It obviously calls for an opinion
8 that involves care and treatment rendered by a
9 codefendant in the case. The doctor was not
10 involved with the care and treatment of the
11 patient in 2018 or 2019 and based upon those
12 factors, I'm going to object and direct him not
13 to answer under the Carvalho versus New
14 Rochelle Hospital decision.

15 MR. SCHWARTZ: I join that objection and
16 note that my audio was not working momentarily
17 for the last few questions. I'm joining the
18 whole line of objections.

19 MR. LAIRD: We also join as well.

20 MR. CHARNAS: No sense my repeating my
21 position again. I think we all know it by now.

22 Q. Doctor, I'm going to show you a
23 photograph. Again, this was taken from Dr. Cortes'
24 record. It's a series of photographs dated
25 January 25th, 2018. They come from page 330,

1 S. Galella

2 Bates-stamp page 330, of Dr. Cortes' record, Exhibit
3 2. It's Exhibit 12 for this deposition.

4 (Exhibit 12, color photographs; 00330,
5 marked for identification.)

6 Q. I represent to you that this is the date
7 that Dr. Cortes first placed an Osseo-Restore Device
8 on Boja Kragulj. I'm going to ask you if you see
9 any signs of root exposure in photograph 0854.

10 MR. FUMUSO: I'm going to object. The
11 doctor has never seen these pictures before
12 today. He was not involved in the care and
13 treatment of the patient in 2018 or 2019 and
14 the answer -- the questions could implicate
15 Dr. Cortes as a codefendant based upon the
16 Carvalho versus New Rochelle Hospital ruling
17 and as the law of the state of New York, I'm
18 going to object and direct the doctor not to
19 answer.

20 MR. SCHWARTZ: I join that objection.

21 Q. Doctor, do you see any signs of root
22 exposure -- strike that.

23 Do you see any signs of gingival
24 recession in the photograph 0854?

25 MR. FUMUSO: Same objection. Direct the

1 S. Galella

2 doctor not to answer.

3 Q. Do you see any signs in that same
4 photograph that would indicate root resorption?

5 MR. FUMUSO: Same objection. Direct the
6 doctor not to answer.

7 Q. Doctor, I'm going to show you a
8 photograph which is Exhibit 13.

9 (Exhibit 13, color photographs; 00449-52,
10 marked for identification.)

11 Q. Do you see that Exhibit 13, Doctor?

12 A. Yes.

13 Q. That's actually four pages of
14 photographs. Again, they're taken from part two of
15 Dr. Cortes' record which was Exhibit 2 in her
16 deposition. It stretches from page 449 to page 452.
17 And they're dated June 17th, 2019.

18 I'm going to ask you a few questions
19 about these. First of all, you see in image 1548
20 there's a metallic device or structure on the
21 maxillary teeth?

22 MR. FUMUSO: Well, once again, I'm going
23 to object to the doctor being questioned about
24 these photographs. They were not part of his
25 records. He never saw these photographs before

1 S. Galella

2 today. These are records from the photographs
3 from the records of Dr. Cortes. He was not
4 involved with the care and treatment of the
5 patient in 2018 nor 2019. And his only
6 involvement was consultation with the patient
7 in March of 2020. He made a recommendation for
8 a treatment plan which she decided not to
9 pursue at that time. I'm going to object to
10 any questions asked of the doctor having to do
11 with treatment rendered by Dr. Cortes,
12 certainly at this time in 2019 under the
13 Carvalho decision, and I'm going to direct the
14 witness not to answer.

15 MR. SCHWARTZ: I continue to join all
16 those objections. And frankly, are we going to
17 keep putting this on the record, Scott or do
18 you want to just --

19 MR. CHARNAS: Yeah.

20 MR. SCHWARTZ: I think you have enough on
21 the record to make your motion already.

22 MR. CHARNAS: Yeah. I'm going to put it
23 on the record because I want the judge to see
24 the questions that the witness was not allowed
25 to answer.

1 S. Galella

2 Q. Dr. Galella, is it fair to say that the
3 hardware in the maxillary teeth is part of your
4 ControlledArch system?

5 MR. CHARNAS: Are we waiting for
6 something?

7 MR. FUMUSO: I'm going to object to any
8 questions with respect to these photographs.
9 He's never seen them before today.

10 MR. CHARNAS: This is simply ridiculous.
11 This is a product liability case. This is part
12 of a ControlledArch system which is part of the
13 overall product and I'm asking him to identify
14 it and you won't let him do that.

15 MR. FUMUSO: Counsel, without waiving my
16 objections to previous questions, I will allow
17 the doctor to answer that over objection. Go
18 ahead, Doctor.

19 A. Those are brackets on the teeth. Is that
20 what you want to know?

21 Q. Well, yes. Is that part of your
22 ControlledArch system?

23 A. The ControlledArch does utilize brackets,
24 orthodontic brackets. But it's not ControlledArch
25 brackets. They're just brackets.

1 S. Galella

2 Q. What do you call those -- I'm sorry. I
3 didn't mean --

4 A. They look like self-ligating brackets.
5 They're just brackets. I'm not sure who makes them
6 or what the prescription is. But they're brackets.

7 Q. Does your ControlledArch system include
8 or can it include the use of brackets?

9 A. Yes.

10 Q. Is that the type of bracket in 1548 that
11 is part of the ControlledArch system or could be
12 part of the ControlledArch system?

13 MR. FUMUSO: You can answer that over
14 objection.

15 A. I'm not sure who makes the brackets.
16 But -- or the prescription. As long as they're
17 orthodontic brackets, they could be included in the
18 ControlledArch, yes.

19 Q. Explain to us, please, how is it that
20 brackets -- strike that.

21 Explain to us, please, what functions
22 brackets have within the ControlledArch system?

23 A. Brackets deliver tip, torque and in and
24 out to the various teeth.

25 Q. Is it fair to say that these brackets, as

1 S. Galella

2 you call them, are designed generally speaking to
3 bring the teeth back into proper position after use
4 of an Osseo-Restore Device?

5 A. I'm not quite sure what you're asking.

6 Q. Tell us what the function is then of
7 those brackets, if any, after the Osseo-Restore
8 Device is removed.

9 A. It's to align the teeth because
10 Osseo-Restore Appliance remodels the bone, the teeth
11 move within the bone but they stay at the same
12 misalignment they were when you began. If it's
13 applied properly. So generally the brackets will
14 serve to align the teeth and to create a harmonious
15 occlusion.

16 Q. Any flaring of the teeth would not,
17 generally speaking, be caused by the
18 Osseo-Restoration Device?

19 A. Osseo. You keep saying osteo.

20 Q. I'm sorry. Osseo-Restoration Device --

21 A. Thank you.

22 (Court reporter requested clarification.)

23 Q. Is it fair to say that flaring of the
24 teeth, generally speaking, would not occur as a
25 result of Osseo-Restoration Appliance use absent any

1 S. Galella

2 errors by the dentist?

3 A. If the appliance is applied properly and
4 monitored properly, then generally flaring will not
5 occur.

6 Q. If the Osseo-Restoration Appliance is
7 used properly, as according to your instructions and
8 guidelines, would root exposure tend to happen?

9 A. No.

10 Q. If the Osseo-Restore Device is used
11 properly, would gingival recession tend to occur as
12 a result of its use?

13 A. If gingival recession already exists and
14 the patient's oral hygiene was poor, it could
15 accentuate it. But under normal condition with good
16 oral hygiene and correct use of the appliance and
17 correct function the appliance, correct fit of the
18 appliance, no.

19 Q. Now I'm going to give you a hypothetical
20 and I'm going to tell you that the person who's
21 depicted in picture 1549, that is that person's
22 mouth, had used an Osseo-Restoration Device from
23 January 25th, 2018 up until at least the time this
24 photo was taken January 17th, 2019.

25 Do you see anything inconsistent with

1 S. Galella

2 this photo, inconsistent with the design goals of
3 the Osseo-Restoration Appliance?

4 MR. FUMUSO: I'm going to object on
5 Carvalho and direct him not to answer that
6 question.

7 MR. SCHWARTZ: Same objection. Wasn't
8 this asked and answered? It's the same
9 question.

10 MR. CHARNAS: These are different
11 photographs.

12 MR. SCHWARTZ: It's the same question
13 though. Same objection.

14 MR. LAIRD: We also join.

15 Q. Dr. Galella, have you ever attempted to
16 determine whether Boja's nasomaxillary complex moved
17 down, forward and transversely as a result of her
18 use of the Osseo-Restoration Appliances?

19 A. I'm sorry. Could you repeat that a
20 little slower.

21 Q. Have you ever made any attempt to
22 determine whether Boja had three-dimensional
23 development of her nasomaxillary complex as a result
24 of an Osseo-Restoration Device or devices being
25 placed there?

1 S. Galella

2 A. The only basis I would have would be the
3 2016 cone beam submitted and the 2020 cone beam that
4 I received. But did I make a comparison to see how
5 much, no.

6 (Simultaneous speakers.)

7 A. Did I try to see how much it had moved,
8 no.

9 Q. What was your purpose of comparing the
10 CBCTs from 2016 and the CBCTs from 2020?

11 A. Well, the purpose was to decide where the
12 teeth were in relation to the nasomaxillary bone and
13 the mandibular teeth to the mandible.

14 (Simultaneous speakers.)

15 Q. Go ahead.

16 A. I'm done.

17 Q. Did you attempt to utilize or ask
18 Dr. Bromage to utilize his overlay method to
19 determine whether Boja's maxilla had advanced?

20 A. At that point in time when I did the
21 report for her, there was no overlay method that was
22 usable.

23 Q. When you say the report --

24 A. It wasn't until late 2020 and early '21
25 that we finally got the overlay method.

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S. Galella

Did I go back and overlay it, no.

Q. When you say the report you did for her, you're talking about a February -- strike that.

What report are you talking about when you say a report you did for her?

A. The 2020 report when she came to my office and we took pictures and she supplied a 2020 cone beam and I did an interview and then I submitted a report to the diagnostic system.

Q. You're talking about the FBI report of 2020?

A. Yes.

Q. Did you attempt when you were comparing the 2016 and 2020 CBCTs to either use Dr. Bromage's old method or first method or ask him to do so to determine whether there had been any advancement of the maxilla in the sagittal plane or any dimension?

A. No. I use them as a comparison to see the position of the teeth and the integrity of the roots and the integrity of the bone. That was the purpose.

Q. Is it fair to say, as you sit here today, that you don't know whether Boja had any development in any of the three dimensions of her nasomaxillary

1 S. Galella

2 complex as a result of her use of an
3 Osseo-Restoration Device?

4 A. No. We did not do the overlays which is
5 the definitive method. We did not have it perfected
6 at the time of her report and I never subsequently
7 did it. I never asked to have it done.

8 Q. Now I'm going to show you the next
9 exhibit which is 14.

10 (Exhibit 14, x-ray; 00481, marked for
11 identification.)

12 Q. Have you ever seen this x-ray before,
13 this cephalometric x-ray?

14 A. I don't recall seeing it.

15 Q. For the record, it's Bates-stamp page 481
16 from Exhibit 2 from Dr. Cortes' deposition.

17 Do you see anything -- strike that.

18 I want to give you a hypothetical and
19 tell you that the person depicted in this x-ray had
20 used or had placed in her an Osseo-Restoration
21 Device between January 25th, 2018, through November
22 of 2018 and that a second such device was placed
23 from November of 2018 to March of 2019.

24 Do you see anything in this x-ray which
25 is inconsistent with the goals of the -- the design

1 S. Galella

2 goals of the Osseo-Restoration Device?

3 MR. FUMUSO: I'm going to object for the
4 reasons previously stated. This is a Carvalho
5 objection. It's a hypothetical question asked
6 to a witness who was not involved in the care
7 and treatment of this patient at that time.
8 He's never seen this before today. But most
9 importantly, his answer could implicate a
10 codefendant. And I will object and direct him
11 not to answer.

12 MR. SCHWARTZ: I join the objection. I'm
13 noting that we've done this several times now.
14 I think you can probably do it in a way,
15 Mr. Charnas, to save some of these questions.
16 We're now looking at an x-ray. You've asked it
17 with braces on, without braces on. If you have
18 more radiographs to show that are taken by my
19 client and for the purpose of commenting them
20 by a codefendant, I can assure you that it's
21 going to be the same objection. So if you have
22 three or four or five more of those, let's just
23 have them in one question.

24 Q. Is tipping the molar backwards the design
25 goal of the Osseo-Restoration Device?

1 S. Galella

2 MR. FUMUSO: You can answer that.

3 A. The molars, all molars? Please be
4 specific on what you're talking about.

5 Q. Well, do you see molars tipped backwards
6 on this x-ray?

7 MR. FUMUSO: Here we go again. I want to
8 make a statement here.

9 MR. CHARNAS: Let me withdraw that
10 question. Okay.

11 Q. Is it a design goal of the
12 Osseo-Restoration Appliance to tip molars backwards
13 in the patient?

14 A. All right. So what we found as during
15 the use of this appliance, the second molars tend to
16 rotate distally or posteriorly, what you call
17 tipping back, with the use of the appliance. And
18 it's probably a result of the force applied to the
19 front is creating a little distalization of the back
20 first molar and the second molar rotates back
21 somewhat.

22 And also the remodeling of the maxilla in
23 three dimensions, which includes the transverse, it
24 allows the freedom of that second molar which is not
25 attached to anything to cause some rotation which is

1 S. Galella

2 corrected when the final braces are applied.

3 Q. Dr. Galella, is it your understanding
4 that Dr. Cortes did not follow your treatment plan?

5 MR. FUMUSO: Do you know that one way or
6 the other?

7 MR. SCHWARTZ: Objection.

8 MR. FUMUSO: What was that?

9 THE WITNESS: He said objection.

10 MR. CHARNAS: I'm sorry. Are you having
11 a conversation with him?

12 THE WITNESS: No. Somebody objected and
13 I --

14 (Simultaneous speakers.)

15 THE WITNESS: -- because they were
16 talking.

17 Q. Is it your understanding that Dr. Cortes
18 did not follow your treatment plan?

19 MR. FUMUSO: You can answer over
20 objection, if you know.

21 MR. SCHWARTZ: Objection.

22 A. So -- not in this picture. But in a
23 picture when I saw --

24 MR. FUMUSO: Objection to the question.

25 MR. CHARNAS: Are you telling him not to

1 S. Galella

2 answer that one, too?

3 MR. FUMUSO: That's a Carvalho objection.

4 MR. SCHWARTZ: It's a Carvalho objection
5 clearly.

6 MR. FUMUSO: Yeah.

7 Q. Doctor, I believe you said earlier that
8 Dr. Cortes did not follow this treatment plan.

9 (Simultaneous speakers.)

10 MR. SCHWARTZ: Mr. Charnas, I'm making a
11 motion to strike that testimony. I'm going to
12 make a comment on the record that you're
13 persisting with questions to this witness
14 directed at the negligence, alleged negligence,
15 of my client. And I'm really getting tired of
16 it because you're doing it deliberately.

17 You have it in front of you now and it's
18 really getting tiresome that you're continuing
19 to use this witness as an expert against my
20 client.

21 MR. CHARNAS: I'm sorry that you're
22 tired.

23 MR. SCHWARTZ: No. I said tiresome. I'm
24 not tired.

25 MR. CHARNAS: I'm sorry you're tiresome.

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S. Galella

MR. SCHWARTZ: No, you're tiresome.

MR. CHARNAS: These questions pertain to the witness' dental malpractice which is a claim of this case. And it also may pertain to the product liability claim as well. We have a difference of opinion on that which the judge will resolve.

MR. SCHWARTZ: Evidently.

MR. CHARNAS: I'd like to take a 10-minute break. I'm going to try to shorten this a little bit based on the objections that have been made. So if no one has any objection, even if somebody does, let's break for ten minutes.

MR. FUMUSO: Okay.

(A recess was taken from 2:32 p.m. to 2:46 p.m.)

Q. Dr. Galella, is it true that one of the design goals of a Generation 8 Osseo-Restoration Device was to reduce the tendency of the device to flare anterior maxillary teeth?

A. Occasionally a doctor would not monitor -- fit the appliance properly. So the Generation 8 put pads on the inside lingual of the

1 S. Galella

2 front teeth, custom pads, in an attempt to let it
3 bond more securely and reduce the incidence of
4 flaring that may occur if it's not monitored. The
5 old design was a bar and the bonding sometimes would
6 come off the bar. If the doctor didn't check it
7 every month, it could cause problems.

8 Q. How did Generation 8 fix that?

9 A. I just explained that.

10 Q. Okay. That's your answer. Thank you.

11 Let me ask you, change directions here.

12 Who was the president of OrthoMatrix in
13 2017 and 2018?

14 A. Ben Shappley.

15 Q. Was there a vice-president or other
16 officers?

17 A. I'm not sure of the officer structure
18 other than Ben Shappley was the president.

19 Q. Sir, you're here as a 30(b)(6) witness
20 for OrthoMatrix and FBI and the first area of
21 inquiry sets forth that the designee is to testify
22 about the identity of officers between June 1st,
23 2013, and May 1st, 2020. I understand you don't
24 know.

25 Did you do anything to obtain that

1 S. Galella

2 information prior to this deposition?

3 MR. FUMUSO: I'll object to the purpose
4 of that question. So please rephrase it
5 without the legalese to it.

6 Q. Doctor, I will represent to you, and I'm
7 sure your counsel will agree, that a 30(b)(6) is
8 required to appear with the knowledge of the
9 corporation in regard to the areas of inquiry set
10 forth in the notice.

11 MR. FUMUSO: I'm -- you're making a legal
12 statement now and I will object to that.

13 MR. MURPHY: If I could just --
14 Mr. Charnas, if I could just say something.
15 This is Mr. Murphy speaking. My understanding
16 was that Mr. Galella would know these
17 categories of information -- Dr. Galella,
18 excuse me. If for some reason there are
19 categories he does not know and we have to
20 produce Ben Shappley to testify with respect to
21 certain categories of information, I will not
22 have a problem doing so. We'll make him
23 available to you.

24 MR. CHARNAS: Okay. I appreciate that
25 comment.

1 S. Galella

2 MR. FUMUSO: So, please, let's have the
3 question. And he will answer it as best he
4 can. We got the 30(b)(6). I reviewed it with
5 Dr. Galella. So what's your question?

6 MR. CHARNAS: Want to read the question
7 back?

8 MR. FUMUSO: Sure. Let's read the
9 question back.

10 (Record read.)

11 MR. FUMUSO: Doctor, do you know,
12 generally speaking, who the officers were in
13 that period of time?

14 MR. CHARNAS: Who's conducting this
15 deposition? Not you.

16 MR. FUMUSO: Counselor, you wanted an
17 answer to your question.

18 MR. CHARNAS: You have a chance to ask
19 questions when I'm finished. You have a chance
20 to ask questions of your own witness during
21 this deposition.

22 MR. FUMUSO: Counselor, I'm trying to get
23 to the bottom of this.

24 MR. CHARNAS: I --

25 MR. FUMUSO: Can I finish my statement?

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S. Galella

MR. CHARNAS: Yes. Go ahead.

MR. FUMUSO: You're making a big statement on the record, you're supposed to be a 30(b)(6), you don't have the information, why don't you have the information. Okay. I mean, it's a very simple question and I asked the doctor to answer the question. Okay.

What is your problem with me asking him now? I'm not tipping off anything. I'm trying to expedite the examination.

MR. CHARNAS: It's not appropriate for you to ask questions of your own witness when I'm questioning the witness. Now, if the doctor wants to answer the question --

MR. FUMUSO: Did you ever do that when your client was questioned for two days? Did you ever talk to your client when she was questioned? I believe that you did.

MR. CHARNAS: Did I ever ask a question on the record? Absolutely not.

MR. FUMUSO: I'll look through the 400 pages of your client's deposition and see if at any time you said anything to your client during the course of the deposition.

1 S. Galella

2 MR. CHARNAS: You do that and bill the
3 insurer for it.

4 MR. FUMUSO: Let's go back to the
5 original question. Okay.

6 (Record read.)

7 Q. Dr. Galella, did you make any effort to
8 obtain information in preparation for your 30(b)(6)
9 deposition today in regard to the identity of
10 officers of OrthoMatrix?

11 A. Yes. But my memory is not so good on
12 that. I'm either vice-president or secretary. I
13 don't know. But I'm one of the officers and a board
14 member. I know I'm a board member.

15 Q. I'm sorry. Did you say you were one of
16 the officers? I didn't quite hear you.

17 A. I'm either vice-president or secretary.
18 I think secretary is probably the appropriate
19 officer. And I know I'm a board member because I'm
20 a principal.

21 Q. Is it fair to say that you were an
22 officer of OrthoMatrix in 2017 and 2018?

23 A. Yes.

24 Q. Does OrthoMatrix have any divisions?

25 A. In doing business as?

1 S. Galella

2 Q. It has a division called Facial Beauty
3 Institute, correct?

4 A. That's doing business as Facial Beauty
5 Institute.

6 Q. It has a division or it does business
7 as --

8 A. OrthoLogic Diagnostics --
9 (Court reporter requested clarification.)

10 Q. It's not a good idea to finish my
11 sentences, Doctor.

12 OrthoMatrix also has a division which is
13 known as OrthoLogic, correct?

14 MR. FUMUSO: Objection.

15 A. Yes.

16 Q. Does OrthoMatrix have any divisions other
17 than those two; FBI, that is Facial Beauty
18 Institute, and OrthoLogic? And let me focus my
19 question on 2017 and 2018.

20 A. I think that pretty much covers it.

21 Q. What is the business generally speaking
22 of OrthoMatrix?

23 A. OrthoMatrix is -- runs -- is designed for
24 the diagnostic system and education.

25 Q. Education of dentists?

1 S. Galella

2 A. Yes.

3 Q. Does that include education of dentists
4 in regard to Osseo-Restoration Devices?

5 A. Yes.

6 Q. For how long has OrthoMatrix been in that
7 business of educating dentists in regard to
8 Osseo-Restoration Devices?

9 A. Since 2013.

10 Q. Can you tell us the number of employees
11 that OrthoMatrix had in 2017 and 2018,
12 approximately?

13 A. Two.

14 Q. Who would they be?

15 A. Ben Shappley and Stacey Ambrose.

16 Q. What is Stacey Ambrose's job title, do
17 you know?

18 A. She manages the office.

19 Q. Can you describe your duties for
20 OrthoMatrix in 2017 and 2018?

21 A. I'm sorry. I -- you tapered off and I
22 couldn't hear the whole question.

23 Q. My apologies. It's getting a little
24 late. We're getting close to the end.

25 Dr. Galella, in 2017 and 2018 were your

1 S. Galella

2 duties for OrthoMatrix essentially the same?

3 A. Yes.

4 Q. And was that also true in 2019?

5 A. Yes.

6 Q. Can you tell us generally speaking what
7 your duties were from 2017 to 2019 for OrthoMatrix?

8 A. OrthoMatrix I would -- I worked with
9 OrthoLogic to -- Diagnostics and I would also
10 educate, teach.

11 Q. Anything else?

12 A. That's pretty much it.

13 Q. When you educated or taught, as you told
14 us, was that for Facial Beauty Institute, was it for
15 OrthoLogic, was it for OrthoMatrix generally or
16 something else?

17 A. Well, the Facial Beauty Institute was
18 what you call a division of OrthoMatrix. It would
19 be under that auspices.

20 Q. So can you explain how these -- strike
21 that.

22 Is it fair to say that you would give --
23 at least from 2013 through the present, you would
24 give seminars or courses to dentists who wanted to
25 learn, among other things, about Osseo-Restoration,

1 S. Galella

2 correct?

3 A. Yes. ControlledArch restoration, TMJ.

4 Q. These courses, were they put together by
5 the FBI or OrthoMatrix?

6 A. I'm not quite sure what you're asking.
7 Put together by, if that means sponsored by.

8 Q. Let's start with that. Were these
9 courses that you're talking about, were they
10 sponsored by OrthoMatrix or some division of
11 OrthoMatrix?

12 A. Yes, it was -- yes.

13 Q. And generally when the courses were
14 advertised or marketed, how did OrthoMatrix or any
15 of its divisions market or advertise those courses,
16 in general?

17 A. Word of mouth.

18 Q. How about by internet?

19 A. Not until early 2021. We did -- in
20 2000 --

21 MR. FUMUSO: You answered the question.

22 THE WITNESS: Well, no, it wasn't
23 correct. It wasn't correct.

24 A. In July 2019 we had a website. Before
25 that it was word of mouth and the website would

1 S. Galella

2 advertise the courses after that.

3 Q. Did you put together the syllabus,
4 generally speaking, for these courses?

5 A. It depends on who was teaching the
6 course.

7 Q. If it was a course on Osseo-Restoration
8 Devices, would you generally put together the
9 syllabus?

10 A. Yes.

11 Q. Again, I'm talking between 2013 and 2019.

12 Would the materials -- strike that.

13 Would there be materials handed out
14 either in a paper form or an electronic form at
15 these educational seminars?

16 A. Generally a flash drive.

17 Q. And was that true in 2013?

18 A. It could have been DVDs. I forgot when
19 we converted from DVDs to flash drives.

20 Q. Was there any material circulated at
21 those meetings that contained the logo or name of
22 FBI or OrthoMatrix?

23 A. It would be on the flash drive.

24 Q. What was the financial arrangement in the
25 sense that, did you get a cut of the fees paid by

1 S. Galella

2 the dentists who attended these courses?

3 A. Well, when the dentists attended courses,
4 they would sign up, they would pay the OrthoMatrix,
5 Facial Beauty Institute, and then my compensation
6 would be whatever the doctor paid less 24 percent
7 would be kept by OrthoMatrix. And that was to cover
8 CE credits and other expenses.

9 Q. So you got 66 percent of the gate,
10 essentially; is that correct?

11 A. Well, 24 percent minus 100, whatever that
12 is.

13 Q. Right.

14 MR. MURPHY: 76.

15 Q. 76 of the gate. That's correct, right?

16 A. Yes.

17 Q. The dentists who attended these courses,
18 did they pay in cash? Did they pay in checks? How
19 did they pay for them, generally speaking?

20 A. Generally credit cards. Occasionally
21 they paid checks or cash.

22 Q. Is it fair to say that OrthoMatrix or one
23 of its divisions took in the fees from the dentists?

24 A. Yes. As a rule, yes.

25 Q. And then you would get a 1099 from

1 S. Galella

2 OrthoMatrix?

3 A. Yes.

4 Q. These courses or seminars, can you
5 estimate for us between June of 2013 and August of
6 2019, approximately, how many of these courses that
7 you gave dealt with Osseo-Restoration Devices?

8 A. I'd be guessing. But it's probably 75
9 percent.

10 Q. Is 75 percent your best estimate?

11 A. Yes.

12 Q. Did these courses take place in a
13 particular place or multiple places?

14 A. Generally in my office and Dr. Deal's
15 office. The courses that did would be in my office.
16 And then occasionally we'd have a TMJ course that
17 was at a hotel.

18 Q. Hotel in the Memphis area?

19 A. In the Memphis area, yes. Or we had some
20 in Chicago, some in Orange County. Various places.

21 Q. Did you ever teach any of these courses
22 in New York State?

23 A. No.

24 Q. Is it fair to say that some New York
25 dentists took your courses between June 2013 and

1 S. Galella

2 August 2019?

3 MR. MURPHY: Objection. No foundation.

4 MR. SCHWARTZ: Objection.

5 Q. You can answer.

6 MR. FUMUSO: Object to the form of the
7 question.

8 Q. You can answer.

9 A. Can you rephrase it?

10 Q. Let's focus on the courses that -- the 75
11 percent of the courses that dealt with
12 Osseo-Restoration Appliances between 2013 and August
13 of 2019.

14 Did any New York dentists attend those
15 courses?

16 A. Dr. Cortes.

17 Q. Anyone else besides Dr. Cortes?

18 A. That's all I remember.

19 Q. Do you remember Leonard Kundel attended
20 those courses?

21 A. He's not New York. He's from
22 Connecticut.

23 Q. He has an office in New York and
24 Connecticut, doesn't he, Doctor?

25 MR. FUMUSO: Objection.

1 S. Galella

2 MR. MURPHY: Objection.

3 A. He's from Connecticut. At the time he
4 took the course he had no New York office.

5 Q. How about Dr. Daniel Chow? He's a New
6 York dentist that you know, correct?

7 A. I didn't really instruct Dr. Chow. He
8 had already been involved with this appliance and
9 the ControlledArch many years ago.

10 Q. As far as you know, Dr. Chow never
11 attended any of your courses in regard to
12 Osseo-Restoration Appliances; is that correct?

13 A. Yes. He attended other courses.

14 Q. Can you think of any other New York
15 dentists who attended your courses on
16 Osseo-Restoration other than Dr. Cortes?

17 A. No.

18 Q. During these courses between 2013 and
19 August of 2019, did you teach these dentists, among
20 other things, that the Osseo-Restoration Appliance
21 was a safe and efficacious appliance?

22 A. If applied properly and monitored
23 correctly, yes.

24 Q. Who is Dr. Boulos Bechara?

25 A. He is the radiologist who works for

1 S. Galella

2 BeamReaders and he read several reports --

3 MR. MURPHY: Can you say that name
4 again? I'm sorry. I didn't mean to cut him
5 off.

6 MR. CHARNAS: I think it's B-O-U-L-O-S
7 B-O-U-C-H-A-R-A [sic].

8 Q. Does that sound right, Dr. Galella?

9 A. Sounds right.

10 MR. CHARNAS: I'm sorry. Could I have
11 the question read back.

12 (Record read.)

13 Q. Dr. Bechara is a radiologist --

14 A. A maxillofacial radiologist that works
15 for BeamReaders who read the OrthoLogic --
16 OrthoAssist/OrthoLogic reports.

17 Q. Those reports, you're referring to
18 specifically the ones for Dr. Cortes for Boja
19 Kragulj?

20 A. Yes.

21 Q. That was in 2018 and 2020, right?

22 A. No. The one in 2020 that I submitted was
23 read by Heidi Kohltfarber of Dental Diagnostic
24 Services.

25 Q. I'm sorry. Her name is Kohltfarber?

1 S. Galella

2 A. Yes.

3 Q. Is Dr. Kohltfarber licensed in the state
4 of New York as a radiologist?

5 A. I don't know. She's a radiologist that
6 has a Ph.D. She's on staff at -- was on staff at
7 the University of North Carolina and she lives in
8 California. I don't know if she's licensed in
9 New York or not.

10 Q. Is she a medical doctor?

11 A. She's a dentist, a Ph.D., maxillofacial
12 radiologist. That's a specialty term that's
13 official.

14 Q. She's not an M.D., correct?

15 A. Not that I know of.

16 Q. Dr. Bechara, is he an M.D.?

17 A. He's a -- no. I don't quite know if he's
18 a D.D.S. or D.M.D. But he's not an M.D.

19 Q. So he's not a radiologist, correct?

20 A. He is a radiologist. The dental
21 specialty is maxillofacial radiology. It's a
22 specialty. And he is a specialist, certified
23 specialist. And so is Dr. Kohltfarber.

24 Q. Do you have to be licensed in that
25 specialty in Tennessee?

1 S. Galella

2 A. You have to be licensed wherever you are.
3 But you can consult anywhere you want, I assume,
4 because it's the consulting services.

5 Q. As far as you know, is Dr. Bechara
6 licensed in New York?

7 A. No. I don't have any idea. I have no
8 idea.

9 Q. Now, you had referred earlier to an
10 arrangement you had in regard to the educational
11 seminars with OrthoMatrix. Was that arrangement in
12 writing?

13 MR. FUMUSO: I'm sorry. Was that
14 arrangement in what?

15 MR. CHARNAS: In writing.

16 MR. FUMUSO: In writing. Okay.

17 A. I don't believe I have a contract that
18 says that. I have a nondisclosure agreement that
19 says I have to stay within certain boundaries. But
20 money-wise, it was just a handshake deal.

21 Q. Have you ever had a contract with Johns
22 Dental?

23 A. Not that I recall. Most of our contracts
24 are just agreements over the phone. I call them
25 handshake deals. But we just -- Jerry

1 S. Galella

2 Neuenschwander and I just agree on whatever we're
3 doing.

4 Q. I didn't mean to limit my question in
5 writing. I'm sorry.

6 At some point you entered into an
7 agreement with the principal of Johns Dental; is
8 that right?

9 A. Yes.

10 Q. And do you have more than one agreement
11 or is it essentially one agreement with him?

12 A. At this point I think we just have the
13 one agreement.

14 Q. At some point did you have more than one
15 agreement with him?

16 A. Maybe years and years ago, 20 years ago
17 when I was teaching for Dr. Witzig.

18 Q. This agreement with Johns Dental, does it
19 date back to at least 2015? This current one you
20 were talking about.

21 A. I'm thinking. Let me think.

22 Q. Go ahead.

23 A. Okay. Thank you.

24 Q. Take your time.

25 A. It could have. I'm not sure of the

1 S. Galella

2 dates. It could be 2014, '15 or '16. I don't
3 remember when we did it.

4 Q. But the agreement was certainly effective
5 2017 and 2018, correct?

6 A. Yes.

7 Q. Tell us, generally speaking, what is this
8 agreement with Johns Dental?

9 A. Well, I would be -- I would check the
10 appliances, the Osseo-Restoration Appliances and the
11 tongue habit appliances and the other appliances
12 I've developed, with a series of pictures. They'd
13 have a checklist after they made it and I had to
14 look at that. And then I had to approve the
15 structure and the appearance of the appliance and
16 the construction and on behalf of that they pay a
17 royalty whenever they had a chance -- there wasn't
18 any deadline -- of \$65. Now it's reduced to \$50.

19 Q. So in this agreement you would get a
20 royalty of \$65 which became \$50 on the sale of every
21 Osseo-Restoration Device; is that what it was?

22 A. Well, not on the sale. Just on the
23 construction. When they made it.

24 Q. So --

25 A. I wouldn't mind trading their sales.

1 S. Galella

2 Q. In 2017 and 2018 when Johns Dental made
3 an Osseo-Restoration Device --

4 A. Osseo. Osseo.

5 Q. I thought I did say osseo.

6 A. No. You said osteo.

7 Q. I'm sorry.

8 A. That's all right.

9 Q. I've got another case involving osteo so
10 that's why. Let me start again.

11 Is it fair to say in 2017 and 2018 for
12 every Osseo-Restoration Device that Johns Dental
13 manufactured you would get a royalty, correct?

14 A. Well, that's what we called it. A
15 royalty. But, it's a fee. Because it was patent
16 pending.

17 Q. The royalty or fee was \$65 at one point.
18 When did it change to \$50?

19 A. When he made the donation of \$100,000 to
20 New York University. So I reduced my royalty to
21 help him recover his costs there.

22 Q. When was that reduction to \$50?

23 A. It was probably two years ago. Maybe a
24 year ago. I don't remember.

25 Q. It was after 2018, though, correct?

1 S. Galella

2 A. Yes.

3 Q. Did that royalty include payment for the
4 services that you've described in terms of looking
5 at the -- each Osseo-Restoration Device --

6 A. Yes.

7 Q. -- as you've described it?

8 A. Yes.

9 Q. Can you tell us approximately how much
10 you made in 2017 and 2018 from this royalty or fee
11 agreement?

12 MR. FUMUSO: Objection. Don't answer
13 that. Irrelevant.

14 MR. CHARNAS: You're instructing the
15 witness not to answer a question that doesn't
16 involve privilege; is that correct?

17 MR. FUMUSO: It's patently improper. You
18 show me the relevance as to what he made by his
19 royalties from the -- from Johns Dental and I'm
20 willing to listen. What's the relevance?

21 MR. LAIRD: I also join in that
22 objection.

23 MR. FUMUSO: Counsel, what's the
24 relevance? I'm willing to listen.

25 MR. CHARNAS: It's our position that this

1 S. Galella

2 device does not work and cannot work and that
3 Dr. Galella, with all due respect, sir,
4 teaching efficacy of the Osseo-Restore
5 Appliance teaches dentists that the device is
6 safe and efficacious and that he derives money
7 from that process and that is a motivating
8 factor for him to continue.

9 So the question is certainly relevant and
10 does not serve an instruction not to answer.
11 But if you instruct him not to answer, that's
12 your business. That will be part of our motion
13 to compel as well.

14 MR. FUMUSO: Fine. I think it's
15 irrelevant how much money he makes. You have
16 established that he gets a royalty and he told
17 you what the royalty is. How much money he got
18 in royalties is not relevant to any aspect of
19 this lawsuit and I think it's an invasion of
20 the doctor's privacy and, based upon that, I'm
21 going to object and direct him not to answer.

22 MR. LAIRD: I also join.

23 Q. Dr. Galella, did you ever have an
24 agreement, whether written or unwritten, with Las
25 Vegas Institute?

1 S. Galella

2 A. Not me personally.

3 Q. Did OrthoMatrix or any of its divisions
4 have an agreement, either written or unwritten, with
5 Las Vegas Institute?

6 A. Yes, for a short time.

7 Q. When was that time, approximately?

8 A. 2015, maybe. 2014, '15. I'm not sure.

9 Q. Was your agreement with Las Vegas
10 Institute ended before 2018 or 2017?

11 A. Yes.

12 Q. Just briefly, what was that agreement?

13 A. It was the ability to have representative
14 at the courses where they were teaching
15 ControlledArch and the Osseo-Restoration Appliances.
16 It was like having a booth, a table.

17 Q. So is it fair to say at some period or
18 point in time Las Vegas Institute or LVI was allowed
19 to teach about the Osseo-Restoration Device by you;
20 is that --

21 A. No. No. No. That's not correct.

22 Q. Sorry. I didn't get it.

23 A. All right. So the agreement was that we
24 paid them so we could have a booth, a table there,
25 to represent the Facial Beauty Institute. And then

1 S. Galella

2 about a year with that. And then we -- it was
3 transferred to Central Orthodontics, a supply
4 company, and Johns Dental Lab. The ability to teach
5 my material was granted to several people with a
6 different agreement, not with LVI. It was an
7 agreement with them that they could teach my
8 material but they worked for LVI, I guess. But I
9 didn't have an agreement with LVI.

10 Q. Was one of those people Dr. David Buck?

11 A. Yes.

12 Q. Who were the other people?

13 A. Dr. Tim Gross and Dr. Anne-Maree Cole.

14 Q. Dr. Anne-Maree Cole, she's an Australian
15 dentist, right?

16 A. That's correct.

17 Q. Her license has been suspended; is that
18 correct?

19 MR. MURPHY: Objection.

20 A. I have no idea.

21 Q. So is it fair to say that between at
22 least 2016 and 2019 Dr. David Buck taught dentists
23 through LVI about the Osseo-Restoration Appliance?

24 A. I'm not quite sure of the dates. But
25 maybe 2017 on. But, yes.

1 S. Galella

2 Q. And Dr. Buck joined Facial Beauty
3 Institute, didn't he?

4 A. He's a member of the Facial Beauty
5 Institute, yes.

6 Q. He's a master instruction at the Facial
7 Beauty Institute, isn't he?

8 A. No.

9 Q. Doctor, just bear with me.

10 A. Okay.

11 Q. We'll get back to that. Sorry.

12 In 2017, 2018 did FBI or OrthoMatrix
13 share in the royalty or fee payments from Johns
14 Dental?

15 A. I'm sorry. I don't understand the
16 question.

17 Q. You told me that you had a handshake
18 agreement with Johns Dental in which they would pay
19 you 65 and later \$50 per Osseo-Restoration Appliance
20 it manufactured, correct?

21 A. Yes.

22 Q. I'm asking whether FBI or OrthoMatrix or
23 any of its divisions shared in that fee in any way?

24 A. No. OrthoMatrix got the whole fee. The
25 agreement was with OrthoMatrix. Not with me. With

1 S. Galella

2 OrthoMatrix.

3 Q. So OrthoMatrix and that has been
4 corrected -- sorry.

5 OrthoMatrix got \$65 and then \$50 per
6 appliance. What did you get personally?

7 A. Nothing.

8 Q. Did you take a share of profits from
9 OrthoMatrix every year in 2017 and 2018 and 2019?

10 A. No.

11 Q. Do you get a salary from OrthoMatrix or
12 did you in 2017 and 2018?

13 A. No.

14 Q. Do you get any financial compensation
15 from OrthoMatrix at all other than the fees you told
16 us about from the educational seminars?

17 A. I get a board member -- whatever you call
18 it -- stipend per year. I think it's \$10,000.

19 Q. Did you ever sell to OrthoMatrix your
20 rights to the Osseo-Restoration Appliance?

21 A. You mean the patent pending? It's not a
22 patent yet, so no.

23 Q. Did you sell any rights, not just the
24 patent, to the Osseo-Restoration Appliance that you
25 developed to OrthoMatrix?

1 S. Galella

2 A. Did I sell it to them? No.

3 Q. Did you agree -- strike that.

4 Does OrthoMatrix have any rights to the
5 Osseo-Restoration Appliance other than the \$65 then
6 \$50?

7 A. I'm not quite sure what you're asking.
8 Can you be a little more specific?

9 Q. Why don't you explain to us the interest
10 that OrthoMatrix has in the Osseo-Restoration
11 Appliances?

12 MR. FUMUSO: Object to the form of the
13 question. Ambiguous, "interest." Please
14 rephrase.

15 Q. Financial interest.

16 A. They get paid from John's Lab when they
17 pay. That's pretty much it. Do they own the
18 appliance? They own -- I think the patent was
19 issued in -- it's not a patent yet. But patent
20 pending was in my name and OrthoMatrix.

21 Q. Did you assign -- I'm sorry.

22 A. There's not a patent issued yet.

23 Q. Did you assign the rights to
24 Osseo-Restoration Devices to anyone?

25 A. You like putting that "T" in there, don't

1 S. Galella

2 you?

3 Q. Did I do it again? Did you assign your
4 rights to the Osseo-Restoration Device to anyone
5 ever?

6 A. No. Not that I know of.

7 Q. Just so I'm clear, when you do that work
8 for Johns Dental you describe in terms of looking at
9 the manufactured Osseo-Restoration Devices, you
10 personally get \$0 for that, correct?

11 MR. MURPHY: Objection.

12 Q. Go ahead and answer.

13 A. Personally, no. Inside Dentistry gets --
14 I think it's \$25.

15 Q. Do you get the money from Inside
16 Dentistry?

17 A. No. No. It's -- no.

18 Q. Just so it's clear, when an
19 Osseo-Restoration Device is manufactured by Johns
20 Dental, OrthoMatrix gets \$65 at one point then \$50.
21 And Inside Dentistry, Inc. -- I think you said it
22 was called?

23 A. Yes.

24 Q. -- gets how much?

25 A. \$25.

1 S. Galella

2 Q. Is that per device?

3 A. Per the ones that I've checked, yes.

4 Q. Do you wholly own Inside Dentistry, Inc.?

5 A. Yes. It's a C corporation.

6 Q. Is it fair to say that Inside Dentistry,
7 Inc. is not a nonprofit organization?

8 A. It is a for profit.

9 Q. Now, these courses that you've told us
10 about, the ones that involve the Osseo-Restoration
11 Devices, were those courses marketed to
12 orthodontists?

13 A. No.

14 Q. Is it fair to say they were generally
15 marketed to general dentists, correct?

16 A. Yes.

17 Q. Is there a particular reason why those
18 courses, that you know of, why those courses were
19 not marketed to orthodontists?

20 A. Because orthodontists generally don't
21 like taking courses from general dentists. So why
22 waste the time and energy.

23 Q. Do you know why orthodontists don't like
24 taking courses from general dentists?

25 MR. FUMUSO: Objection to that.

1 S. Galella

2 MR. MURPHY: Objection.

3 MR. LAIRD: Objection as well.

4 MR. FUMUSO: It calls for the operation
5 of someone else's mind. I'll object to that.

6 Q. Have you been told by any orthodontists
7 why they don't want to take courses from general
8 dentists?

9 A. Because they're specialists.

10 Q. Specialists in the movement of teeth?

11 A. So they tell me. Because they're
12 specialists and we're not.

13 Q. Did you ever operate Facial Beauty
14 Institute on your own without OrthoMatrix?

15 A. It was under Inside Dentistry for a short
16 time.

17 Q. When was that?

18 A. 2010 to 2013.

19 Q. Why did you bring it in to OrthoMatrix?

20 A. Because it was more suitable for
21 OrthoMatrix to manage it. Inside Dentistry is just
22 a corporation to separate my private practice from
23 my teaching income.

24 Q. I want to show you another exhibit.
25 Actually, back to Exhibit 1.

1 S. Galella

2 Can you see that, Doctor, Exhibit 1?

3 A. Yes.

4 Q. You see there's some verbiage there under
5 number 2? I represent to you that that was taken
6 from the website of OrthoMatrix. I want to ask you
7 a few questions about that.

8 MR. FUMUSO: Can I ask when this was
9 taken from, what date?

10 MR. CHARNAS: It was taken recently.
11 Within the last 60 days.

12 MR. FUMUSO: So after the lawsuit was
13 commenced, right?

14 MR. CHARNAS: That's correct.

15 MR. FUMUSO: Okay.

16 MR. CHARNAS: I'm happy to answer any
17 other questions for you.

18 MR. FUMUSO: I'm sorry. What was that
19 last comment?

20 MR. CHARNAS: I'm happy to answer any
21 questions for you.

22 Q. Dr. Galella, have you --

23 MR. FUMUSO: It's not answering questions
24 for me. It's so the record is clear as to when
25 this was taken from the website.

1 S. Galella

2 MR. CHARNAS: I understand.

3 MR. FUMUSO: And you understand the
4 importance of that, right?

5 MR. CHARNAS: I understand.

6 MR. FUMUSO: That's right. I'm glad you
7 understand the importance.

8 MR. CHARNAS: I understand why you made
9 your comment.

10 MR. FUMUSO: So let's continue.

11 Q. Dr. Galella, have you ever seen this
12 verbiage before? I'll scroll down for you. I don't
13 want to go too fast for you. So you tell me the
14 appropriate pace.

15 A. Yeah, that's -- keep going. Okay.

16 Q. Is it fair to say that FBI is an entity
17 that creates or produces complex diagnostic
18 treatment plans based on individual patient needs?

19 A. Yes, that's the OrthoLogic.

20 Q. That's a division of OrthoMatrix, right?

21 A. It's under -- it's labeled as the Facial
22 Beauty Institute, yes.

23 Q. Was that true in 2017 and 2018?

24 A. Yeah.

25 Q. Can you explain generally speaking how

1 S. Galella

2 that works in 2017 and 2018?

3 MR. MURPHY: Objection. Vague.

4 (Simultaneous speakers.)

5 MR. FUMUSO: If you can, answer it.

6 A. I just don't understand the question.

7 How what works?

8 Q. The creating or producing complex
9 diagnostic treatment plans, is that the same process
10 that you described for us earlier in regard to the
11 treatment plan that you produced for Dr. Cortes?

12 A. Yes. At OrthoLogic, yes.

13 Q. And then there's a statement about a
14 unique radiographic and tracing process. It says
15 that: Focuses on a highly technical process of
16 unique radiographic and anatomy tracing process.
17 I'll stop there.

18 What is this unique radiographic and
19 anatomy tracing process?

20 A. It's done by Anatomage, A-N-A-T-A-M-A-G-E
21 [sic]. They're developers of the 3-D software that
22 is universally used. And the tracing system is ABO,
23 American Board of Orthodontics plus which the plus
24 indicates the mammalian growth boundaries set forth
25 by the paleontologists and archeologists. That's

1 S. Galella

2 the growth boundaries. And they're all combined in
3 the tracing and then they get eight screenshots and
4 various interpretations of the numbers, et cetera,
5 et cetera. What I've already described.

6 Q. So it says here, I should read the
7 sentence in entirety. It says: The OrthoLogic
8 program is a provider service that offers
9 individualized through -- I think they might have
10 meant "thorough" -- diagnostic data and suggested
11 patient treatment options that focuses on a highly
12 technical process of unique radiographic and anatomy
13 tracing process that is reviewed -- studied and
14 reviewed at every step of patient treatment by a
15 staff of highly qualified internationally known
16 orthodontic specialists, maxillofacial radiologists
17 and biochemical engineers.

18 A. That's from the OrthoMatrix website that
19 that was drawn. And that biochemical was a spell
20 checker that's since been corrected. It should say
21 biomedical engineers.

22 Q. I see. With that correction, Doctor, is
23 that what Dr. Cortes bought in November of 2018 with
24 that treatment plan, this program that I've just
25 described from the literature?

1 S. Galella

2 MR. FUMUSO: I'm sorry. Can I have that
3 question read back, please.

4 (Record read.)

5 MR. FUMUSO: Object to the form of the
6 question. You can answer over objection if you
7 understand it.

8 A. Yes.

9 Q. Would you agree that OrthoLogic or
10 OrthoMatrix studied and reviewed the unique
11 radiographic and anatomy process at every step of
12 patient treatment?

13 A. No. We're not in patient treatment. We
14 just provide the treatment plan. And it's not
15 orthodontic specialists. It should have said
16 orthodontic practitioners.

17 Q. So that would not include Dr. Cortes?

18 A. What wouldn't include Dr. Cortes?

19 Q. Are you saying Dr. Cortes is not an
20 orthodontic practitioner?

21 A. She's an orthodontic practitioner. I'm
22 just correcting the things that were corrected on
23 the website. There were typing errors by the --
24 whoever entered the information that you have here.
25 I'm just correcting that. That's all.

1 S. Galella

2 Q. Right. I'm trying to find out whether --
3 once the treatment plan was issued that we've
4 discussed earlier that there was any monitoring in
5 any way either Dr. Cortes' treatment of Boja or
6 Boja's progress by OrthoMatrix or FBI or OrthoLogic?

7 A. If a doctor --

8 MR. MURPHY: Objection.

9 MR. FUMUSO: Wait until the question is
10 finished. Is the question finished?

11 MR. CHARNAS: Yes.

12 MR. FUMUSO: Please read back the
13 question to Dr. Galella.

14 (Record read.)

15 A. Generally, if a doctor has -- you know,
16 the treatment plan suggested they can modify it any
17 way they want. If they have issues with the
18 treatment plan, then generally they contact
19 OrthoLogic or -- usually OrthoLogic and sometimes
20 call my office. And ask for help on the case.

21 Q. So it's -- just so I understand, in 2018
22 it's the treating doctor's responsibility, as far as
23 OrthoMatrix is concerned, if they need any
24 information after the treatment plan is issued to
25 come back and ask OrthoMatrix about any additional

1 S. Galella

2 information they need?

3 A. Well, if they have trouble or
4 complications or they're having a hard time with
5 whatever treatment plan they decided to use, then
6 that's part of the package. We'll help them with
7 more records. We'll have to help them troubleshoot
8 it.

9 MR. FUMUSO: Off the record.

10 (Discussion held off the record.)

11 Q. Doctor, going back to that paragraph 2
12 again, and quoting the website of OrthoMatrix, it
13 says: All courses and seminars are accredited by
14 Academy of General Dentistry (PACE) Program Approved
15 Continuing Education.

16 I take it then where it says "all courses
17 and seminars," that would include the educational
18 seminars that you've told us about that you gave,
19 right?

20 A. That's correct.

21 Q. By the way, does Dr. Buck give those
22 seminars for Facial Beauty Institute currently?

23 A. No.

24 Q. What is the Academy of General Dentistry?

25 A. The Academy of General Dentistry is an

1 S. Galella

2 association of general dentists. They provide
3 continuing education hours which are given in every
4 state.

5 Q. Were your courses on Osseo-Restoration
6 Appliances that you gave through FBI approved by the
7 Academy of General Dentistry at least by 2018 or
8 2017?

9 A. They're approved. I think Inside
10 Dentistry is the holder of the certificate of the
11 ability to provide the CE credits.

12 Q. What information or documents did you
13 provide to the Academy of General Dentistry in
14 connection with obtaining that certification?

15 A. A lot. There's about 40 pages.

16 Q. Well, can you tell us by category what
17 documents you gave them?

18 A. Probably the syllabus of the courses, the
19 hours that are spent, the code for the subject
20 matter, et cetera.

21 Q. Did you provide any peer-reviewed
22 literature that supported your claims concerning
23 Osseo-Restoration Appliance?

24 A. Not required.

25 Q. Did you provide to them any clinical

1 S. Galella

2 trials or clinical studies that support those
3 claims?

4 A. No.

5 Q. At the end of that number 2 it says:
6 ControlledArch is a patented system that
7 incorporated the latest scientific and clinical
8 techniques to remodel bone structure by controlling
9 torque and tooth movement resulting in a very
10 predictable desired outcome.

11 Do you agree with that statement?

12 A. No. It should say patent pending system.

13 Q. Other than that, do you agree with the
14 statement?

15 A. Yes.

16 Q. What's the basis of the statement that
17 the ControlledArch system results in a very
18 predictable desired outcome?

19 A. Because it's predictable. There are very
20 few complications in treatment. It's predictable
21 because the force is light and the system -- it's
22 the way the system is designed.

23 Q. Dr. Galella, does Johns Dental have an
24 exclusive right -- let me strike that.

25 In 2018 did Johns Dental have an

1 S. Galella

2 exclusive right in the United States, at least, to
3 manufacture Osseo-Restoration Appliances?

4 A. Well, they were the only ones that we had
5 an agreement with.

6 Q. Are you aware of any other American
7 manufacturers making your Osseo-Restoration
8 Appliance in 2017 or 2018?

9 A. Not to my knowledge other than maybe --
10 2017, '18? Not in the U.S.

11 Q. What about 2019 or 2020? Anybody besides
12 Johns Dental manufacturing your appliance?

13 A. Well, without the specifics, I gave them
14 the specifics of measurements that details, but
15 there's other labs that are making them on their own
16 without understanding the force and the method that
17 would be required to make it properly. Yeah,
18 there's counterfeits all over the place.

19 Q. You would consider Osseo-Restoration
20 Appliances made by Numerica (phonetic), made by
21 companies other than Johns Dental to be counterfeit?

22 MR. FUMUSO: Objection. He didn't say
23 that.

24 MR. LAIRD: Objection. I don't think he
25 said that either.

1 S. Galella

2 Q. Okay. So that's not a true statement?

3 MR. FUMUSO: The question is objected to.

4 MR. CHARNAS: I know.

5 A. Can you rephrase that?

6 MR. CHARNAS: Are you instructing him not
7 to answer?

8 A. No. I just need a rephrase.

9 Q. As far as you're concerned, it's fair to
10 say that Johns Dental is the only lab that has your
11 permission to make the Osseo-Restoration Appliance,
12 correct?

13 A. They're the only ones that know how to
14 make it with the right forces, the measurement, et
15 cetera. Nobody else has the details.

16 Q. How do you know that?

17 A. Because nobody has asked me. They're the
18 only ones that asked me.

19 Q. Does Johns Dental manufacture for --
20 strike that.

21 Does Johns Dental in -- strike that.

22 Other than the FBI report of December --
23 strike that.

24 Other than the FBI report of November 26,
25 2018, and other than the treatment plan that we've

1 S. Galella

2 talked about, are you aware of any documents that
3 have been furnished by OrthoMatrix or its divisions
4 to Dr. Cortes in regard to the care and treatment of
5 Boja Kragulj?

6 A. Not that I recall.

7 MR. CHARNAS: Hang on, Doctor. We're
8 getting to the end.

9 Q. Is it fair to say that the FBI
10 newsletter, the November 2017 newsletter was
11 marketed to dentists all around the country?

12 MR. MURPHY: Objection.

13 MR. FUMUSO: You can answer over
14 objection if you know the answer to that.

15 A. The word marketed, what does that mean,
16 marketed? It was put -- it was disbursed by the
17 Essential Orthodontic Supply Company. And our
18 website, Facial Beauty Institute website, didn't go
19 live until 2019 in July. So I'm not quite sure how
20 marketed...

21 We did send emails to people that had
22 taken the courses concerning the Osseo-Restoration
23 Appliances and ControlledArch. Those people got the
24 newsletter. And then Essential Orthodontics gave it
25 to their people that were buying the ControlledArch

1 S. Galella

2 components from them. So if that's marketing, I
3 guess that's --

4 MR. FUMUSO: You've answered the
5 question.

6 Q. This Essential Orthodontics Supply, where
7 are they located?

8 A. In Greenbrier, Arkansas.

9 Q. Sorry, Doctor. I'm just skimming things
10 off here.

11 MR. MURPHY: Can we take maybe five
12 minutes, Scott, so we can use the restroom.

13 MR. CHARNAS: Sure. I'm getting towards
14 the end. Why don't we take a 10-minute break?
15 How's that?

16 MR. MURPHY: Thanks.

17 (A recess was taken from 3:49 p.m. to
18 3:59 p.m.)

19 Q. Dr. Galella, do you know whether
20 OrthoMatrix or any of its divisions have done any
21 research into the efficacy and safety of
22 Osseo-Restoration Devices other than what you have
23 done?

24 A. No.

25 Q. Since 2013 through at least 2019 when a

1 S. Galella

2 dentist takes a course of yours through FBI in
3 regard to Osseo-Restoration Devices is it fair to
4 say that one of the things he or she would learn
5 from you is that that device creates
6 three-dimensional growth or development or
7 advancement in the nasomaxillary complex?

8 MR. FUMUSO: Objection to the form. You
9 can answer over objection if you can.

10 A. Can you rephrase that? You're getting
11 way out.

12 Q. Is it fair to say -- strike that.

13 I'm talking about if a dentist took a
14 course that you gave between 2013 and 2019,
15 inclusive, a course in the Osseo-Restoration
16 Appliance, and fair to say that one of the things
17 that you would have taught the dentist would be that
18 the device creates three-dimensional development or
19 causes three-dimensional development in the
20 nasomaxillary complex?

21 A. More to it but --

22 Q. I didn't say that was it. That's one
23 thing, though, right, Doctor?

24 A. Yes.

25 Q. And you would also teach them that the

1 S. Galella

2 Osseo-Restoration Device can create 8 to 10
3 millimeters of advancement of the maxilla in the
4 sagittal plane depending upon the patient, correct?

5 A. No. I would say that each individual
6 patient would determine how much remodeling in the
7 sagittal plane would occur.

8 Q. Would you give them a range?

9 A. No.

10 Q. Would you give them an upper limit?

11 A. No.

12 Q. During these courses during that time
13 period did you teach the dentists who attended the
14 course that the Osseo-Restoration Device was safe
15 and efficacious?

16 A. If used properly.

17 Q. Did you also teach these dentists that
18 the safety and efficacy of the Osseo-Restoration
19 Appliance was shown by peer-reviewed articles or
20 publications?

21 A. No. There were no publications offered.

22 Q. Did you also tell the dentists during
23 these courses in that time period that the concept
24 of Osseo-Restoration Appliances was proven through
25 clinical trials or studies?

1 S. Galella

2 A. No.

3 Q. Now you mentioned earlier that the FBI
4 November 2017 newsletter -- and I apologize if I got
5 this wrong, but I thought you told me that one of
6 the things that OrthoMatrix or FBI did was to send
7 that newsletter to dentists that had taken courses
8 through FBI in the past, correct?

9 A. That's correct. They had taken -- yes.

10 Q. Is it fair to say that from at least 2017
11 and 2018 dentists who had taken FBI courses in
12 Osseo-Restoration Appliances would have their
13 information listed somewhere at OrthoMatrix?

14 A. Yes.

15 Q. Sir, one of the things that you as a
16 representative of FBI were asked to come here to
17 talk about was number 17 of the areas of inquiry.
18 Let me see if I can get that up for you to read it
19 into the record. This is from Exhibit 1.

20 The number of dentists and dental
21 professionals with dental practices in New York
22 State between January 25th, 2013, and April 1st,
23 2019, A, attended any course, seminar or educational
24 presentation regarding the use, safety or efficacy
25 of AGGA and/or CAB, which course, seminar or

1 S. Galella

2 educational presentation was taught by Dr. Galella
3 or by any agent, servant or employee of OrthoMatrix.

4 So at least in 2017 and 2018, Doctor, how
5 many dental professionals and dentists with dental
6 practices in New York State attended your courses in
7 regard to the Osseo-Restoration Appliance?

8 MR. FUMUSO: Asked and answered. He
9 already gave you that information.

10 Q. Did you consult the records of
11 OrthoMatrix in this regard, sir, in preparation for
12 this deposition?

13 A. Yes. And to my recollection that's
14 pretty much it. New York is not high on our list.

15 Q. So how did you consult -- tell us what
16 you did in that regard.

17 A. Checked with the database.

18 Q. Do you remember I asked you in the
19 beginning of this deposition what documents you
20 reviewed, things you reviewed in preparation for the
21 deposition. You didn't mention the database; is
22 that right?

23 A. I had just an inquiry to the IT guy who
24 from New York took the courses.

25 Q. What else did you do in preparation for

1 S. Galella

2 this deposition other than speak to attorneys and
3 other than what you've told us to this point?

4 A. I don't understand the question. What
5 else did I do?

6 Q. In preparation for this deposition.

7 A. I reviewed the information that I had,
8 the discovery information.

9 Q. Anything else?

10 A. Not that I recall.

11 Q. What other information did you request
12 from OrthoMatrix other than the information I just
13 read in regard to number 17 in preparation for this
14 deposition?

15 A. I don't recall.

16 Q. In regard to David Buck, for example,
17 teaching the Osseo-Restoration Appliance through
18 LVI, do you get a cut or percentage of or any
19 remuneration from that?

20 A. No.

21 Q. Did you ever?

22 A. No.

23 Q. Let me show you another document, Doctor,
24 which is Exhibit 15.

25 (Exhibit 15, LVI clinical curriculum; 492

1 S. Galella

2 pages, marked for identification.)

3 Q. Have you ever seen this document before?

4 A. Keep scrolling. I don't think so. No.

5 Q. Let me just scroll a little bit further
6 first. You've never seen any of this material
7 before that we're scrolling through?

8 A. No. Looks like it's --

9 MR. FUMUSO: No. There's no question
10 before you. Right?

11 Q. It looks like a course that Dr. Timothy
12 Gross may have given through LVI; is that right?

13 A. I don't know. Never seen it.

14 Q. I'm going to represent to you that this
15 is course material from a course that was given
16 through LVI.

17 MR. FUMUSO: Are we going to take you --
18 are we going to take your oath?

19 MR. CHARNAS: Well --

20 MR. FUMUSO: Counsel, you know, I
21 received this for the first time ever this
22 morning and I'm not going to take your
23 representation as to what it is. Okay. So let
24 me be clear about that.

25 MR. CHARNAS: It doesn't matter whether

1 S. Galella

2 you take my representation or not. I'm going
3 to ask him some questions about some things
4 that are in there and I'm going to ask him
5 whether he agrees with it or not. You don't
6 need to take my representation for anything.

7 MR. FUMUSO: You can ask your questions.
8 I'm going to tell you right now I'm going to
9 object to it. So let's go.

10 Q. Now, I paginated this exhibit for ease of
11 reference, Doctor. And I'm going to turn to page
12 255. Let me ask you this question. Let me strike
13 that question.

14 Do you agree that malocclusion and jaw
15 growth are epigenetic and not genetic?

16 A. Yes and no. The Class II Division 2
17 malocclusion is 90 percent genetic. It's the only
18 malocclusion that is genetic. The rest are caused
19 by the epigenetics with a soft tissue influence on
20 the body which makes it change its growth patterns.

21 Q. Now I'm going to read something from page
22 343. I'm going to ask you whether you agree with
23 this. The pressure against the nasopalatine
24 branches below the papilla creates a micro-trauma
25 which signals bone remodeling to occur in an

1 S. Galella

2 accelerated fashion.

3 MR. FUMUSO: I'm going to object to this.

4 Q. Do you agree with that?

5 MR. FUMUSO: I'm going to object to you
6 referencing this document with that question.
7 Okay. If you want to ask it -- I'm just
8 letting you know what I don't have an issue
9 with. If you want to ask a general medical
10 question, fine. But anything you're going to
11 reference from this document I'm telling you
12 right now I'm going to object to based upon the
13 fact that no one in this lawsuit saw this
14 document, to my knowledge, until a half an hour
15 before this deposition. The doctor has never
16 seen it before. He's not associated with LVI
17 which is the genesis of this document, so I'm
18 going to object on a substantive basis to any
19 questions.

20 Now, if you want to ask general medical
21 questions, fine. But not in reference to this
22 document.

23 MR. CHARNAS: You're instructing him not
24 to answer this question?

25 MR. FUMUSO: That's correct. But I've

1 S. Galella

2 given you parameters in which I will not object
3 to general medical questions. But if you're
4 going to make reference to this document then
5 I'm going to object to that, because I think
6 your reference to this document in this
7 deposition is totally improper.

8 MR. CHARNAS: Because he hasn't seen it
9 before?

10 MR. FUMUSO: Correct. No one has seen it
11 before.

12 MR. CHARNAS: Is there some rule that I'm
13 not aware of where a witness cannot be
14 questioned about a document he hasn't seen
15 before the deposition?

16 MR. FUMUSO: Yes. It's my understanding
17 that a witness can only be questioned about
18 anything that he's reviewed prior to the
19 deposition. Okay. That's my understanding.
20 Including his own records, obviously. So I
21 don't think in a deposition you can just take
22 any document that you want and show it to a
23 witness for the first time. That's my
24 understanding of how depositions are conducted
25 and I've been doing them for 45 years. Okay.

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If you have a different understanding, fine. That's my understanding and that's my practice. And that's the way everyone that I associate with in litigation, that's their practice as well.

MR. CHARNAS: I'm going to state for the record that there's no such rule and there never has been, at least in the 40 years I've been practicing law. Regardless, it is completely inappropriate to instruct the witness not to answer.

MR. FUMUSO: I disagree.

MR. CHARNAS: This is not the rules. The Rules of Civil Procedure in federal court require an instruction not to answer only in cases of privilege. And there's no question of privilege here. So it's completely improper.

MR. SCHWARTZ: Counsel, the problem that you're having is that you're trying to surprise witnesses in this litigation. That's your intention. That is not how the federal rules work. You are trying to do it now. You've been given a great deal of leeway in that regard. To just produce a document at any time

1 S. Galella

2 to have a witness respond to is clearly
3 improper. You should be producing documents
4 that are relevant in the case.

5 You just want to produce it a half an
6 hour before the deposition and have the witness
7 answer it, I agree that's improper practice.
8 We're not supposed to be surprised. We'll be
9 deposing each other's experts. You tried to do
10 that, which is your practice apparently.
11 That's not how the federal rules work.

12 MR. MURPHY: I want to make a statement.
13 I'm not as familiar with the facts as my
14 associate. But it does seem like there's a lot
15 of documents here, Mr. Charnas, and were
16 probably responsive document requests that are
17 being seen for the first time today. I mean,
18 was this produced pursuant to a subpoena to
19 LVI?

20 It is a little unusual. I'm not going to
21 take a position on whether Mr. Fumuso can
22 direct or not direct his client not to answer.
23 But it is a little puzzling to me. I, too,
24 have been doing for a while. There's an awful
25 lot of new documents that I don't think were

1 S. Galella

2 produced previously and I suspect they would be
3 responsive to some of the document demands that
4 were served by multiple defendants here.

5 MR. CHARNAS: Your suspicion would be
6 wrong, Mr. Murphy. I agree that if there are
7 documents that were requested, that's
8 different. But I don't believe that any
9 request has been made for this document. As
10 far as the documents I was accused of springing
11 on you earlier, both the -- all those text
12 messages were produced in discovery. The
13 recording was produced by Dr. Cortes. So
14 there's a lot of loose talk here about --

15 MR. SCHWARTZ: That was my objection.

16 (Simultaneous speakers.)

17 MR. SCHWARTZ: That's me saying it about
18 documents you produced at our deposition.
19 Look, I don't recall specifically. I just know
20 that there's a tendency with the way you
21 practice, Mr. Charnas, to try to surprise
22 witnesses.

23 And you're being given an opportunity to
24 ask the same question without the document, so
25 why don't you proceed and just ask the question

1 S. Galella

2 without the document?

3 MR. FUMUSO: And I want the record to be
4 clear that this document that was served a half
5 an hour before this deposition is over 400
6 pages long. Now if this isn't trial by ambush,
7 I don't know what is. This is not proper.

8 I'm not going to allow my witness to be
9 asked -- if you want to question my witness
10 about this document, you could have exchanged
11 them long ago. We've exchanged thousands of
12 pages of documents in this lawsuit. Okay. You
13 could have exchanged this long ago. Now, I
14 made it very clear, you want to ask him general
15 medical questions about the Osseo-Restoration
16 Device, fine. I'm going to object to any
17 reference out of this document. That's my
18 position.

19 MR. CHARNAS: Did you request this
20 document in discovery, sir?

21 MR. FUMUSO: I don't have to request it.
22 What am I going to request? I requested your
23 client's records. I can't just request
24 everything under the sun. You just can't --
25 don't disarm my witness, a surprise witness, a

1 S. Galella

2 surprise document. We get this a half an
3 hour -- this was supposed to start at
4 9 o'clock. 8:30 I get this document, 450 pages
5 long, and you want to question my witness about
6 it without me having an opportunity to discuss
7 this with my witness? I don't think so.

8 MR. MURPHY: Let me note that I believe
9 Rule 26 might cover the production of documents
10 that are in the possession of a party that
11 they're going to use or rely upon in making
12 their case and it's an ongoing obligation. I'm
13 noting it. I'm going to keep my mouth shut.
14 We'll move on.

15 MR. CHARNAS: There are lots to say in
16 response, but I don't want to waste more of our
17 time. This is all going to be taken up with
18 the court.

19 Q. Dr. Galella, are you still there?

20 THE WITNESS: Yeah. I need a minute with
21 my attorney, please.

22 MR. CHARNAS: Sure. Take a five-minute
23 break.

24 (A recess was taken from 4:19 p.m. to
25 4:23 p.m.)

1 S. Galella

2 Q. I'm going to read you a statement,
3 Doctor. Not from a document. Just going to read
4 you a statement. I'm going to ask whether you agree
5 with it.

6 The pressure against the nasopalatine
7 branches below the papilla creates a micro-trauma
8 which signals bone remodeling to occur in an
9 accelerated fashion. This stimulation to the
10 nasomaxillary complex creates three-dimensional
11 changes, not linear.

12 Do you agree with that?

13 A. Doesn't agree with the literature. No.

14 Q. You don't agree with that statement?

15 A. It's more hypothetical than true.

16 Q. Can you tell me what part specifically
17 you don't agree with or you don't agree with the
18 whole statement?

19 A. The whole statement.

20 Q. Does your claim of the Osseo-Restoration
21 Device causing three-dimensional changes in the
22 nasomaxillary complex depend in any way on the
23 theory that nasopalatine stimulation causes bone
24 remodeling?

25 A. Theoretically, it's possible.

1 S. Galella

2 Q. And it's theoretically possible not; is
3 that correct?

4 A. Theoretically means we don't know for
5 sure.

6 Q. What's your belief in that regard?

7 A. My personal belief?

8 Q. Yes, sir.

9 A. My personal belief is the pressure on the
10 bone and Wolff's Law which states in prosthetics for
11 35 years and over 460 articles, published articles,
12 he's an orthopedist studied all the bones in the
13 body and he's suggested that this is occurring. And
14 Enlow "Essentials of Facial Growth," first edition,
15 second edition, with added authors in the second
16 edition, suggests similar things can occur. But
17 there's not much mention of the pressure on the
18 trigeminal nerve as you stated.

19 Q. So it's fair to say there are no
20 peer-reviewed journals that you know of that support
21 that theory in regard to the nasopalatine nerve --

22 A. Yes.

23 Q. -- correct?

24 MR. FUMUSO: I'll object to the form of
25 that question and the way it's phrased.

1 S. Galella

2 A. Could you rephrase it, please?

3 Q. I think you already answered it.

4 A. Well, you interrupted me.

5 Q. I did?

6 A. Well, somebody did.

7 MR. CHARNAS: Could you read the --

8 A. To my knowledge, I don't know of any peer
9 review. I'm not aware of it at this point.

10 Q. That's what I thought you said. Thanks.

11 MR. FUMUSO: My objection was the way the
12 question was phrased.

13 MR. CHARNAS: Right.

14 Q. Dr. Galella, is it your position that
15 when the Osseo-Restoration Appliance causes the
16 maxilla to advance down and forward that the ramus
17 of the mandible responds by growing vertically with
18 displacement to match the new maxillary position?

19 A. Say that one more time.

20 MR. CHARNAS: Could you read back.

21 (Record read.)

22 A. You're talking about the fixed appliance?

23 Q. Yes.

24 A. Is that correct? That's not true.

25 Q. Did you ever take an opposite position,

1 S. Galella

2 sir?

3 A. In normal growth the maxilla grows
4 down and -- it grows up and back, displaced down and
5 forward. We've explained that. In the removable
6 appliance, it stimulates the displacement of the
7 maxilla, it's displaced forward and downward. The
8 fixed appliance according to Dr. Bromage, he sees a
9 pure horizontal remodeling and no downward.

10 Q. I'm going to show you Exhibit 16.

11 (Exhibit 16, Kragulj FBI report; 25
12 pages, marked for identification.)

13 Q. Do you see that, Doctor, Exhibit 16?

14 A. Yes.

15 Q. Now, that is the 2020 FBI report you were
16 referring to earlier, correct?

17 A. Yes.

18 Q. When you met -- strike that.

19 You met with Boja Kragulj in your office
20 in Tennessee in March of 2020, correct?

21 A. It was either February or March.

22 Q. You see there's a finding in this report,
23 Exhibit 16: Generalized moderate with localized
24 severe periodontal bone in the anterior mandibular
25 region was noted. Multiple teeth demonstrated crown

1 S. Galella

2 ratio of less than one to one.

3 Then it says: Multiple teeth
4 particularly in the maxilla and anterior mandible
5 demonstrate severe apical root resorption with
6 minimal to no remaining bone support. The maxillary
7 teeth, in particular, number 6, 7, 8, 9, 10 and 11
8 present with only minimal remaining palatal bone
9 support and no buccal bone support.

10 Do you see that there?

11 A. Yes.

12 Q. Did you discuss those findings with Boja
13 during that office meeting in February or March of
14 2020?

15 A. I'm pretty sure I did.

16 Q. Did you tell her what you thought the
17 cause of the severe apical root resorption was?

18 A. Well, I didn't -- I don't recall exactly
19 what I said, but that it was probably a result of
20 the root absorption she had before treatment.

21 Q. Before any Osseo-Restoration Appliance
22 treatment; is that what you mean?

23 A. Yes.

24 Q. Did you tell her that in regard to these
25 other findings concerning the mandible about the

1 S. Galella

2 maxillary teeth presenting --

3 A. Yes. As a matter of fact, I think I
4 probably sent her a radiology report.

5 Q. What's the basis of your belief that
6 these findings that I've just read in regards to
7 maxilla are due to circumstances that occurred
8 before the Osseo-Restoration Appliance was first
9 placed in her?

10 A. Repeat that again.

11 Q. Sure. What's the basis of your
12 conclusion that the injury or damage to the maxilla
13 and the maxillary teeth discussed in this report are
14 due to circumstances or causes before she had the
15 first appliance installed, the first
16 Osseo-Restoration Appliance?

17 A. Because she had another report sent to
18 Dr. Cortes that suggested she had root resorption.
19 And it was a warning to discuss it with the patient.

20 And this was after an appliance. I
21 didn't know how many. But that's why it's evident.

22 (Simultaneous speakers.)

23 Q. I'm sorry.

24 A. She had root absorption before she was
25 treated in -- with the 2016 scan. That's all I went

1 S. Galella

2 by.

3 Q. So the --

4 A. 2018. The 2018 report in November based
5 on the 2016 scan and pictures.

6 Q. So just so it's clear, the 2018 treatment
7 plan that we talked about that.

8 That red writing in reference to root
9 resorption was specifically about Boja; is that your
10 testimony?

11 A. The treatment plan had her name on it.
12 Are we talking about the same plan?

13 Q. Yes, sir.

14 A. Okay.

15 Q. So that treatment -- strike that. Thank
16 you.

17 Last exhibit, Doctor. I'm going to show
18 you this in a moment. It's going to be Exhibit 17.

19 (Exhibit 17, 3/9/20 handwritten note,
20 marked for identification.)

21 Q. Let me ask you this. Different question.
22 You were asked to produce your records in discovery,
23 your records in regard to Boja. And you produced an
24 Exhibit A and Exhibit A1 to 3. And your lawyers
25 produced a video which was a video of a Zoom or some

1 S. Galella

2 sort of remote conversation that you had with Boja
3 in 2020.

4 Do you remember that video?

5 A. That was a GoToMeeting consult when I
6 talked to her about what our findings were and her
7 proposed treatment plan.

8 Q. At some point thereafter -- let me show
9 you -- strike that. Let me show you the Exhibit
10 first. This is Exhibit 17. Let me get it up for
11 you there. I'm going to represent to you that this
12 Exhibit 17 was a page taken out of your records that
13 were supplied in discovery.

14 Does this look like one of your records,
15 generally speaking, concerning Boja?

16 A. Yes.

17 Q. And does this help you remember that you
18 saw her in your office in Tennessee on March 9th of
19 2020?

20 A. Yes. Let me just read it first before
21 you get there.

22 Q. Sure.

23 A. Okay. Scroll up. Okay. Ready to go.

24 Q. This is a part of your record in regard
25 to Boja, correct?

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2 A. Yes.

3 Q. Now, when you examined her in March,
4 March 9th, actually, of 2020, I take it you asked
5 her a history concerning her condition and
6 treatment?

7 A. Yes.

8 Q. And it's fair to say she came to Memphis
9 to you looking for help, right?

10 A. She wanted me to evaluate her for
11 treatment.

12 Q. Please tell us what you did in regard to
13 trying help Boja that day.

14 A. The cone beam machine was out of service.
15 So she had one from 2020 and she opened the portal
16 so I could get all of them that she ever had taken.
17 And we took pictures. And I examined her and then I
18 told her we would get a cone beam analysis and
19 radiologist report and treatment plan offered up.
20 And then on March, whatever it was, the 9th or
21 whenever, we did the consultation.

22 Q. This is -- if I'm reading this correctly,
23 May 14th, 2020, scheduled GoToMeeting today at 11?

24 A. Right. That's it.

25 Q. And that you recorded, right?

1 S. Galella

2 A. That's what you had received.

3 Q. Right. Thank you.

4 And then according to this record on
5 June 1st, she called for a summary of the fees for
6 treatment and spoke to you.

7 Do you remember that?

8 A. I think I went over the fees on the
9 GoToMeeting and then she called about the fees and
10 my office manager gave her the fee information.

11 Q. So on the fourth to bottom line of this
12 record, am I reading this right, it says "ortho
13 treatment \$15,000"?

14 A. Yeah.

15 Q. What were you going to do for that
16 \$15,000, Doctor?

17 A. Treat her.

18 Q. That I know. Can you give us a little
19 bit more detail?

20 A. Try to put the teeth -- the roots of the
21 teeth, what was left of the roots of the teeth back
22 in the bone. Get them aligned and try to save the
23 teeth. If she needed implants, they were going to
24 have a consequence. If she needed grafts, we'd have
25 to do that as well.

1 S. Galella

2 Q. Did you tell her at any time that it was
3 more probable than not or more likely than not that
4 you would be able to save the teeth through this
5 orthodontic treatment?

6 A. I told her that it was a procedure we can
7 try but there was no guarantee. She may lose the
8 teeth. Even if it worked, they would be very mobile
9 and she may lose the teeth. Implants was a better
10 option to replace the teeth because they were pretty
11 mobile.

12 Q. In order to have implants, she would
13 first have to have grafts, right?

14 A. Not necessarily first to have to have it.
15 But, yes, she would have to have bone grafts in
16 addition to the implants.

17 Q. It says "grafts" on the third to bottom
18 line. Is that bone grafts?

19 A. Yes.

20 Q. It says 6,000 each?

21 A. Each implant. Everything is based on the
22 tooth.

23 Q. Each tooth would need a \$6,000 bone
24 graft, correct?

25 A. No. No. Bone graft was 6,000 -- I'm

1 S. Galella

2 sorry. I don't know why each was there. And the
3 implants were 10,000 each. The bone graft was
4 \$6,000.

5 Q. So that each is an error, correct?

6 A. No. It was the bone graft was each. I
7 may have to do the lower jaw as well. If I had to
8 do the lower jaw, then that would really turn into
9 another 6,000. Per jaw.

10 Q. So it was \$6,000 for the --

11 A. Upper.

12 Q. Uppers and if she needed it, it would be
13 \$6,000 for the lowers?

14 A. That's correct.

15 Q. Is that right? And then implants, 10,000
16 each, that's each tooth, right, that needed
17 replacement?

18 A. Yes.

19 Q. Did you tell her how many teeth she would
20 need replacement?

21 A. Well, there was several options on that.
22 She could have a fixed denture, permanent denture,
23 which looks better than each individual tooth. And
24 that would pretty much be a -- if she did the bar,
25 it would cost 10,000. Probably be four implants.

1 S. Galella

2 If she did individual teeth, it was 10,000 each.

3 Q. If she did individual teeth, did you tell
4 her how many teeth that would be?

5 A. I probably did. I don't recall the
6 conversation.

7 Q. And then it says, with crowns, in
8 addition to?

9 A. Yes.

10 Q. Did I read that right? What were you
11 going to charge her for the crowns?

12 A. That's determined by -- the office
13 manager has all that in her notes, what to charge
14 for implant crowns. But they're probably around
15 3500 each.

16 Q. Did you tell her at any time that the
17 orthodontic treatment was not likely to save the
18 teeth?

19 A. Yes.

20 MR. CHARNAS: I would like to take a
21 five-minute break. I just want to review my
22 notes. I think I'm finished, but I just want
23 to make sure. Is everybody okay with that?

24 MR. FUMUSO: Sure.

25 MR. CHARNAS: Thank you. Five minutes.

1 S. Galella

2 (A recess was taken from 4:42 p.m. to
3 4:50 p.m.)

4 Q. We're almost done, Doctor. I promise.

5 Dr. Galella, can one measure fairly and
6 accurately maxilla advancement from an
7 Osseo-Restoration Appliance using dental models?

8 A. Not really because of the -- they're
9 separated from the rest of the body. You have to
10 have the whole body to make the correct
11 measurements.

12 Q. Do you have any financial relationship
13 with Dr. Bromage?

14 A. The question again? I'm hard of hearing.
15 Dr. Bromage?

16 Q. Do you have any financial relationship
17 with Dr. Bromage?

18 A. No.

19 Q. Does Dr. Bromage -- sorry?

20 A. I was done.

21 Q. To your knowledge, does Dr. Bromage have
22 a financial relationship with OrthoMatrix?

23 A. No.

24 Q. Did he have such a financial relationship
25 with you in 2017 or 2018?

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S. Galella

A. No.

Q. Doctor, don't take offense, I ask all the defendants this question.

Have you had a felony conviction in the last 10 years?

A. No.

MR. CHARNAS: I have no further questions at this time. I wish to state for the record that I am suspending the deposition. I don't want to repeat ad infinitum the discussions that have gone on, objections, et cetera and retorts to the objections.

I will say just briefly that I believe that my ability to fairly inquire concerning the dental malpractice claim against Dr. Galella has been unreasonably and unfairly curtailed and limited, that the use of objections and instructions not to answer is inappropriate.

And also, I believe that my ability to inquire concerning the product liability claim and among other things, particularly the effect of the Osseo-Restoration Appliance or appliances on Boja Kragulj, the design goals in

1 S. Galella

2 regard to that product as contrasted with the
3 actual results.

4 So, again, I'm suspending the deposition
5 and will make a motion to compel to have
6 Dr. Galella return for further questioning.

7 MR. FUMUSO: Who's next up on the list?

8 MR. SCHWARTZ: I have no questions for
9 this witness.

10 MR. LAIRD: I'm last named.

11 MR. SCHWARTZ: Henry Schwartz. I don't
12 have any questions for the witness.

13 MR. MURPHY: This is Casey Murphy. I
14 have two questions. Ken Murphy for the record.

15 EXAMINATION BY

16 MR. MURPHY:

17 Q. Good afternoon, Dr. Galella.

18 A. Good afternoon.

19 Q. Dr. Galella, can you estimate how many
20 times in your professional capacity as a dentist you
21 have been involved in the preparation of treatment
22 plans involving the use of Osseo-Restoration Devices
23 similar to your role here with respect to the
24 plaintiff and her treatment by Dr. Cortes?

25 A. 9800 -- 9,800.

1 S. Galella

2 Q. How many times have you personally or
3 OrthoMatrix or Facial Beauty Institute been sued
4 with respect to your role in the preparation of
5 those 9,800 treatment plans?

6 A. None.

7 Q. This is the first time you've been sued?

8 A. Yes.

9 Q. Have you personally observed these
10 devices work with patients?

11 A. Yes.

12 MR. MURPHY: No further questions.

13 MR. LAIRD: I don't have any questions
14 for the witness.

15 MR. FUMUSO: I have a few.

16 EXAMINATION BY

17 MR. FUMUSO:

18 Q. Doctor, you were questioned by
19 Mr. Charnas about clinical trials. Can you tell us
20 in your experience whether it is common for dental
21 appliances to have -- to be evaluated by clinical
22 trials before they are utilized in patients?

23 A. In dentistry most appliances are based on
24 other appliances. It's a growth thing. And
25 clinical trials are usually not common.

1 S. Galella

2 Q. Now you've indicated there was literature
3 that you have referenced what you think -- which you
4 state is the anatomic basis, scientific basis -- one
5 of the scientific bases for your appliance; is that
6 correct?

7 A. That's correct.

8 Q. You mentioned Dr. Enlow and Dr. Bromage
9 and other authors as well; is that correct?

10 A. Yes.

11 Q. Doctor, you have a private practice of
12 dentistry; is that true?

13 A. That's correct.

14 Q. In addition -- withdrawn.

15 Is it important and educational and
16 instructive in a private practice of dentists to
17 observe the clinical result to a patient of a
18 particular form of treatment?

19 A. Yes.

20 Q. And approximately how many patients in
21 your career have you applied the Osseo-Restoration
22 Device?

23 A. About 600.

24 Q. Out of those 600 patients, have you had
25 the opportunity to review and analyze and observe

1 S. Galella

2 the efficacy of this particular appliance?

3 A. Yes.

4 Q. And have you formed an opinion with those
5 600 patients as to whether or not this appliance has
6 efficacy and is of value to the patients?

7 A. I've seen excellent results in the cases.

8 Q. Has there ever been any governmental
9 agency, state agency, governmental agency which has
10 ever brought a cease and desist order against you or
11 OrthoMatrix or the manufacturer for the
12 dissemination of the Osseo-Restoration Device?

13 A. Never.

14 Q. Any governmental agency as far as
15 you're -- do you have any knowledge, have they
16 investigated this particular device, to your
17 knowledge?

18 A. Not to my knowledge, no.

19 Q. Have you ever received any notification
20 from any governmental or state agency that this
21 device is unsafe to patients?

22 A. No.

23 Q. With respect to your relationship with
24 the plaintiff, Boja Kragulj, prior to March,
25 approximately March, of 2020, did you ever have a

1 S. Galella

2 conversation with Boja Kragulj?

3 A. No.

4 Q. Did you ever examine Boja Kragulj?

5 A. No.

6 Q. Prior to March of 2020 did you ever have
7 a doctor-patient relationship with Boja Kragulj?

8 A. No, I did not.

9 MR. FUMUSO: No further questions.

10 MR. CHARNAS: I have a few follow-up
11 questions.

12 BY MR. CHARNAS:

13 Q. Dr. Galella, how many dentists who placed
14 your Osseo-Restoration Device in patients have been
15 sued by those patients for adverse effects allegedly
16 caused by that device?

17 MR. FUMUSO: To your knowledge.

18 A. To my knowledge, just Dr. Cortes.

19 MR. SCHWARTZ: Note my objection to the
20 last question and answer.

21 MR. CHARNAS: He asked -- anyway.

22 Q. You said you had determined efficacy of
23 the -- your Osseo-Restoration Device in, I think --
24 was it 600 of your patients, 600 plus?

25 A. Yes.

1 S. Galella

2 Q. How did you determine efficacy?

3 A. Treatment -- during treatment and then
4 long-term follow up, some as long as 15 years.

5 Q. Did you confirm three-dimensional
6 nasomaxillary growth or development in those 600
7 plus patients as a result of use of your
8 Osseo-Restoration Device?

9 A. Well, now you said -- when you said that
10 word, that means fixed.

11 Q. Yes.

12 A. That's what I was -- the 600 is the
13 fixed. I've done a lot more removables as well.
14 The fixed, did I see the three-dimensional fixed,
15 yes.

16 Q. How did you measure those
17 three-dimensional fixed?

18 A. By the occlusion. Measuring the models
19 on the teeth, the teeth on the model, the width, the
20 length, et cetera and position on an x-ray. Now
21 that we have a new overlay technique, we can really
22 measure better, the anterior and posterior
23 dimensions.

24 Q. And you've retained those 600 plus films?
25 I should say you've retained those films on those

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S. Galella

600 plus patients?

A. Yes.

MR. CHARNAS: Thanks. That's all I have
subject to the suspension that I mentioned
earlier. Doctor, thank you very much.

THE WITNESS: You bet.

(Whereupon, the proceedings were
adjourned at 5:01 p.m.)

J U R A T

I do hereby certify that I have read
the foregoing transcript of my deposition.

STEVE GALELLA, D.D.S.

Sworn and subscribed
before me
this _____ day of
_____, 2021.
A Notary Public
of the State of _____

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CERTIFICATE

STATE OF NEW YORK)

) ss.

COUNTY OF SUFFOLK)

I, Elizabeth F. Tobin, a Registered Professional Reporter and Notary Public within and for the State of New York, do hereby certify:

That Steve Galella, D.D.S., the witness whose deposition is hereinbefore set forth, was duly sworn by me remotely and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage and that I am in no way interested in the outcome of this matter.



ELIZABETH F. TOBIN, RPR

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July 7, 2021

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In the Matter Of:

BOJA KRAGULJ V. MARTHA CORTES, D.D.S.

1-20-cv-08390-RA

STEVE GALELLA

February 04, 2022

VOLUME II



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1
2 UNITED STATES DISTRICT COURT
3 SOUTHERN DISTRICT OF NEW YORK
4 -----

4 BOJA KRAGULJ,

5 Plaintiff,

6 V.

Civil Action No.
1-20-cv-08390-RA

7 MARTHA CORTES, D.D.S, STEVE
8 GALELLA, D.D.S., ORTHOMATRIX CORP.,
9 INC., FACIAL BEAUTY INSTITUTE

9 and

10 JOHN'S DENTAL LABORATORY, INC.,

11 Defendants.
12 -----

13 VOLUME II

14
15 CONTINUED VIDEO-TELECONFERENCE

16 DEPOSITION OF STEVE GALELLA, D.D.S., a Defendant
17 herein, and 30(b)(6) witness on behalf of
18 Orthomatrix and Beauty Facial Institute, witness
19 located in the Law Offices of
20 Fumuso, Kelly, Swart, Farrell, Polin &
21 Christesen, held on February 4, 2022, commencing
22 at 10:07 a.m., and before Helene Gruber, a
23 certified shorthand reporter and notary public
24 within and for the state of New York.
25

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A P P E A R A N C E S :

CHARNAS LAW FIRM, P.C.
Attorneys for Plaintiff
455 East 51st Street
New York, New York 10022
BY: SCOTT CHARNAS, ESQ.

FUMUSO, KELLY, SWART, FARRELL, POLIN &
CHRISTESEN LLP
Attorneys for Defendant Steve Galella, D.D.S
110 Marcus Boulevard, #500
Hauppauge, NY 11788
BY: ALAN FUMOSO, ESQ.

FRENCH & CASEY
Attorneys for Defendant John's Dental Lab
29 Broadway
New York, New York 10006
BY: SCOTT LAIRD, ESQ.

LAW OFFICE OF HENRY SCHWARTZ, ESQ.
Attorneys for Defendant Martha Cortes
32 Court Street, No. 908
Brooklyn, NY 11201
BY: HENRY SCHWARTZ, ESQ.

RIVKIN RADLER LLP
Attorneys for Defendants Orthomatrix and Facial
Beauty Institute
926 RXR Plaza
Uniondale, New York 11553
BY: BRIAN FELD, ESQ.

1 S. Galella, D.D.S.

2 COURT REPORTER: My name is Helene
3 Gruber, a New York State notary public and
4 certified shorthand reporter. This deposition
5 is being held via video conferencing equipment.
6 The witness and reporter are not in the same
7 room. The witness will be sworn in remotely
8 pursuant to agreement of all parties. The
9 parties stipulate that the testimony is being
10 given as if the witness was sworn in person.

11 MR. CHARNAS: Stipulated.

12 MR. FUMOSA: Agreed.

13 MR. FELD: Agreed.

14 MR. LAIRD: Agreed.

15 MR. SCHWARTZ: Agreed.

16 STEVE GALELLA, D.D.S.,

17 Having first been duly sworn, was examined and
18 testified as follows:

19 MR. FUMOSA: For the record, this
20 deposition is a continuation of a deposition of
21 Dr. Steve Galella and Defendants OrthoMatrix
22 and Facial Beauty Institute. The 30(b)(6)
23 Notice of OrthoMatrix was previously introduced
24 as an Exhibit 1-A through D.

25 It is my understanding, again, that

1 S. Galella, D.D.S.

2 Dr. Galella is being produced in regard to that
3 notice on behalf of OrthoMatrix and FBI.

4 Is that correct, Brian?

5 MR. FELD: That's correct, but I am
6 going to just object to any questioning that
7 has already been covered on day one of Dr.
8 Galella's deposition. I am obviously not going
9 to instruct the witness not to answer, but I am
10 just going to have a running objection to any
11 questions that have already been asked and
12 answered during Dr. Galella's first deposition.

13 MR. FUMOSA: I join in that.

14 EXAMINATION

15 BY MR. CHARNAS:

16 Q. Dr. Galella, I know I gave you some
17 instructions when we began your first day of
18 deposition, but I am going to go over them
19 again because it's been a while.

20 I'm going to ask you a series of
21 questions to which you are expected to respond
22 audibly. Shrugs of the shoulder, shakes of
23 the head, don't show up very well in the
24 transcript.

25 If at any time I ask you a question

1 S. Galella, D.D.S.

2 that you don't fully hear or understand, let
3 me know and I will be glad to repeat or
4 rephrase it for you.

5 If you don't let us know, then we
6 will assume you heard and understood the
7 question.

8 Any time you want to take a break to
9 speak to your attorney or use the facilities,
10 just let us know. We will be glad to
11 accommodate you. If there is a pending
12 question when you want to break, I may ask for
13 a response to that question, but otherwise,
14 glad to accommodate you. Do you understand
15 all that, sir?

16 A. Yes.

17 Q. Did you review any documents in
18 preparation for this second day of your
19 deposition?

20 A. Yes.

21 Q. Tell us, what did you review?

22 A. I reviewed the previous deposition
23 and some evidence, the videotapes and --
24 sorry -- CD, video, of Dr. Buck.

25 Q. Anything else?

1 S. Galella, D.D.S.

2 A. I don't recall what else, but I'm
3 sure there were other things.

4 Q. Other than attorneys, did you talk to
5 anyone to get any information in regard to this
6 deposition today?

7 A. No.

8 Q. Did you speak to Dr. Buck about this
9 deposition?

10 A. No.

11 Q. Did you speak to Dr. Gross about this
12 deposition?

13 A. No.

14 Q. Did you speak to anybody from
15 OrthoMatrix about this deposition?

16 A. Ben Shappley, the CEO/president of
17 OrthoMatrix that I was coming here.

18 Q. Did you discuss anything substantive
19 with Mr. Shappley?

20 A. I did ask for some records, financial
21 records, that you asked about last time.

22 Q. More specifically, what financial
23 records?

24 A. How much John's Dental paid for
25 consultant fees.

1 S. Galella, D.D.S.

2 Q. As you did last time, I want to make
3 sure that we are using the same terminology
4 here. Just so it is clear, more than 20 years
5 ago you codeveloped a product that at one time
6 you called an Anterior Growth Guidance
7 Appliance, correct?

8 MR. FELD: Objection. Asked and
9 answered.

10 A. Yes.

11 Q. And you have referred to that and it
12 is generally referred to as an AGGA, correct?

13 A. I don't refer to it as AGGA.

14 Q. Have you heard people refer to it as
15 an AGGA?

16 A. That was term developed by lay
17 people. I have heard it but I don't use it.

18 Q. Would you agree it is commonly called
19 AGGA?

20 A. I have no idea what the common name
21 is. The proper name is Osseo-Restore
22 Appliance.

23 MR. FUMOSA: I am just going to
24 object to the form of the question.

25 Q. At some point it was called Anterior

1 S. Galella, D.D.S.

2 Growth Guidance Appliance, correct?

3 A. Yes.

4 Q. And that was called that by you,
5 correct?

6 A. Yes.

7 Q. And you said you changed the name to
8 Osseo-Restore. When was that, approximately?

9 A. In 2000 -- when we applied for a
10 trademark.

11 Q. Was it after 2018?

12 A. No. It was prior, maybe. I can't --
13 I can't recall the year. I'm sorry. It may
14 have been after 2018. I can't recall exactly.

15 Q. We don't want you to guess, Doctor.
16 What was the full name that you changed it to?

17 A. The Osseo-Restore Appliance. There
18 was a fixed facial, a fixed lingual, and
19 removable.

20 Q. When I refer to AGGA during this
21 deposition, I am talking about a Fixed Anterior
22 Growth Guidance Appliance, okay? Understand?

23 A. Well, no, because the Anterior Growth
24 Guidance Appliance is not the Osseo-Restore
25 Appliance. It has changed over time.

1 S. Galella, D.D.S.

2 Q. I am going to show you Exhibit 10
3 from your day one deposition, and I am going to
4 show you some photographs, sir. It's the
5 fourth page of Exhibit 10. Do you recognize
6 the appliance in that fourth page?

7 A. Could you put it in the center of the
8 screen, please? It's cut off halfway.

9 Q. Let me try another one. Can you see
10 that?

11 A. It's still cut off, but I can see
12 half of it.

13 Q. Can you identify the appliance? I am
14 scrolling through some photographs. Can you
15 identify it?

16 A. Half of it is covered up by the
17 images of the attendees. It's not in the
18 center of the screen.

19 Q. You can move that box, or you can
20 minimize that box for a moment and be able to
21 see the whole screen.

22 (Pause in the proceedings.)

23 Q. What appliance are we looking at on
24 the fourth page of Exhibit 10? Is that a Fixed
25 Anterior Growth Guidance Appliance, Doctor?

1 S. Galella, D.D.S.

2 A. Hang on. Let me look at it, please.

3 Q. I have other views if you want. Just
4 let me know.

5 A. It appears to be an Osseo-Restore
6 Appliance.

7 Q. This was part of John's Dental
8 production in regard to my client, Boja
9 Kragulj, in 2018. If this product was being
10 sold in 2018, would it be an Anterior Growth
11 Guidance Appliance?

12 MR. FUMOSA: Objection to form.

13 A. If it was from John's Dental Lab,
14 they may have called it the Anterior Growth
15 Guidance Appliance, but that appears to be the
16 appliance, that adaptation of the appliance.

17 Q. Would it be fair to call -- sorry. I
18 didn't mean to step on you. Go ahead.

19 A. And that adaptation of the appliance
20 to fit the models in this particular case.

21 Q. Would it be fair to call this a Fixed
22 Anterior Growth Guidance Appliance?

23 A. Facial version.

24 Q. Facial version. Yes. Thank you.
25 Let me just show you another shot of the

1 S. Galella, D.D.S.

2 seventh page of Exhibit 10. Is that the same
3 type of appliance?

4 A. It appears to be.

5 Q. Thank you. So when I speak about
6 AGGA or Anterior Growth Guidance Appliance in
7 this deposition, unless I tell you otherwise, I
8 am talking about a Fixed Anterior Growth
9 Guidance Appliance Facial. Do you understand?

10 A. I understand, but the issue to me is
11 if it's an appliance that was designed by me --
12 there are a lot of appliances that are called
13 AGGA that aren't the AGGA appliance, so you are
14 trying to put it in the same boat as other
15 appliances made by other labs that don't
16 understand the principle of it.

17 I prefer -- I prefer you call it the
18 Osseo-Restore, and then we know it's the
19 appliance that I designed and we are talking
20 about.

21 Q. Can we call the appliances I just
22 showed you in Exhibit 10 Osseo-Restore? Would
23 that be a fair --

24 A. Yes.

25 Q. I will use Osseo-Restore to make you

1 S. Galella, D.D.S.

2 happy.

3 A. Thank you.

4 MR. FUMOSA: I just want to comment,
5 it's not a question of making him happy. It's
6 a question of making it accurate.

7 MR. CHARNAS: Yes.

8 Q. And we have the added advantage of
9 having both, right, Doctor?

10 MR. FUMOSA: Next question, please.

11 Q. Are you familiar with Dr. David Buck?

12 A. Yes.

13 Q. He is a dentist, correct?

14 A. Yes.

15 Q. And he practices in Seattle?

16 A. Yes.

17 Q. Let me show you a document which we
18 had premarked as Exhibit 18. Can you see that
19 document, Doctor?

20 (Document premarked Exhibit 18.)

21 A. Yes.

22 Q. Can you read it? I am not asking you
23 to read it. I just want to know if you can
24 read it.

25 A. Off the screen, no. It's too small.

1 S. Galella, D.D.S.

2 Q. How about now?

3 A. Yes.

4 Q. Do you consider yourself a mentor to
5 Dr. Buck?

6 A. No.

7 MR. FUMOSA: Let me just stop right
8 here. I have an objection to this entire line
9 of questioning about Dr. Buck. Dr. Buck is not
10 a treating dentist. Dr. Buck is not an expert
11 witness, as you have indicated.

12 I am going to allow the doctor to
13 answer, but I am going to object to this entire
14 line of questioning about Dr. Buck as being
15 totally irrelevant with respect to the
16 allegations in this lawsuit.

17 Go ahead.

18 MR. CHARNAS: Before you answer that,
19 sir, I only have five hours to ask questions,
20 so speaking objections are inappropriate. If
21 you have an objection, just make it. I am
22 going to start timing any objections beyond the
23 word "objection" or brief description of it,
24 and I intend to tack that time on to the five
25 hours to make sure I get a total of five hours.

1 S. Galella, D.D.S.

2 MR. FUMOSA: Counsel, I am explaining
3 for the record the basis of my objection, okay?
4 Now, we just wasted a minute with your
5 gratuitous comments, so if you want to
6 continue, fine.

7 MR. FELD: I join in the objection by
8 Mr. Fumosa.

9 Q. Now, sir, would you just read that
10 post to yourself? I am going to ask you some
11 questions about it.

12 (Pause in the proceedings.)

13 A. Could you do the next page, please?

14 Q. That's it. Have you read it?

15 A. I have read it.

16 Q. Thank you. Did you certify at some
17 point Dr. Buck to teach other dentists about
18 Osseo-Restore on behalf of Las Vegas Institute?

19 MR. FELD: Objection to form.

20 MR. FUMOSA: Objection. You can
21 answer.

22 A. Can you repeat the question again,
23 please?

24 Q. At some point did you certify Dr.
25 Buck to teach other dentists about

1 S. Galella, D.D.S.
2 Osseo-Restore on behalf of Las Vegas Institute?

3 MR. FELD: Objection to form.
4 Relevance.

5 A. On behalf -- rephrase the question.
6 I'm sorry. I don't understand how you -- what
7 you're trying to say.

8 Q. Sure. At some point did you certify
9 Dr. Buck to teach Osseo-Restore, to teach about
10 the appliance?

11 MR. FUMOSA: Objection. You can
12 answer.

13 MR. FELD: Same objection to form.

14 A. I didn't certify anybody, no, sir.

15 Q. So the third line at the top there
16 where he says "and I am certified by him to
17 teach this revolutionary material to other
18 dentists," is it your testimony that you
19 certified him for nothing?

20 MR. FUMOSA: Objection to the form.

21 Q. Let me ask that question again,
22 Doctor. Is it your testimony that you have
23 never certified Dr. Buck for anything?

24 MR. FUMOSA: Objection to the form.

25 MR. FELD: Objection.

1 S. Galella, D.D.S.

2 A. That's not what I said, no, sir. I
3 said --

4 Q. Go ahead.

5 A. I didn't certify him to teach on
6 behalf of LVI, no.

7 Q. Did you certify Dr. Buck to teach
8 anything?

9 MR. FELD: Objection. Vague.

10 MR. FUMOSA: Objection to the form.

11 A. Certification, I'm sorry, what do you
12 mean by certification?

13 Q. I am just using the term Dr. Buck
14 used in his post, where he said "I am certified
15 by him to teach."

16 A. No, it is not a certification to
17 teach orthodontics.

18 Q. Did you ever teach Dr. Buck about
19 Osseo-Restore?

20 A. Yes.

21 Q. When you taught him about
22 Osseo-Restore, was it in the context of his
23 becoming, to your knowledge, a teacher himself
24 about Osseo-Restore?

25 MR. FELD: Objection. Form.

1 S. Galella, D.D.S.

2 MR. FUMOSA: Go ahead. You can
3 answer.

4 A. It was at a course. He took a
5 course, and that's not a certification. He
6 received credit hours, but it's not a
7 certification.

8 Q. I see. Thank you. And where was
9 that course taught?

10 A. It was Costa Mesa, California, I
11 believe.

12 Q. Did you ever certify Tim Gross, I
13 should say Dr. Tim Gross, in regard to
14 Osseo-Restore?

15 MR. FUMOSA: Objection. Irrelevant.
16 You can answer.

17 A. No.

18 Q. Do you know who Dr. Tim Gross is?

19 A. Yes.

20 Q. Do you know whether Dr. Tim Gross
21 teaches courses on Osseo-Restore?

22 MR. FUMOSA: Objection. Go ahead.

23 A. Yes. He was -- there was an
24 agreement between Dr. Gross and Dr. Buck that
25 they could teach my material of my protocol

1 S. Galella, D.D.S.

2 under the certain circumstances that it would
3 be an introductory course to the Osseo-Restore
4 Appliance and controlled arch technique.

5 MR. FUMOSA: Move to strike as
6 irrelevant. Go ahead.

7 Q. When was this agreement made, sir,
8 approximately?

9 A. I have no idea. It was 2016, maybe.

10 MR. FUMOSA: Object to this line of
11 questioning. Go ahead.

12 MR. FELD: Join.

13 Q. Was that agreement made between you
14 and Dr. Gross and Dr. Buck, or between you and
15 some other person or entity?

16 A. The agreement was made between both
17 the Matrix -- I was representing both the
18 Matrix and Dr. Gross in two separate agreements
19 that were called NDAs.

20 Q. So there was an agreement between
21 you --

22 MR. CHARNAS: Strike that.

23 Q. There was an agreement between
24 OrthoMatrix and Dr. Gross, and a separate
25 agreement between you and Dr. Buck --

1 S. Galella, D.D.S.

2 MR. CHARNAS: Strike that.

3 Q. There were two agreements, one
4 between OrthoMatrix and Dr. Gross, and one
5 between OrthoMatrix and Dr. Buck, correct?

6 MR. FUMOSA: Objection. Irrelevant.

7 Answer.

8 A. Yes.

9 MR. CHARNAS: Why don't we save time.
10 Why don't we just give you a standing objection
11 that all my questions are irrelevant so you
12 don't have to waste time and bother with it,
13 okay?

14 MR. FUMOSA: I am not going to
15 respond to that. You just wasted time. Please
16 continue.

17 Q. Did OrthoMatrix have any agreement
18 with LVI, to your knowledge, concerning
19 teaching Osseo-Restore or anything to do with
20 Osseo-Restore?

21 MR. FELD: Objection.

22 MR. FUMOSA: Objection. Go ahead.

23 A. No.

24 Q. What were the terms of the agreement
25 between you and Dr. Buck in regard to the

1 S. Galella, D.D.S.

2 teaching of Osseo-Restore?

3 MR. FUMOSA: Objection. Irrelevant.

4 Go ahead.

5 MR. FELD: Objection.

6 A. Dr. Buck would be provided the
7 synopsis, protocol, the information of how and
8 what he was supposed to teach, and then he
9 would -- it was in the aspect that he would --
10 it would be an introductory-type course
11 concerning Osseo-Restore and controlled arch
12 braces technique.

13 There was no agreement between --
14 well, part of the agreement was that he would
15 be given this if he stayed within the
16 protocol, and if not, I would request that he
17 not do that or do a cease and desist.

18 Q. Was it your understanding that
19 Dr. Buck would teach this Osseo-Restore course
20 through or at LVI?

21 MR. FELD: Objection. Relevance.

22 MR. FUMOSA: Objection. Irrelevant.
23 Go ahead, Doctor.

24 A. It was my understanding that -- well,
25 at the time we made the agreement, that that

1 S. Galella, D.D.S.

2 was the premise; that he would teach at LVI,
3 yes.

4 Q. Just for the record, LVI is Las Vegas
5 Institute, correct?

6 A. Yes.

7 Q. And it was the same agreement with
8 Dr. Gross, essentially?

9 A. Yes.

10 Q. Were there any other dentists or
11 dental professionals besides Dr. Gross or
12 Dr. Buck with whom you had a similar
13 arrangement about teaching the material?

14 MR. FUMOSA: Objection. Irrelevant.
15 Go ahead.

16 A. Dr. Anne-Maree Cole from Australia.

17 Q. Anyone else?

18 A. That's all.

19 Q. Was it your understanding that
20 Dr. Anne-Maree Cole would teach her course in
21 Osseo-Restore through LVI?

22 MR. FELD: Objection. Relevance.

23 MR. FUMOSA: Same objection. Answer,
24 please.

25 A. Yes.

1 S. Galella, D.D.S.

2 Q. I'm not sure. Did you see that these
3 agreements with Dr. Buck and Dr. Gross were in
4 approximately 2016?

5 A. I don't recall the year, no, sir, but
6 I think '16. Could have been before, could
7 have been after. I would have to look at a
8 document.

9 Q. Did you receive compensation from
10 either Dr. Buck, Dr. Gross, or LVI for this
11 agreement?

12 MR. FELD: Objection.

13 MR. FUMOSA: Objection. Relevance.
14 You can answer.

15 A. No. By "you," you meant OrthoMatrix
16 or me personally?

17 Q. You or OrthoMatrix.

18 MR. FELD: Objection.

19 A. Neither OrthoMatrix nor myself
20 received any compensation.

21 Q. At the time you made this agreement
22 with these dentists, as you described, Dr.
23 Galella, were you also at the same time or
24 approximately the same time teaching
25 Osseo-Restore through Facial Beauty Institute?

1 S. Galella, D.D.S.

2 MR. FELD: Objection. Asked and
3 answered.

4 A. Yes.

5 Q. Were these dentists, in effect,
6 competitors to you in regard to the teaching of
7 these courses on Osseo-Restore?

8 MR. FUMOSA: Objection. Relevance
9 and form.

10 MR. FELD: Join.

11 MR. FUMOSA: You can answer.

12 A. Repeat the question, please.

13 Q. At the time that you entered into
14 this agreement with Dr. Gross and Dr. Buck, is
15 it fair to say that their teaching the course
16 or courses on Osseo-Restore was in competition
17 with your teaching the same material through
18 FBI?

19 MR. FELD: Objection.

20 A. No.

21 Q. Did you ever travel to Nevada for
22 purposes of teaching Dr. Gross or Dr. Buck
23 concerning Osseo-Restore?

24 MR. FELD: Objection to form.
25 Relevancy.

1 S. Galella, D.D.S.

2 After this question, can we go off
3 the record, please?

4 MR. FUMOSA: Objection. Form.
5 Relevance. Go ahead, Doctor. You can answer.

6 A. Repeat the question. Let me hear it
7 one more time.

8 Q. Did you ever travel to Nevada for
9 purposes of teaching Dr. Gross or Dr. Buck
10 concerning Osseo-Restore?

11 A. No.

12 MR. FELD: Can we go off the record
13 for a second?

14 MR. CHARNAS: Sure.

15 (Discussion off the record.)

16 MR. FUMOSA: The doctor has now left
17 the room.

18 (Witness left the deposition room.)

19 (A recess was taken.)

20 (Witness returned to the deposition
21 room.)

22 Q. Looking further down on this -- can
23 you still see Exhibit 18 on your screen?

24 A. Yes.

25 Q. Do you see my cursor there?

1 S. Galella, D.D.S.

2 A. Yes.

3 Q. Do you see the phrase "face forward
4 horizontal development"?

5 A. Yes.

6 Q. Have you ever seen that phrase
7 before?

8 A. That was a term -- yes.

9 Q. What does that mean, sir?

10 MR. FUMOSA: Objection. You can
11 answer.

12 A. It was a term that LVI used to
13 describe their bastardized technique.

14 Q. Bastardized technique in regard to
15 what, sir?

16 A. Facial development.

17 Q. Let me show you another document,
18 sir, which was marked prior to the deposition
19 as Exhibit 19.

20 (Document premarked Exhibit 19.)

21 Q. Now, I am going to represent to you
22 that this was part of Dr. Buck's website which
23 was recently taken off the internet. I am just
24 going to refer you to -- to give you some
25 context, I am going to scroll to the bottom.

1 S. Galella, D.D.S.

2 Can you see this, by the way?

3 A. No.

4 Q. Do you see it now?

5 A. Yes.

6 Q. The top says Balance Epigenetic
7 Orthodontics. There is a picture of someone on
8 the left. Is that Dr. Buck? Do you recognize
9 him?

10 A. The image is pretty damned small.

11 Q. How about now?

12 A. It appears to be Dr. Buck, yes.

13 Q. And just to give you context in terms
14 of vintage of this, you see on the bottom it
15 says copyright 2016 Balance Epigenetic
16 Orthodontics? Do you see that?

17 A. Yes.

18 Q. In the section that says This is Not
19 Your Parents' Orthodontics, on the third
20 paragraph, can you see there it says "Dr. Buck
21 is a master certified instructor with the
22 Facial Beauty Institute which teaches dentists
23 advanced craniofacial orthopedics and
24 orthodontics?

25 MR. FUMOSA: I am going to object to

1 S. Galella, D.D.S.

2 the inquiry about Dr. Buck and about his
3 website and anything that's on his website as
4 totally irrelevant to the claims being made in
5 this case, but you can answer over objection.

6 MR. FELD: Join.

7 Q. Do you see that?

8 A. Yes.

9 Q. Is it true that Dr. Buck at least at
10 some point was a master certified instructor
11 with the Facial Beauty Institute?

12 MR. FELD: Relevance.

13 A. No.

14 Q. Was Dr. Buck ever an instructor with
15 the Facial Beauty Institute?

16 A. No.

17 Q. Did you know before this deposition
18 that Dr. Buck is claiming to be a master
19 certified instructor with the Facial Beauty
20 Institute at least as of 2016?

21 MR. FUMOSA: Object to the form.

22 Relevance. No foundation. You can answer if
23 you can.

24 MR. FELD: Join.

25 A. Please repeat the question.

1 S. Galella, D.D.S.

2 Q. Sure. Before this deposition, were
3 you aware that Dr. Buck was claiming to be a
4 master certified instructor with the Facial
5 Beauty Institute?

6 MR. FUMOSA: Objection. Go ahead.

7 A. I can't answer that question yes or
8 no. I heard nothing --

9 Q. Were you -- sorry. Say that again,
10 Doctor.

11 A. I can't answer yes or no. I'm sorry.

12 Q. You heard that Dr. Buck was claiming
13 to be an instructor with the Facial Beauty
14 Institute; is that correct?

15 MR. FUMOSA: Objection to the form.

16 A. I may have heard that, yes, but not
17 from him.

18 Q. Just so it's clear, as far as you
19 know, Dr. Buck has never been an instructor
20 with the Facial Beauty Institute or instructed
21 dentists on behalf of the Facial Beauty
22 Institute; is that correct?

23 A. I can't answer it the way you are
24 phrasing it. Can you -- can we break it up in
25 two parts?

1 S. Galella, D.D.S.

2 Q. Sure. What problem are you having
3 with the question, Doctor?

4 A. It's two parts, and I can't answer it
5 that way.

6 Q. Fair enough, fair enough. Has
7 Dr. Buck ever taught any courses in regard to
8 Osseo-Restore on behalf of Facial Beauty
9 Institute, to your knowledge?

10 A. He was permitted to teach the
11 introductory classes, you know, at the Las
12 Vegas Institute with our agreement.

13 Q. Has he ever, to your knowledge,
14 instructed dentists or taught dentists
15 concerning Osseo-Restore in a course or courses
16 under the auspices of the Facial Beauty
17 Institute?

18 A. No.

19 MR. FUMOSA: Object to the line of
20 questioning. Go ahead. Continue, please.

21 Q. Give me a moment, Doctor.

22 A. Sorry. I am getting a little hard of
23 hearing. You have to speak up.

24 Q. I wasn't saying anything, Doctor. I
25 will try to speak up. Thank you.

1 S. Galella, D.D.S.

2 I am just looking through it so I
3 can try to cut out some of these questions for
4 you.

5 Have you ever represented to
6 dentists that Osseo-Restore can give someone
7 cosmetic facelift effect?

8 A. Rephrase the question. It's not
9 making sense to me.

10 Q. Sure. Have you ever represented to
11 dentists that Osseo-Restore can give a patient
12 cosmetic face lift effect?

13 A. No.

14 Q. Doctor, I'm going to show you another
15 exhibit which is premarked as Exhibit 20. I
16 believe that you have seen this exhibit
17 already. I think this is the movie that you
18 spoke about, or video.

19 (Video premarked Exhibit 20.)

20 (Pause in the proceedings.)

21 Q. Can you see that on your screen,
22 Doctor?

23 A. Yes.

24 Q. Again, this is Exhibit 20. The
25 fellow on the top right is Dr. Buck, correct?

1 S. Galella, D.D.S.

2 A. That's correct.

3 Q. I want you to make note that the date
4 on this on the left is November 12 to 14, 2020.
5 As far as you know, was Dr. Buck still
6 permitted in November of 2020 to lecture to
7 dentists on Osseo-Restore? When I say
8 "permitted," I mean permitted by OrthoMatrix.

9 MR. FELD: Objection.

10 A. I don't recall the date we sent the
11 cease and desist letter.

12 Q. Was that cease and desist letter sent
13 in the year 2020?

14 A. I'm sorry. I couldn't hear you.

15 Q. Was that cease and desist letter sent
16 in the year 2020?

17 A. I don't recall.

18 Q. Who sent the cease and desist letter
19 to whom?

20 A. Matrix sent it to Dr. Buck,
21 Dr. Gross, and Dr. Anne-Maree Cole.

22 MR. FUMOSA: Objection to this entire
23 line of questioning as being totally irrelevant
24 to this case. Continue.

25 MR. FELD: Join.

1 S. Galella, D.D.S.

2 Q. Was this --

3 MR. CHARNAS: Did you finish your
4 objection, Alan?

5 MR. FUMOSA: Yes.

6 Q. Was a cease and desist letter also
7 sent to LVI?

8 MR. FELD: Objection.

9 A. There was no relationship with LVI so
10 no cease and desist letter.

11 Q. Who was the signatory to that letter?
12 Who signed the letter?

13 A. Attorney Steven Markowitz.

14 Q. Can you give me the sum and substance
15 of the letter, Doctor, the best you can recall?

16 A. I don't recall. I'm not a lawyer,
17 and I don't recall exactly the words.

18 Q. What was the basis for sending the
19 letter, Doctor?

20 A. The basis was to stop the -- no
21 longer teaching our material. We were
22 withdrawing our permission, and we also -- as
23 part of the requirement they were supposed to
24 destroy the information or return it in five
25 days.

1 S. Galella, D.D.S.

2 Q. And the letter was sent on behalf of
3 OrthoMatrix and yourself; is that correct?

4 A. OrthoMatrix. That was -- the
5 agreement was with OrthoMatrix. I was a
6 principal of OrthoMatrix.

7 MR. FUMOSA: Object to this entire
8 line of questioning. Go ahead.

9 Q. Did you have any input into making a
10 decision to withdraw that permission?

11 MR. FELD: Objection to form.

12 MR. FUMOSA: Form as well objection.
13 Go ahead.

14 A. Yes.

15 Q. Why was that letter sent?

16 MR. FUMOSA: Objection. You can
17 answer.

18 A. What was the question again?

19 Q. Sure. What was the basis for
20 OrthoMatrix having their lawyer send this
21 letter?

22 A. Because the teaching material was not
23 in line with the protocol that was established
24 for teaching. It was not the same technique,
25 it was not the same information. It had been

1 S. Galella, D.D.S.

2 modified.

3 Q. How did you become aware that they
4 were deviating from the course material?

5 MR. FELD: Objection. Relevance.

6 MR. FUMOSA: Same objection. Go
7 ahead.

8 A. Several doctors made comments about
9 the course.

10 Q. I am going to move the video ahead to
11 16 minutes 42 seconds.

12 MR. FUMOSA: While you are doing
13 that, let me state for the record that I object
14 to utilizing a video that was prepared by
15 Dr. Buck that has nothing to do with this
16 patient or this case, as far as I am concerned;
17 to question Dr. Galella about it at his
18 deposition. Go ahead.

19 MR. FELD: Join.

20 MR. CHARNAS: I am going to for the
21 record state my objection to the continuous or
22 continual speaking objections, which are
23 completely inappropriate, which reduce my time
24 for asking questions.

25 If it persists, I will take further

1 S. Galella, D.D.S.

2 action.

3 Q. Now, at 16:42 sir, I stopped it, and
4 you can see on the top left there it says key
5 principles regarding the Anterior Growth
6 Guidance Appliance. Do you see that there?

7 A. Yes.

8 Q. And on the right center it says
9 Inventor: Dr. Steve Galella. Do you see that?

10 A. Yes.

11 Q. Below that where it says your name,
12 there's an appliance, a photograph of an
13 appliance, correct?

14 A. Yes.

15 Q. Is that an Osseo-Restore device?

16 A. It appears to be.

17 Q. Is that the same model, can you tell,
18 of an Osseo-Restore device which were in the
19 photographs I showed you in Exhibit 10 of
20 John's Dental?

21 MR. FELD: Objection. Form,
22 foundation.

23 MR. FUMOSA: Join.

24 A. It's a pretty small image. I
25 couldn't say exactly. It appears to be.

1 S. Galella, D.D.S.

2 Q. I can't make it bigger because it is
3 a video, but it appears to be that device; is
4 that fair to say?

5 MR. FELD: Same objection.

6 MR. FUMOSA: Join.

7 A. It appears to be. There are some
8 minor differences that I can't tell.

9 Q. Now I am going to move it forward,
10 that video forward, to 20:59, and I want you to
11 listen -- I am going to play it from 20:59 to
12 approximately 21:28 on the video, and I want
13 you to listen to what Dr. Buck says, and I am
14 going to ask you one or two questions about it.

15 If you have any trouble hearing it,
16 Dr. Galella, let me know and I will try to
17 make it louder.

18 MR. FELD: Before you play the video,
19 is this marked as an exhibit?

20 MR. CHARNAS: It is marked as
21 Exhibit 20.

22 (Pause in the proceedings.)

23 MR. FUMOSA: There is no sound.

24 MR. CHARNAS: You can't hear it? I
25 am not going to belabor it then.

1 S. Galella, D.D.S.

2 Q. Is one of your claims concerning
3 Osseo-Restore that it can change the gonial
4 angle of the ramus by as much as 11 degrees?

5 MR. FELD: Objection to form.

6 MR. FUMOSA: Join.

7 A. I can't answer it as you are asking
8 it because you are being specific 11 degrees.
9 I never said that.

10 Q. Is it your claim that Osseo-Restore
11 can change the gonial angle of the ramus?

12 MR. FUMOSA: Objection to form.

13 MR. FELD: Join.

14 MR. CHARNAS: What is your objection
15 to the form?

16 MR. FUMOSA: You are wasting time.

17 MR. CHARNAS: That is your objection?

18 MR. FUMOSA: You don't want me to
19 explain so I am wasting time by explaining.
20 Objection to form.

21 MR. FELD: My issue is the word
22 claim.

23 Q. Do you want that question back,
24 Doctor?

25 A. Yes, please.

1 S. Galella, D.D.S.

2 Q. Is one of the claims you make about
3 Osseo-Restore that it can change the gonial
4 angle of the ramus?

5 MR. FUMOSA: Objection to form.

6 MR. FELD: Join.

7 A. I have indicated that it may change
8 the gonial angle depending on the growth
9 pattern of the mandible based on several
10 factors, not just the appliance, but nasal
11 breathing, the head posture, et cetera. It's a
12 complex subject.

13 Q. Have you made any representations as
14 to the amount of change in the gonial angle of
15 the ramus that can be accomplished by
16 Osseo-Restore?

17 MR. FELD: Objection to form.

18 MR. FUMOSA: Objection to form.

19 A. No.

20 Q. Do you have an opinion as to the
21 amount of change in the gonial angle of the
22 ramus that one of your Osseo-Restore devices
23 can make?

24 A. Rephrase the question.

25 MR. FELD: Can we just narrow down

1 S. Galella, D.D.S.

2 time frame, Scott?

3 Q. We are talking about the
4 Osseo-Restore device that I showed you in
5 regards to Exhibit 20 of the John's Dental
6 production. Talking about that device, do you
7 have an opinion as to the amount of change in
8 the gonial angle of the ramus of the maxilla
9 that that device can cause or create?

10 A. No. It could change zero, it could
11 increase, or it could decrease. It just
12 depends on the circumstances of each patient.

13 Q. Depending on the circumstances of a
14 patient, could it increase as much as
15 11 degrees?

16 A. I have no idea. I never measured.

17 Q. Can you see an image on your screen,
18 Doctor, of --

19 A. Yes.

20 Q. At 22:05 of Exhibit 20, on the top
21 left it says Fixed Osseo-Restore Growth
22 Guidance Appliance, with the trademark
23 expression.

24 Did you ever call your Osseo-Restore
25 devices or any of your Osseo-Restore devices

1 S. Galella, D.D.S.

2 Fixed Osseo-Restore Growth Guidance Appliance?

3 A. I'm sure if it's written there I must
4 have. That's one of my slides.

5 Q. What does the term "growth" mean in
6 that term?

7 MR. FUMOSA: Off the record a second.

8 (Discussion off the record.)

9 MR. CHARNAS: I believe you just
10 coached the witness off the record.

11 MR. FUMOSA: I did not coach the
12 witness. I wanted to make sure the doctor
13 understood what he was looking at. That's all.

14 MR. CHARNAS: From now on, we are
15 only going off the record unless we all agree
16 to go off the record.

17 MR. FUMOSA: Okay, fine.

18 Q. Sir, this is your term, right, Fix
19 Osseo-Restore Growth Guidance Appliance, right?

20 A. Yes.

21 Q. What does the term "growth" mean in
22 that name?

23 A. It's a term that most dentists and
24 lay people do not understand the difference
25 between growers and non-growers.

1 S. Galella, D.D.S.

2 In this particular instance, this is
3 a 54-year-old patient, so a non-grower. It
4 means remodeling.

5 Q. You are saying growth in that context
6 is a term that dentists don't know?

7 MR. FELD: Objection to form.

8 MR. FUMOSA: Object to the form.

9 Q. You could answer.

10 A. I said that a lot of dentists don't
11 understand the difference between growers and
12 non-growers, and so this was used as a
13 reference, meaning remodeling in this
14 particular instance.

15 Q. Is there a reason you didn't call it
16 Fixed Osseo-Restore Remodeling Guidance
17 Appliance?

18 A. There's no appliance in there, so why
19 even say appliance?

20 Q. Well, the word "appliance" is right
21 here.

22 A. I know, but there is no appliance in
23 the mouth on those images, so it was just a
24 term. It's just a label for a slide that's in
25 this case he wasn't authorized to use my

1 S. Galella, D.D.S.

2 material.

3 Q. But the trademark designation, that's
4 trademarked by you, or OrthoMatrix, or somebody
5 else, to your knowledge?

6 MR. FELD: Objection.

7 MR. FUMOSA: Objection. Go ahead.

8 A. OrthoMatrix. Thank you for showing
9 that, because that's unauthorized use of my
10 material.

11 Q. You're welcome. I am just trying to
12 figure out what you were trying to convey by
13 using the word "growth" in that title of your
14 appliance, so What were you trying to convey by
15 using the word "growth" in Fixed Osseo-Restore
16 Growth Guidance Appliance?

17 MR. FELD: Objection. Asked and
18 answered.

19 MR. FUMOSA: Same objection. Go
20 ahead.

21 A. Remodeling. There was a change in
22 the structure. In this case, it was
23 remodeling.

24 Q. You will see there it says "copyright
25 2018 FBI/Inside Dentistry, Inc., all rights

1 S. Galella, D.D.S.

2 reserve." I assume the D is cut out. All
3 rights reserved; is that right, Doctor?

4 A. Yes.

5 Q. Did you personally create -- strike
6 that.

7 We are looking at two skull-like
8 images or skeletal images, correct, generally
9 speaking?

10 A. Correct.

11 Q. Did you create this image personally?

12 MR. FELD: Form.

13 A. Yes.

14 Q. Did you create it for OrthoMatrix?

15 MR. FELD: Form.

16 A. Yes, as part of the teaching process,
17 yes.

18 Q. Is it fair to say that you used
19 Anatomage as the software for creating these
20 two images?

21 MR. FELD: Form, foundation.

22 MR. FUMOSA: Same objection. Join.

23 MR. FELD: You can answer, Doctor.

24 A. Anatomage was most likely the
25 software that I used.

1 S. Galella, D.D.S.

2 Q. Do you recall what view setting you
3 used when you created this Anatomage image or
4 images?

5 A. So let's -- you are talking about
6 this particular slide.

7 Q. Yes.

8 A. So Anatomage was used to orient the
9 bone structures that you see visible, but it
10 was done -- the complete slide was done in
11 PowerPoint.

12 Q. I understand.

13 A. I didn't mean to mislead you on that.

14 Q. I appreciate you clarifying that. Is
15 it fair to say that the images were created in
16 Anatomage and then PowerPoint was used to put
17 them in a presentation form such as what we are
18 looking at now?

19 A. The images were viewed in Anatomage
20 and screenshots were taken in Anatomage of the
21 bony structures that you see.

22 Q. When you were using Anatomage to
23 create these images, did you have it in a
24 particular setting, for example volume
25 rendering?

1 S. Galella, D.D.S.

2 MR. FELD: Objection. Relevance.

3 MR. FUMOSA: Join. Go ahead.

4 A. Question, please?

5 Q. I don't blame you.

6 A. Sorry.

7 Q. When you used and -- let me strike
8 that.

9 Anatomage has different view
10 settings that one can use to view images,
11 correct?

12 A. Yes.

13 Q. Do you recall what view setting you
14 had Anatomage in that made this or these two
15 images?

16 MR. FELD: Relevance.

17 MR. FUMOSA: Join.

18 A. It was more than likely the -- yes --
19 say it -- are you implying --

20 Q. I am not implying a setting. I am
21 asking what setting you used?

22 A. It was the volume render that allows
23 you to see and resize it, orient, et cetera,
24 thinking about what I did.

25 Q. When you used Anatomage in the volume

1 S. Galella, D.D.S.

2 rendering mode, is it important to make sure
3 that your --

4 MR. CHARNAS: Strike that.

5 Q. When you are using Anatomage in the
6 volume rendering mode to make comparisons
7 between different images, is it important to
8 make sure that settings such as lighting,
9 rotation, magnification, settings such as that,
10 are the same for both images?

11 MR. FELD: Objection. Form,
12 foundation, relevance.

13 MR. FUMOSA: Join.

14 A. I don't think I can answer it the way
15 you are asking it. Can you rephrase it so it
16 makes more sense? I am trying to understand
17 it.

18 Q. Let me try it a different way. When
19 you made those two images, you were trying to
20 compare one image to the other for certain
21 purposes, correct?

22 A. Yes.

23 Q. What purposes were you trying to
24 compare one image to the other?

25 A. The structural change.

1 S. Galella, D.D.S.

2 Q. Structure change to the bone?

3 A. Yes.

4 Q. Would that include any forward
5 advancement of the maxilla?

6 MR. FELD: Objection. Foundation.

7 MR. FUMOSA: Join.

8 A. We went through this last time, that
9 the maxilla in non-growers doesn't advance; it
10 remodels. So I'm sorry about -- maybe I'm
11 being quirky, but you don't advance the maxilla
12 in non-growers. It remodels.

13 Q. Were you looking to see whether the
14 maxilla moved forward in any way, whether you
15 call it growth or remodeling?

16 A. The remodeling.

17 Q. You were looking to see whether the
18 maxilla moved forward, correct?

19 A. Remodeled.

20 Q. The net result of remodeling is
21 forward movement of the maxilla, correct?

22 MR. FELD: Objection to form.

23 MR. FUMOSA: Objection to form.

24 A. You are talking in lay terms. I am
25 talking in medical/physiological/scientific

1 S. Galella, D.D.S.

2 terms.

3 Q. We'll get back to that, Doctor.

4 Would it be important to make sure
5 when you are comparing one image to the other
6 that all the settings for an Anatomage program
7 were the same for each?

8 MR. FELD: Vague.

9 MR. FUMOSA: Objection to the form.

10 A. In this particular case, we tried to
11 make the comparisons that the images are
12 approximately the same size, so you could see a
13 difference. In other situations you may have
14 to put a calibration module inside so that you
15 can measure.

16 Q. Would it be important if the angle of
17 rotation of the two images was identical?

18 A. Yes.

19 Q. And did you take any steps to make
20 sure that angle of rotation of the two images
21 was, in fact, identical?

22 A. In this particular case, yes.

23 Q. I am only talking about this
24 particular case now. Did you make any attempt
25 to determine whether the lighting, opacity,

1 S. Galella, D.D.S.

2 contrast and brightness were the same for both?

3 A. They were, yes.

4 Q. And how did you do that exactly, make
5 sure that they were identical?

6 A. Do you have an hour?

7 Q. I have five hours.

8 A. Then I'll take an hour, and I'll be
9 glad to demonstrate.

10 Q. Can you give me a brief description
11 of what you did to make sure that these two
12 images were shown in the same identical light,
13 including contrast, brightness, and opacity?

14 MR. FUMOSA: Objection to the form.

15 A. There are settings in Anatomage that
16 allow you to adjust, and in each particular
17 case the images were taken by the same machine.
18 Since there are variances in machines and there
19 is variances in the voxels, variances in the
20 intensity of the X-ray, X-ray radiation can
21 change the difference in the sensors.

22 In this particular case, the images
23 were from the same machine so you can set the
24 sliding bars to approximately the same amount
25 to get the contrast, brightness, and opacity.

1 S. Galella, D.D.S.

2 Q. So you made sure that the contrast,
3 brightness, and opacity settings were the same
4 for both images. Is that your testimony?

5 A. Yes.

6 Q. Thank you, Doctor.

7 MR. CHARNAS: Can we take a
8 five-minute break everybody.

9 MR. FUMOSA: That's fine.

10 (A recess was taken.)

11 Q. Doctor, I am going to show you what
12 was premarked as Exhibit 24. Can you see that
13 on your screen, the first page?

14 (Document premarked Exhibit 24.)

15 A. Yes.

16 Q. Do you see it says Patient 1,
17 TMJ/craniofacial pain?

18 A. Yes.

19 Q. I am going to represent to you this
20 is 31 pages, and it was produced for five
21 patients by your attorney in the course of this
22 litigation.

23 You are familiar with these
24 documents, correct?

25 A. Yes.

1 S. Galella, D.D.S.

2 Q. Did you collect these documents
3 yourself?

4 MR. FUMOSA: Object to the form.

5 MR. CHARNAS: Let me rephrase that.

6 Q. Did you put these 31 pages together
7 for these five patients?

8 A. Yes.

9 Q. What were you trying to do when you
10 were collecting those papers for this document?

11 A. Could you rephrase that question?

12 Q. What was your understanding as to
13 what you were attempting to accomplish by
14 collecting these documents?

15 A. To demonstrate that the Osseo-Restore
16 Appliance works in the sagittal direction and
17 in the transverse direction.

18 Q. When you said "works in the sagittal
19 direction," what do you mean by that?

20 A. You had referred previously in the
21 deposition that using the word sagittal, so
22 anterior/posterior dimension, that it remodels
23 in that direction. That's what I was showing.

24 Q. You have made over the years certain
25 claims about what AGGA or Osseo-Restore can

1 S. Galella, D.D.S.

2 accomplish. Were there any other claims that
3 you made other than this sagittal direction
4 movement that you just spoke of concerning what
5 Osseo-Restore can do?

6 MR. FELD: Objection to form.

7 A. I used the term three-dimensional
8 when I described the appliance,
9 three-dimensional changes.

10 Q. Right. That would include changes in
11 the airway, correct?

12 A. The description of what the appliance
13 does, we talk about the three-dimensional
14 changes in the bony or osseous structure.

15 Q. Isn't it fair to say that one of the
16 claims that you have made about the
17 Osseo-Restore device is that it can make
18 changes to the airway?

19 MR. FUMOSA: Objection to the form.

20 MR. FELD: Join.

21 A. I have not -- studies are being done,
22 I'm sure, but there's no evidence that it does
23 or does not affect the airway; you know, the
24 literature.

25 Q. I am asking about your claim, sir.

1 S. Galella, D.D.S.

2 A. No.

3 Q. You never made such a claim?

4 A. I may have said that it is possible
5 the airway can change, but I have no proof.

6 Q. Is it fair to say if any dentist
7 trained by you put an Osseo-Restore device in a
8 patient for the purpose, among others, of
9 making changes to the airway, that would be
10 something that you hadn't authorized, correct?

11 MR. FUMOSA: Objection. Form. No
12 foundation. Speculative.

13 Go ahead.

14 Rephrase it.

15 MR. CHARNAS: Sure.

16 Q. You have never told a dentist, any
17 dentist, including Dr. Cortes, that using an
18 Osseo-Restore device on a patient can make
19 changes to the patient's airway; is that
20 correct?

21 A. The way you phrased the question, I
22 can answer that I have no -- I didn't say the
23 word "can." I said it may, it's possible, but
24 it may not. It all depends on other factors.

25 Q. What other factors?

1 S. Galella, D.D.S.

2 A. Nasal breathing, lip seal, no tongue
3 habit, head posture, cranial strain,
4 malocclusion, et cetera, et cetera.

5 Q. So it's fair to say that you have
6 told dentists that the Osseo-Restore device may
7 under certain circumstances make changes in a
8 patient's airway; is that correct?

9 MR. FUMOSA: Object to the form.

10 A. Please rephrase it so I can
11 understand it.

12 Q. Sure.

13 MR. CHARNAS: Can you read the
14 question back, please?

15 (Record read.)

16 A. And you were going to rephrase it for
17 me.

18 Q. What problem do you have with that
19 question, Doctor, so I can help you?

20 A. The ending.

21 Q. Did you ever tell any dentists that
22 under certain circumstances, a patient's airway
23 can be changed by an Osseo-Restore device?

24 A. No.

25 Q. Are there any other claims that you

1 S. Galella, D.D.S.
2 have made about the Osseo-Restore device in
3 terms of its efficacy that you believe the five
4 patient documents support under than the change
5 in the sagittal direction that you talked
6 about?

7 MR. FUMOSA: Objection to the form of
8 the question.

9 A. Can you rephrase it? Because you
10 are -- just rephrase. I don't understand.

11 Q. Sure. You have told us that you
12 gathered these five patient documents because
13 you wanted to show or prove that the
14 Osseo-Restore device can make changes in the
15 sagittal direction, correct?

16 A. No, not correct.

17 Q. Let me ask you again. What were you
18 hoping to accomplish or what were you trying to
19 accomplish by gathering these documents in
20 Exhibit 24?

21 MR. FUMOSA: Asked and answered.

22 Q. What proof?

23 MR. FUMOSA: Asked and answered. You
24 can answer it again.

25 A. It's hard to measure the

1 S. Galella, D.D.S.
2 three-dimensionals, but I could measure the
3 sagittal, and if you looked at the documents,
4 you will see that there's a transverse, or
5 width, measurement included in the document, so
6 you are limiting your question to just one
7 aspect instead of the full picture.

8 Q. You are right. I apologize. I'm
9 sorry. So you were trying to show proof by
10 gathering these documents in Exhibit 24 of
11 changes in the nasomaxillary complex including
12 the transverse changes and changes in the
13 sagittal plane; is that fair?

14 A. That's fair.

15 Q. Anything else you were trying to
16 accomplish in terms of proof in those five
17 documents or these five sets of documents?

18 A. The measurements were not
19 measurements, but the lines or planes on the
20 inferior border of the mandible and the
21 posterior border of the ramus were utilized so
22 you could see if there was any difference in
23 the gonial angle of the mandible. Any
24 remodeling, slash, of the mandible as well as
25 the maxilla you could see the remodeling.

1 S. Galella, D.D.S.

2 Q. Did anyone assist you in the endeavor
3 to put together these five patient files or
4 documents?

5 A. Could you rephrase that, please?

6 Q. Sure. Did anybody help you put these
7 documents together in Exhibit 24?

8 A. No.

9 MR. FELD: Sorry to interrupt. Can
10 we just put on the record and stipulate that
11 these documents were also produced pursuant to
12 court order and pursuant to a demand you made?
13 I'm not sure that's clear on the record.

14 MR. FUMOSA: Join in that.

15 MR. CHARNAS: That's fine with me.
16 These documents were produced pursuant to a
17 court order.

18 Q. Did you understand that, Dr. Galella?

19 MR. FUMOSA: And pursuant to a demand
20 that you made.

21 MR. CHARNAS: Yes.

22 A. Yes.

23 Q. Other than the sagittal changes, the
24 transverse changes, and the gonial angle
25 changes, is there anything else that you were

1 S. Galella, D.D.S.

2 trying to prove when you put together these
3 documents in Exhibit 24?

4 MR. FUMOSA: Object to the form. Go
5 ahead.

6 A. It's my understanding that you wanted
7 proof that the Osseo-Restore Appliance works.

8 Q. Your claims concerning that, yes,
9 sir. And you did that?

10 MR. FUMOSA: Object to the form.

11 A. I did what? I'm sorry. Rephrase
12 that.

13 Q. Is it fair to say that these
14 documents in Exhibit 24, as far as you
15 understand it, prove your claims as to the
16 efficacy of AGGA?

17 MR. FUMOSA: Object to the form.

18 A. Based on what was asked of me, that's
19 what I was trying to prove, yes.

20 Q. I think you have testified earlier
21 that you have over 600 patient files for
22 patients who have received fixed AGGA devices;
23 is that correct?

24 A. If that's what I said in my previous
25 deposition.

1 S. Galella, D.D.S.

2 Q. What criteria did you use to cull the
3 documents in Exhibit 24 from those 600 or more
4 documents?

5 MR. FELD: Objection. Form.

6 MR. FUMOSA: Also join.

7 A. Okay. Let's rephrase that so -- you
8 are asking for a lot of information here.

9 Q. Why don't you take us through the
10 process, Doctor. You were informed that you
11 were supposed to do something in regard to a
12 court order. What did you do when you were
13 informed that you were supposed to do something
14 in regard to a court order?

15 MR. FELD: I am just going to
16 instruct the witness not to disclose any
17 discussions he had with either me or Mr. Fumosa
18 or anyone from our office as those are
19 privileged.

20 MR. CHARNAS: I asked what he did,
21 not what he said or heard.

22 Q. What did you do, sir?

23 A. Reviewed the patient records and
24 picked out the patients that had as close as I
25 could get to -- there was a transition of use

1 S. Galella, D.D.S.

2 of machines. I tried to keep the machines the
3 same machine so that the variables would be
4 minimal, and then I took it and completed the
5 thing.

6 I used various agents with a
7 criteria of one had to be over 35, and blah
8 blah blah, and some were post-op four or five
9 years, so it showed how stable it was; that
10 kind of thing.

11 Q. Did you look through all 600 plus
12 cases?

13 A. No.

14 Q. How did you choose which five?

15 A. I'm sorry. The question is how did I
16 choose?

17 Q. I would like to know did you take the
18 first five cases you found for people over the
19 age of 30, or some other methodology?

20 MR. FUMOSA: Object to the form.

21 A. I tried to get some -- enough -- you
22 know, simple before and after, before and
23 before for a full five years, maybe right out
24 of the appliance. I tried to get a variety of
25 examples that would give you a broader view of

1 S. Galella, D.D.S.

2 results.

3 Q. You used Anatomage to create the
4 views that are in the documents Exhibit 24?

5 A. Is this Exhibit 24? I'm sorry.

6 Q. Yes. This is the five patient cases.
7 This is Exhibit 24. You used Anatomage, right?

8 A. Anatomage, yes, and then I put them
9 in PowerPoint to do the labeling.

10 Q. When you say the labeling --

11 A. In order to label, there's no --
12 Anatomage doesn't have -- it has a system, but
13 it's not very user friendly, so I put them in
14 PowerPoint so that I could label the
15 measurements based on the grid that was
16 provided by Anatomage.

17 MR. CHARNAS: Could you read his
18 answer?

19 (Record read.)

20 Q. When you say label the measurements,
21 Dr. Galella, for example, looking at the second
22 page of Exhibit 24, you are talking about
23 4.92 millimeters and 8.03 millimeters? That's
24 what you mean by labeling the measurements?

25 A. Yes.

1 S. Galella, D.D.S.

2 Q. Do you remember testifying that
3 Dr. Bromage's overlay method is the definitive
4 method for measuring growth?

5 A. Yes.

6 Q. Did you use Dr. Bromage's overlay
7 method to look for changes in the nasomaxillary
8 complex of these five patients?

9 A. No.

10 Q. Can you tell us why not?

11 A. Well, in order to use his method, you
12 have to have a full head shot of a craniofacial
13 complex, front brain and inferior brain, and
14 some of these images, that part was cut off.

15 Additionally, the Bromage technique
16 is not perfected yet. We're still working on
17 it to be very accurate, so it wasn't quite at
18 the final stages yet.

19 Q. Do you still consider it the
20 definitive method for measuring growth?

21 A. Yes. It should be as soon as
22 everything is finished and it's published.

23 Q. There are over 600 patient files. Is
24 it your testimony that none of those patient
25 files contained sufficient photographic

1 S. Galella, D.D.S.

2 evidence for you to use Dr. Bromage's overlay
3 system?

4 MR. FUMOSA: Objection to the form,
5 and also no foundation.

6 A. Repeat the question, please.

7 Q. Did you look through your 600 plus
8 cases to see whether any of them contained
9 sufficient photographic evidence such that
10 Dr. Bromage's overlay system could be used?

11 MR. FUMOSA: Objection. No
12 foundation.

13 A. You are using the term "photographic
14 evidence."

15 Q. You said that one of the reasons, if
16 I understood it, the reason that you couldn't
17 have used Dr. Bromage's overlay on these five
18 patients was that there wasn't sufficient
19 either photographic evidence or imagery of some
20 kind; is that correct?

21 A. I didn't say the word "photographic,"
22 no, sir.

23 Q. So these five patients lacked some
24 sort of imagery which would have allowed you to
25 do or apply Dr. Bromage's overlay system; is

1 S. Galella, D.D.S.

2 that correct?

3 MR. FUMOSA: Objection to form.

4 A. There were some with the same machine
5 and the full thing, but the overlay system was
6 not completed. It's not finished. There was a
7 couple of flaws that we have to work out, or
8 Dr. Bromage has to work out.

9 Q. I guess I'm a bit confused. If it's
10 flawed and not completed, how could it be the
11 definitive method for measuring growth?

12 A. Well, the problem is the sizing of
13 the images to do the overlay, and Anatomage and
14 other software doesn't have that capability to
15 accurately size. That's the problems we're
16 working out.

17 We have to find a way to make them
18 exactly the same size for the overlay.

19 In order to do the overlay, it would
20 take -- it takes several hours to complete
21 this, the sizing, because it's almost like a
22 trial and error.

23 Q. Is it your testimony that you could
24 have used the overlay system but you didn't
25 because it was too time consuming?

1 S. Galella, D.D.S.

2 MR. FUMOSA: Objection to the form.

3 A. Please rephrase the question.

4 Q. If I understood your testimony, you
5 told us that using the overlay system could
6 take a few hours, correct?

7 A. It could, yes, sir.

8 Q. Is that the reason that you didn't
9 use the overlay system to provide proof of your
10 claims about the changes to the nasomaxillary
11 complex because it would be too time consuming?

12 MR. FELD: Asked and answered.

13 MR. FUMOSA: Object to the form.

14 A. It would be time consuming, and I'm
15 not capable of getting the sizes correct yet.
16 I'm not good at it yet. I didn't have that
17 ability.

18 Q. Other than Dr. Bromage's overlay
19 system and the Anatomage system that you used
20 for the five cases, is there any other method
21 of measuring growth that you are aware of?

22 A. Sorry. Measuring growth -- I don't
23 understand the question. I'm sorry.

24 Q. Did you testify at some point that
25 one way of measuring the efficacy of AGGA in

1 S. Galella, D.D.S.

2 terms of movement in the sagittal plane was to
3 measure the gap in teeth?

4 MR. FELD: Object to the form.

5 MR. FUMOSA: Objection to form.

6 A. Yes. That was my last deposition.

7 The way -- the way that we communicate with the
8 doctors is to take the space that's distal of
9 the cuspid to the medial of the first bicuspid,
10 or wherever, the second, whatever tooth the
11 space is created, and measure each side and
12 together divide by two. That's the
13 communications to measure what happened in any
14 type of complex system.

15 Q. Do you have a shorthand way of
16 referring to that system of measurement?

17 A. No, sir.

18 Q. Well, I'll call it the gap
19 measurement, if that's okay with you, just for
20 a shorthand description of it.

21 Did you utilize this gap measurement
22 methodology on any of these five patients?

23 MR. FUMOSA: Object to the form of
24 the question.

25 A. No, because if you'll notice, it's

1 S. Galella, D.D.S.
2 not a standard in my office to take before and
3 then right after the appliance, and then at the
4 end of treatment and four years out. I take
5 them before and after, so there was not --
6 there were not films where I could measure that
7 gap.

8 Q. Is that true for all 600 plus
9 patients?

10 A. I have no idea. I didn't go through
11 every 600 patients.

12 Q. Is it fair to say that in this gap
13 method, what you are measuring is the movement
14 of teeth, correct?

15 A. No, sir.

16 Q. What are you measuring if you are not
17 measuring the movement of teeth?

18 A. You are measuring the bone that was
19 developed in remodeling.

20 The teeth are moved in a segment, as
21 I described at the last deposition. There's
22 the six anterior teeth are just adrift of the
23 alveolar bone for remodeling, so the bone
24 that's formed or the gap that's formed is the
25 result of additional remodeling and additional

1 S. Galella, D.D.S.

2 development of the maxilla, not physical
3 movement of the teeth.

4 The teeth don't change the position
5 in the alveolar ridge.

6 Q. Doctor, could you describe for us
7 your education and training in the field of
8 radiology?

9 A. I'm not a radiologist, no. As a
10 specialty, I'm not a specialist. Radiology was
11 done through my education at dental school,
12 continuing education courses, and working with
13 various maxillofacial radiologists.

14 Q. Working with various maxillofacial
15 radiologists, would that include Dr. Bouchara?

16 A. Yes, I have had communications with
17 him.

18 Q. I am probably going to butcher her
19 last name, but would they include Heidi
20 Kohltfarber?

21 A. Kohltfarber. She is a Ph.D.
22 radiologist, maxillofacial radiologist with a
23 specialty in dentistry.

24 Q. Those are two radiologists you worked
25 with in regard to your work at FBI from time to

1 S. Galella, D.D.S.

2 time, correct?

3 A. Yes -- well, yes, two of many.

4 Q. You have already told us that you
5 used the Anatomage system before. Tell us for
6 the record, what is the Anatomage system?

7 A. It's a software that reads 3D CBCTs,
8 cone-beam spiral -- cone-beam radiology images.

9 Q. Is it fair to say the Anatomage
10 system allows you to load the DICOM data from a
11 CBCT machine and view images?

12 A. Yes. It has a view aspect, but the
13 software I use is the software, the full
14 software.

15 Q. Can you briefly summarize for us your
16 training and experience concerning the use of
17 the Anatomage system?

18 A. Well, I was trained by the Anatomage
19 people. They have -- plus I read all the
20 information. Dr. Tamini, a maxillofacial
21 radiologist, also spent time and training with
22 the use of Anatomage.

23 Q. Do you do anything to keep up to date
24 with Anatomage in the last five years?

25 A. I have the most current -- I keep up

1 S. Galella, D.D.S.

2 with the current software, and I read the -- I
3 don't know what you call them -- the papers
4 they put out on changes, and tips, et cetera.

5 Q. When is the last time you had a
6 software update in regard to Anatomage?

7 A. The last software update, I don't
8 know. It was probably a year ago.

9 MR. FELD: Object to the relevance of
10 that question.

11 MR. CHARNAS: Sure.

12 Q. Are you familiar with the 3D analysis
13 view of Anatomage?

14 A. Yes.

15 Q. And do you have that 3D analysis view
16 module?

17 A. Not on my computer. The Anatomage
18 people and our -- the people at Orthologic, one
19 of the diagnostic doctors has that image, that
20 module on his computer.

21 Q. Why don't you have the 3D analysis
22 module on your Anatomage computer?

23 A. Because I don't do the 3D analysis.
24 The 3D analysis is -- I don't do that. That's
25 not my job.

1 S. Galella, D.D.S.

2 Q. What is your understanding as to what
3 the 3D analysis view or module does?

4 A. It lets you place markers or points
5 throughout the skull that normally would be
6 done on a 2D image, and so the 3D analysis,
7 it's really not a 3D analysis. It's more of a
8 2D analysis sort of combined into tracings.

9 Q. Do you use Anatomage on a regular
10 basis for your dental practice?

11 A. Yes.

12 Q. Do you continue to do research in the
13 field of Osseo-Restore devices?

14 A. What research are you talking about?

15 Q. Any kind of research, Doctor.

16 A. I'm not a researcher in this aspect.
17 I have been making notes, and I make
18 observations, and I maintain data, but I
19 don't -- I'm not -- I haven't published
20 anything, no.

21 Q. Is it fair to say that Anatomage
22 comes with a user's manual, correct?

23 A. Online user's tutorial, yes.

24 Q. And when is the last time you read
25 that manual in whole or in part?

1 S. Galella, D.D.S.

2 A. Since the last update.

3 Q. From time to time do you communicate
4 with anyone at Anatomage if you have questions
5 about how it functions, it's limitations?

6 A. Not recently.

7 Q. You know they have a phone number you
8 can call, right, if you have any questions
9 about Anatomage's uses or limitations, correct?

10 A. Yes.

11 Q. Let's talk about Patient 1 for a
12 moment. Can you see that on the screen, the
13 Anatomage image dated 9/21/2016?

14 A. Yes.

15 Q. And let me show you the next image,
16 page 3 of Exhibit 24, dated 4/13/2015. Do you
17 see that there? Do you see that?

18 A. Yes. It says 4/3/2015.

19 Q. 4/13/2015. Can you take us through
20 what you did using this image as an example in
21 terms of how you prepared the proof that is
22 Exhibit 24?

23 A. I oriented the image so that it's a
24 patient facing left, which is standard in the
25 U.S., or a right profile.

1 S. Galella, D.D.S.

2 Then I lined up the mandible and
3 condyles and coronoid processes so it overlaid
4 over one another so the rotational from left
5 to right was the same.

6 Also I overlaid -- made sure that
7 the orbitale are the same to prevent any left
8 or right rotation.

9 Then I organized or did the rotation
10 so I could determine the Frankfort horizontal
11 plane was horizontal.

12 Then I enlarged the image so that it
13 was readable.

14 Then I put the grid, which is the
15 little -- looks like a little cross with
16 markers on it. That's your measurement tool
17 for that particular image that's enlarged. It
18 matches the image.

19 Q. You are talking about this one right
20 here?

21 A. That's correct. The measurement.

22 Then I did from the nasion, which is
23 the junction of the nasal bone to the frontal
24 bone.

25 Then I dropped a perpendicular line

1 S. Galella, D.D.S.

2 that was perpendicular to the horizontal
3 Frankfort horizontal plane, made sure it was
4 at 90 degrees.

5 Then the measurements were the dots
6 that were measured below. I put dots on the
7 measurements. One was at A point, which is
8 the junction of the alveolar bone and the
9 maxillary bone.

10 And then at the prosthion, which is
11 the most anterior/inferior part of the
12 alveolar bone.

13 Then I drew lines, tangent lines,
14 from the inferior mandible, and then from the
15 posterior ramus and made a cross over there.

16 Then I took measurements.

17 Q. Did you attempt to make the
18 horizontal line at the same location relative
19 to the orbitale on each image?

20 A. Yes.

21 Q. Just for the record, to make sure we
22 are talking about the same thing, the orbitale
23 is this point at the bottom of the eye socket,
24 correct?

25 A. It's the inferior orbitale. Yes,

1 S. Galella, D.D.S.

2 that's what the term is.

3 Q. In fact, on the third page, the
4 orbitale is basically touching the horizontal
5 line, correct?

6 A. I don't know if this is -- is this
7 the third page?

8 Q. Yes, that's it.

9 A. It says initial records, so that's
10 the third page?

11 Q. Yes, sir.

12 A. Yes.

13 Q. Now, you mentioned that you made a
14 mark at the A point; is that right?

15 A. Yes. Here.

16 Q. I think I know what A point is, but
17 can you describe what A point is?

18 A. A point is the most posterior point
19 in the concavity from the ANS, anterior nasal
20 spine, to the alveolar ridge. It's a little
21 concavity, and the A point is generally the
22 juncture of the alveolar bone and maxillary
23 bone. It's generally the depth of the
24 concavity.

25 Q. You actually made a mark of image,

1 S. Galella, D.D.S.

2 correct, at the A point?

3 A. I made -- I put a dot. I think it
4 was a colored dot. Maybe it was a yellow one.

5 Q. Obviously this is black and white so
6 we can't see the colors.

7 Where I have the cursor right now,
8 and we will describe it in a moment, is that
9 the A point?

10 A. Yes.

11 Q. Just for the record, that is to the
12 left of the plus 0.77 millimeters on the image,
13 right?

14 A. Yes. That means that the A point is
15 .77 millimeters anterior to the vertical line
16 from the nasion to A point.

17 Q. There is another --

18 A. Sorry. The vertical line from nasion
19 perpendicular to Frankfort horizontal plane.
20 The A point is anterior to that line.

21 Q. To the left of where it says positive
22 2.03 millimeters, there is another mark which
23 is white on the image. Did you make that mark
24 where the cursor is now?

25 A. Yes. That represents the alveolar

1 S. Galella, D.D.S.

2 bone in front of the nasion perpendicular line
3 to the Frankfort horizontal. It represents the
4 prosthion or the most anterior -- in this case
5 the most anterior part of the alveolar bone.

6 Q. How did you decide where to locate
7 the vertical line?

8 A. The vertical line?

9 Q. Yes.

10 A. It goes from nasion, which is the
11 juncture of the nasal spine and frontal bone,
12 perpendicular to the Frankfort horizontal line.

13 Q. Did you do the same thing for all
14 these images in Exhibit 24, your five cases?

15 A. Yes.

16 Q. I am going to show you an image which
17 is the 21st page, which is patient -- I
18 represent to you it is Patient 4. Do you see
19 Patient 4 there, Doctor?

20 A. Yes.

21 Q. Do you see nasion in that image on
22 the 21st page?

23 A. No, but if you go to the next
24 image --

25 Q. You mean the 22nd page?

1 S. Galella, D.D.S.

2 A. Keep going. One more. Right there.
3 You can see nasion there.

4 So I took an estimate -- estimated
5 where it should be, nasion, based on that
6 image, and then transposed it onto the other
7 image.

8 Q. Why is it you couldn't see nasion in
9 the image which is on page 21?

10 A. Because it was not really clear, the
11 image was not clear. The scan didn't show the
12 complete image, the complete part.

13 Q. So you estimated where nasion was on
14 that one, correct?

15 A. Yes, that's correct.

16 Q. Let me show you the fifth image of
17 Exhibit 24. Do you see orbitale on that image?

18 A. Yes.

19 Q. Is orbitale in the same location
20 relative to the horizontal line in that image
21 as it was on the image on page 3?

22 A. I don't know. I would have to see
23 the image on page 3.

24 Q. Take a look at 5, and I am going to
25 show you 3 again.

1 S. Galella, D.D.S.

2 A. Okay.

3 Q. Is it your understanding that
4 orbitale is in the same location relative to
5 the horizontal line on both?

6 A. Are we talking about two different
7 pages?

8 Q. We are talking about 3, take a look
9 at 3, and then I will go back to 5.

10 A. Okay.

11 Q. Would you agree that orbitale in 5 is
12 above the horizontal line whereas in 3 it's
13 touching the horizontal line?

14 A. Are we talking about the same
15 patient?

16 Q. Yes, the same patient. This is
17 Patient 1.

18 A. Okay. Go back to the first one.

19 Q. There is the first one.

20 A. Go to the second.

21 Q. There is the second.

22 A. It looks the same to me.

23 Q. Thank you. Now, we discussed this
24 briefly before, but you can see on the third
25 page of Exhibit 24 that -- you see the vol/ren

1 S. Galella, D.D.S.

2 setting, right, at the top?

3 A. Yes.

4 Q. That stands for volume rendering or
5 volume render?

6 A. Yes.

7 Q. Then to the left there are certain
8 settings like, for example, here on the left
9 the O is cut off, but you will agree it is
10 opacity?

11 A. Yes.

12 Q. And then the brightness under that,
13 and then contrast under that, correct?

14 A. Yes.

15 Q. Now, why is it important that the
16 settings for opacity, brightness, and contrast
17 be the same for each image?

18 A. Well, it depends on the machine.

19 Q. All these images are from the same
20 machine, aren't they?

21 A. I don't recall.

22 Q. I'm sorry. I thought you said
23 earlier all the images are from the same
24 machine. That is not correct?

25 A. I didn't say that. There are

1 S. Galella, D.D.S.

2 variations. If I could see the other picture,
3 I could probably tell you.

4 Q. Which other picture?

5 A. The other one you referred to, the
6 same patient.

7 That's two different machines.

8 Q. How do you know that?

9 A. Because this machine has a full head,
10 and the other machine had partial. One was
11 taken by a Soredex, one was taken by a
12 Planmeca.

13 I switched machines at some point in
14 my practice.

15 Q. When was that, Doctor, approximately?

16 A. I have no idea.

17 Now, the horizontal line is the same
18 in both pictures. The elevation of the
19 horizontal line, because it's right on the
20 inferior orbitale or slightly above, makes no
21 difference in the measurements, because the
22 line was set to horizontal based on the
23 setting that lets you do rotations to create
24 the horizontal line.

25 Q. Just so it is clear, on the same

1 S. Galella, D.D.S.

2 patient --

3 MR. CHARNAS: Strike that.

4 Q. What did you do to make sure that the
5 degree of rotation of the images was the same
6 for each patient?

7 A. Degree of rotation in which
8 direction?

9 Q. The skull rotation.

10 A. We are talking apples and oranges.
11 You mean the rotation to make the horizontal
12 line horizontal, or right to left rotation?

13 Q. I'm sorry. Right to left rotation.

14 A. That means that your head will be
15 right or left.

16 Q. Right. What did you do?

17 A. I lined up the ramus borders, the
18 condyles, the coronoid process, and the
19 orbitale so that there was no head rotation.

20 As the patient sits in the machine,
21 you have a little rotation, so that eliminates
22 the rotation. Apples to apples.

23 Q. The horizontal and vertical lines on
24 the screen on the third page of Exhibit 24,
25 just to be clear, were they generated by you or

1 S. Galella, D.D.S.

2 by the machine?

3 A. The machine allowed me to generate
4 the lines, and then I took -- did an overlay of
5 the -- I put lines in PowerPoint because the
6 lines that were there were, you could barely
7 see them, and it had a rotational thing, and it
8 would interfere with seeing clearly the image,
9 so I overlaid the lines so it was precisely
10 vertical, precisely horizontal. I had the
11 lines so you could see them.

12 Q. The vertical line that we see in the
13 third page of Exhibit 24 was not a line that
14 was created in Anatomage, it was created in
15 PowerPoint; is that correct?

16 A. Yes, but it matches the line that was
17 created in Anatomage.

18 Q. And the reason you didn't use the
19 Anatomage lines, horizontal and vertical, is
20 because you couldn't see it well?

21 A. Yes. You couldn't put the
22 calibration tool on at the same time you had
23 the rotational thing in play. They're not --
24 you couldn't do them both.

25 Q. Can you explain the importance of

1 S. Galella, D.D.S.

2 using the A point and the prosthion point as
3 comparison points for multiple images?

4 A. The A point is the junction of the
5 alveolar bone and the maxilla, and the
6 prosthion is the most anterior and inferior
7 part of the alveolar bone, generally in the
8 center of the mouth if the midline is correct.

9 When the bone remodels, it remodels
10 three dimensionally, and these things can be
11 measured.

12 Q. When you say "when the bone
13 remodels," the A point and the prosthion point
14 will move with the bone?

15 A. As it remodels, it changes its shape,
16 and they are the standard points that are used
17 in orthodontic tracings.

18 Q. You made a determination based on a
19 comparison of these images, various images for
20 Patient 1, that there had been certain movement
21 in the sagittal plane of the maxilla; is that
22 fair to say?

23 MR. FUMOSA: Object to the form.

24 A. You keep using the word advance and
25 movement, and I keep saying that it remodels or

1 S. Galella, D.D.S.

2 changes its shape, so we're talking two
3 different languages here.

4 Q. Well, it moved, didn't it? The
5 maxilla moved, according to you, correct?

6 MR. FUMOSA: Objection.
7 Argumentative.

8 A. The maxilla changed its shape, and as
9 it changed its shape it enlarged, and you are
10 not moving, physically moving, anything. It's
11 a change in shape. I'm sorry, but it's a
12 different thing.

13 Q. Don't be sorry. We'll figure it out.
14 So it's an enlargement of the
15 maxilla?

16 A. Yes, that would be good.

17 Q. So how much in Patient 1, and we will
18 go through the scans, did --

19 MR. CHARNAS: Strike that.

20 Q. I am going to go through the scans on
21 Patient 1. I would like you to tell me how
22 much of an enlargement of the maxilla in the
23 sagittal plane occurred as a result of the use
24 of the Osseo-Restore device.

25 Here is the initial record, and you

1 S. Galella, D.D.S.

2 will see the numbers there. This is treatment
3 completed, the second page of Exhibit 24, and
4 the date on the right is 9/21/2016.

5 Can you tell us how much enlargement
6 occurred in the maxilla as a result of the use
7 of the Osseo-Restore device?

8 A. Based on A point, about 4 millimeters
9 give or take a few tenths.

10 Q. You testified that Osseo-Restore can
11 cause an enlargement in the sagittal plane of
12 the maxilla as much as 8 to 10 millimeters; is
13 that right?

14 A. It's possible, yes.

15 Q. Is it fair to say that none of the
16 documents that you produced in Exhibit 24 show
17 that much enlargement, correct?

18 A. That's correct.

19 Q. Did you look for patient files or a
20 patient file that would show enlargement of the
21 maxilla in the sagittal plane by as much as 8
22 to 10 millimeters?

23 A. In my practice, most of my patients,
24 as I have told you before, it was 4, maybe
25 6 millimeters, so I don't think -- I don't

1 S. Galella, D.D.S.

2 recall treating somebody 8 to 10 millimeters in
3 my practice.

4 Q. Is it fair to say that you have
5 lectured to dentists and told them they can
6 achieve as much as 8 to 10 millimeters or more
7 of enlargement of the maxilla in the sagittal
8 plane by using the Osseo-Restore device?

9 A. In a lecture? I don't think I said
10 that. I think I said it's possible to get up
11 to 8 to 10, and I have reports that Orthologic
12 has done that recommended in certain situations
13 of a Class 3 possible surgery case 8 to
14 10 millimeters, but it's not the normal. The
15 normal is 4 to 6.

16 Q. It is fair to say, sir, you did not
17 provide proof in these five cases of an
18 Osseo-Restore device causing maxillary
19 enlargement in the sagittal plane by as much as
20 8 to 10 millimeters?

21 A. No. I don't have any patients that
22 did that.

23 Q. So what's the basis of your belief
24 that the Osseo-Restore device is capable of
25 causing as much as 8 to 10 millimeters or more

1 S. Galella, D.D.S.
2 of maxillary enlargement in the sagittal plane?

3 A. Can you rephrase that again? I'm
4 trying to understand what you are trying to
5 ask.

6 Q. You have told us that you believe
7 that the Osseo-Restore device can cause as much
8 as 8 to 10 millimeters or more of enlargement
9 of the maxilla in the sagittal plane, correct?

10 MR. FUMOSA: Object to the form.

11 A. I don't make those -- I said it's
12 possible, but I don't say -- it's not the norm.

13 I'm trying to understand what you're
14 trying to ask me.

15 Q. I'm asking you if you have any proof
16 that an Osseo-Restore device can cause as much
17 as 8 to 10 millimeters or more of maxillary
18 enlargement in the sagittal plane?

19 A. I have seen images of -- from doctors
20 that have treated patients with the gap, as you
21 call it, that were 8 to 10 millimeters.

22 Q. So you have -- sorry. I thought you
23 finished. Go ahead.

24 A. So I have seen those results, but I
25 didn't see the cone beams or done any

1 S. Galella, D.D.S.

2 comparisons.

3 Q. Other than other dentists'
4 measurements using the gap method, you know of
5 no proof that an Osseo-Restore device can cause
6 8 to 10 millimeters or more of maxillary
7 enlargement in the sagittal plane, correct?

8 MR. FUMOSA: Objection to the form.
9 Asked and answered.

10 Q. Is that correct, Doctor?

11 A. Remember, I'm slow here in answering.
12 I'm not from New York. I'm sorry.

13 Q. Doctor, we are not trying to rush
14 you. Would you like the court reporter to read
15 the question back?

16 A. Please.

17 MR. CHARNAS: Would you read it back?
18 (Record read.)

19 A. No, I don't have any proof like I
20 presented here.

21 Q. Are you aware that my client went to
22 Dr. Cortes to try to achieve 9 millimeters of
23 maxillary enlargement in the sagittal plane?

24 MR. FUMOSA: Objection to the form.
25 Also now foundation.

1 S. Galella, D.D.S.

2 A. I have no idea what -- why she went
3 there.

4 Q. If Dr. Cortes hypothetically told my
5 client that she could achieve 9 millimeters of
6 maxillary enlargement in the sagittal plane
7 using an Osseo-Restore device, would that be an
8 accurate statement?

9 MR. FUMOSA: Objection.

10 MR. FELD: Objection.

11 A. I don't know -- it wasn't my patient.
12 I didn't know -- I can't tell you without
13 having evaluating all the records. I couldn't
14 even tell you that.

15 Q. Hypothetically, Dr. Galella, if I
16 asked you whether I could, or any patient
17 could, achieve 9 millimeters of maxillary
18 enlargement in the sagittal plane using an
19 Osseo-Restore device, what would your answer
20 be?

21 MR. FUMOSA: Objection to the form of
22 that question.

23 A. Rephrase it. I'm just trying to get
24 this concept.

25 Q. Sure, sure. If a dentist came to you

1 S. Galella, D.D.S.

2 and said, "Dr. Galella, can I achieve
3 9 millimeters of maxillary enlargement in the
4 sagittal plane using an Osseo-Restore device on
5 a patient," what would your answer be?

6 MR. FUMOSA: Objection to the form.
7 No foundation. Hypothetical.

8 A. It would be based on a lot of factors
9 that I'd have to know.

10 Q. So you are saying that you would tell
11 that dentist that "It's possible, but I have to
12 know certain information"? Is that your
13 answer?

14 MR. FUMOSA: Objection to the form of
15 the question.

16 A. It could be possible, yes, but I have
17 to know more information.

18 Q. What additional information would you
19 need to know to make a judgment as to whether
20 it was possible for an Osseo-Restore device to
21 create as much as 9 millimeters of maxillary
22 enlargement in the sagittal plane?

23 MR. FUMOSA: Objection.

24 A. You would have to have the tracings,
25 which Anatomage does for us, and Orthologic,

1 S. Galella, D.D.S.
2 the ABO, plus tracing. You would have to have
3 the patient's health history. You'd have to
4 have the periodontal situation. You'd have to
5 have the dental situation; are teeth absorbed
6 or not, et cetera. You'd have to know if they
7 are mouth breathers or nasal breathers. You'd
8 have to know about their airway. You would
9 have to know about the bone, et cetera, the
10 status of the bone. You would have to know
11 about the condylar position, and you'd have to
12 know if they have osteoarthritis in the joints
13 or any kind of rheumatoid arthritis; if they
14 are on any kind of medications that could
15 prevent remodeling; and, of course, the age of
16 the patient is a critical factor.

17 Q. How many dentists or dental
18 professionals or radiologists have shown you
19 gap method measurements of 8 to 10 millimeters
20 or more?

21 A. I have no idea of the number.

22 Q. More than one?

23 A. Yes.

24 Q. Name one.

25 A. I don't recall the names.

1 S. Galella, D.D.S.

2 Q. Have more than 100 dentists shown you
3 such gap method measurements --

4 A. No.

5 Q. -- which demonstrate that kind
6 of maxillary enlargement?

7 A. No. I would say it would be closer
8 to ten to twelve over the years.

9 Q. Who is the last one to do that?

10 A. I have no idea what their names are
11 because I don't -- it's not the norm, and I
12 don't recall names very well.

13 MR. CHARNAS: I would like to take a
14 break for five minutes, if we could. It
15 is 12:16.

16 (A recess was taken.)

17 Q. Getting back to Anatomage for a
18 moment, is it fair to say that if one changes
19 the opacity, contrast, or brightness settings,
20 it can affect how much bone is visible on the
21 image?

22 A. Yes.

23 Q. And that's one reason why you want to
24 make sure that when you are comparing one image
25 to another on Anatomage that those settings are

1 S. Galella, D.D.S.

2 consistent, correct?

3 A. No. When you compare -- if it's the
4 same machine with the same radiation exposure,
5 yes, but if it's two different machines with
6 varying radiation exposures, they would be
7 different.

8 So the borderline is -- you get on
9 your images as you adjust these things, you
10 get noise, and that's the scatter radiation
11 that creates this noise, so you have to adjust
12 so that you see approximately the same amount
13 of bone as you do on each image.

14 Q. So if it's the same machine that took
15 both images, you want to make sure that those
16 three settings on opacity, contrast, and
17 brightness are the same?

18 A. No. I just explained that it depends
19 on the radiation setting when you took the
20 image even if it's the same machine. That
21 varies the amount of noise that you encounter.

22 Q. How do you determine, generally
23 speaking, when you are comparing two images on
24 Anatomage, how do you determine whether the
25 contrast, opacity, and brightness settings are

1 S. Galella, D.D.S.

2 appropriate for each?

3 A. Well, you adjust them so you can see
4 the maximum amount of bone with the minimal
5 amount of noise.

6 Q. So that's a determination that you
7 make as the one who is making the comparison?

8 A. Right. The differences in the
9 bone -- if the noise is minimal, the
10 differences in the opacity, contrast, and
11 brightness of the bone is probably not a big
12 variation.

13 Q. Got you.

14 A. I mean, it's not even a millimeter or
15 two.

16 Q. I am going to show you again back to
17 Exhibit 24. Take a look at the second page.
18 Notice it says Anatomage 9/21/2016 on the top
19 right. Can you see this now?

20 A. Yes.

21 Q. The third page --

22 MR. FUMOSA: What patient are we on?

23 MR. CHARNAS: This is Patient 1.

24 MR. FUMOSA: Okay I got it.

25 Q. We already talked about these two

1 S. Galella, D.D.S.

2 images. Page 3, it says Anatomage 4/13/2015.

3 Do you see that?

4 A. Yes.

5 Q. What I did was I took both of those
6 two images and I put them one on top of the
7 other to make it easier for you to contrast
8 them: Do you see there is the one 4/13/2015,
9 and there is the 9/21? Do you see that?

10 A. I don't see anything.

11 Q. Sorry. Now do you see it? Do you
12 see it, sir?

13 A. What am I looking at now?

14 (Document marked Exhibit 24-A.)

15 Q. What I did was I took those two
16 images I just showed you, the second and third
17 page of Exhibit 24, and I made it Exhibit 24-A
18 and put them one on top of the other, so the
19 top one is the 4/13/2015 image, and the one
20 below it is the 9/21/2016 image. Do you see
21 that?

22 A. Scroll slower so I can see what you
23 did, please.

24 There it is. There is the first
25 one.

1 S. Galella, D.D.S.

2 Q. You tell me when to go to the second
3 one.

4 A. Go to the second one.

5 Q. Can you tell whether these two images
6 were taken with the same machine?

7 A. Yes.

8 Q. And were they?

9 A. Yes.

10 Q. Is that your new machine?

11 A. No. That's the old machine.

12 Q. If you take a look to the left, you
13 will notice the opacity setting, brightness
14 setting, and contrast setting, right?

15 A. Yes.

16 Q. You would agree that the opacity
17 setting is approximately 50 percent?

18 A. I would have to see the other image.
19 You are going to have to flip back and forth.

20 Q. Why would you --

21 A. I only see one image.

22 Q. I am only showing one image.

23 A. I thought you were comparing.

24 Q. No. That comes later. The opacity
25 is approximately 50 percent on the

1 S. Galella, D.D.S.

2 4/13/2015 image, correct?

3 A. Yes.

4 Q. Showing you the second image, the
5 after-image, the 9/21/2016 image, that opacity
6 is about at the same amount, correct?

7 A. Yes.

8 Q. Now, the brightness on the second
9 image is at 100 percent, essentially, correct?

10 A. It appears to be.

11 Q. But on the first image it's less than
12 100 percent; would you agree?

13 A. I think that it's somewhat less,
14 maybe 2 percent.

15 Q. Did you make that adjustment between
16 the first and second images intentionally?
17 When I say "the adjustment," I mean the
18 difference between the brightness settings.

19 A. It was the ideal image. It was for
20 no purpose other than to get the clearest
21 image.

22 "Intentionally," I'm trying to
23 understand the word. Sorry.

24 Q. I just want to make sure it wasn't
25 something you -- you intentionally set it at

1 S. Galella, D.D.S.

2 that setting, less than 100 percent, correct,
3 on the first one?

4 A. I'm sorry. Rephrase the question. I
5 feel like you are accusing me of something.

6 Q. No, no, no.

7 A. I don't think you are.

8 Q. I am not. I am not saying you did it
9 for some bad purpose. I'm just trying to find
10 out whether it was just a mistake or you
11 intended to set it at less than 100 percent?

12 MR. FUMOSA: Objection to the form.

13 Q. Let me rephrase it. Did you intend
14 to set the brightness on the first image, the
15 4/13/2015 image, at the setting that it is
16 depicted on that image?

17 MR. FUMOSA: Object to the form.

18 A. I said it because I wanted the noise
19 to be approximately the same, and that's how it
20 came out that way. The noise, you could see
21 the noise on the images, and they are
22 approximately the same, very close to being the
23 same.

24 It is one machine two different
25 times.

1 S. Galella, D.D.S.

2 Q. Sir, is one of your claims about
3 Osseo-Restore that it can make a person's
4 forehead move forward or enlarge?

5 MR. FUMOSA: Object to the form, the
6 use of the word "claims." Objection.

7 A. Ask it so I can hear the whole
8 question.

9 Q. Is one of your claims about what the
10 Osseo-Restore device can do, is one of those
11 claims that it can enlarge a person's forehead
12 in the sagittal plane forward direction?

13 MR. FUMOSA: Same objection.

14 A. No.

15 Q. Is it fair to say, sir, that when you
16 made marks representing the location of A point
17 in prosthion, you were marking bone and not
18 teeth; is that correct?

19 MR. FUMOSA: I'm sorry. I didn't get
20 the question.

21 MR. CHARNAS: Let me start again.

22 Q. Is it fair to say on these images in
23 Exhibit 24 when you were making marks with
24 prosthion and A point, you were intending to
25 mark points of bone and not teeth, correct?

1 S. Galella, D.D.S.

2 A. That's correct.

3 Q. And I think you told us every
4 Anatomage image in Exhibit 24 was done in the
5 vol/ren or volume rendering setting, correct?

6 A. Yes.

7 Q. And you agree that's a 3D view,
8 right?

9 A. Yes.

10 Q. Why did you choose when you are
11 putting these five patient files together, why
12 did you choose to use the volume rendering
13 setting as opposed to another setting such as
14 CEPH, which I think we can agree stands for
15 cephalometric?

16 A. Because the volume rendering section
17 gives you more detail. It allows you to line
18 up everything so the rotations are nonexistent.

19 The CEPH is a standard thing that
20 is -- it shows soft tissue and bone, but it
21 also is a little bit distorted because of the
22 way that Anatomage treats the image. This is
23 the most accurate image for the bone.

24 Q. These points that you made, sir, on
25 nasion, A point, prosthion, those are called

1 S. Galella, D.D.S.

2 osseometric points, right?

3 A. They're called what?

4 Q. Osseometric points.

5 A. You mean osteometric?

6 Q. No. I mean osseometric.

7 A. It could be a term. I am not
8 familiar with that term.

9 Q. Those points, whatever you want to
10 call them, those are two-dimensional points,
11 correct?

12 A. I don't understand the question. I'm
13 sorry.

14 Q. The points are made in two
15 dimensions, aren't they?

16 MR. FUMOSA: Object to the form.

17 Q. Do you understand the question,
18 Doctor?

19 A. I understand the question. I don't
20 understand what you mean by two dimensions.
21 That's a three-dimensional object with the
22 rotation taken out. It looks like it's a
23 two-dimensional representation, but they are
24 placed at the most anterior in the proper place
25 for that image.

1 S. Galella, D.D.S.

2 If you rotate the image and put the
3 points in Anatomage, they would rotate with
4 the image.

5 So the points were put on in
6 PowerPoint to show you the sagittal
7 difference.

8 Q. But it's fair to say, sir, you are
9 making two-dimensional points on a
10 three-dimensional image, correct?

11 MR. FUMOSA: Object to the form.

12 A. If I was in Anatomage and I put the
13 points on the maxilla in Anatomage, as I
14 rotated the image, the points would be in the
15 same spot as you rotate it, so it's like a
16 three-dimensional point.

17 Q. Perhaps I misunderstood earlier. You
18 not only made the vertical and horizontal lines
19 in PowerPoint, you made the marks for A point,
20 nasion, and prosthion in PowerPoint as well?

21 A. Yes.

22 Q. Dr. Galella, what is the basis --

23 MR. CHARNAS: Strike that.

24 Q. I take it it's your opinion that one
25 can use Anatomage in the vol/ren setting to

1 S. Galella, D.D.S.

2 make accurate measurement of bone enlargement,
3 true?

4 MR. FUMOSA: Object to the form.

5 A. If you could just -- we've been
6 talking apples and oranges, and I'm just trying
7 to get the same language, so please make it so
8 we are talking the same.

9 Q. Sure. You used Anatomage in the
10 vol/ren setting and made marks on those images
11 in the vol/ren setting, as you described, for
12 the purpose of showing to what degree, among
13 other things, the maxilla was enlarged,
14 correct?

15 A. Yes.

16 Q. On what basis did you believe that
17 that was an appropriate and accepted
18 methodology for making such measurements?

19 A. Because you can see the difference in
20 the position. Everything is standardized. All
21 the lines, all the points, are all
22 standardized.

23 If you wanted a representation
24 rotated, it would look different.

25 Q. Is there anything in the user manual

1 S. Galella, D.D.S.

2 for Anatomage that suggests that you can use
3 the Anatomage system in the vol/ren setting for
4 those measurement purposes we just discussed?

5 A. You could place the points, but you
6 couldn't see them. They would be difficult to
7 see, and I made it where you could see it.

8 Q. Is it fair to say there is nothing in
9 the vol/ren manual that supports your
10 methodology; is that right?

11 MR. FUMOSA: Objection.

12 A. Methodology of what?

13 Q. What you just described. You are
14 using the Anatomage in the vol/ren setting
15 making marks that you described for us, nasion,
16 prosthion, A point, in a PowerPoint setting,
17 and using that to compare images to determine
18 maxilla enlargement. That's the methodology
19 I'm referring to.

20 A. The points were put on -- as I did
21 this, the points were put on in Anatomage, and
22 then I overlaid points on top of that to make
23 it where you could see it.

24 Q. I thought you said you put the points
25 on in PowerPoint.

1 S. Galella, D.D.S.

2 A. I did, but they are over the top of
3 the points you put on in Anatomage. I mean,
4 the points in Anatomage are really tiny points.
5 Does that make sense?

6 Q. Yes, it does. Thank you for
7 clarifying.

8 So the methodology you just
9 described is called the vol/ren methodology
10 where you used Anatomage in the vol/ren
11 setting, made points on nasion, prosthion, A
12 point, as you described, made the vertical
13 lines as you described, and the horizontal
14 line.

15 Is there anything in the Anatomage
16 user manual that supports that methodology as
17 an accurate way of measuring bone changes or
18 bone enlargement?

19 MR. FUMOSA: Objection.

20 A. In the user's manual?

21 Q. Yes, sir.

22 A. No. It describes how to put a point.
23 Anatomage will not put a point in
24 mid air. It has to be on a bone, so it
25 doesn't talk about measuring growth or

1 S. Galella, D.D.S.

2 enlargement or remodeling or any such thing as
3 that. It's not the intention of Anatomage to
4 get you that information.

5 Q. So you will agree there is nothing in
6 the vol/ren user manual that discusses that
7 methodology?

8 MR. FUMOSA: Same objection.

9 A. If you mean the volume render section
10 of the user's manual, no.

11 Q. Any section of the user's manual.
12 There's nothing that supports that methodology,
13 correct?

14 MR. FUMOSA: Asked and answered.
15 Objection.

16 A. No.

17 Q. Before you utilized this methodology,
18 did you attempt to call anyone from Anatomage
19 to ask them if that was an appropriate means of
20 measuring bone enlargement?

21 A. No, I did not.

22 Q. So what was the basis for your belief
23 that using this vol/ren methodology would allow
24 you to obtain accurate measurements of bone
25 enlargement?

1 S. Galella, D.D.S.

2 MR. FUMOSA: Objection. Asked and
3 answered. You can answer it again.

4 A. It's the comparison of each 3D
5 screenshot, the 3D renderings, that shows the
6 difference in the sagittal plane. That was
7 your contention in the last deposition.
8 Sagittal movement, as you called it.

9 Q. Any other basis other than what you
10 just said?

11 A. The comparison. Points in space.
12 The structure changed. The bony structure
13 changed. You could see that.

14 Q. Is there any peer-reviewed literature
15 that supports your use of that methodology?

16 MR. FUMOSA: Objection. Asked and
17 answered at the previous deposition.

18 You can answer again.

19 A. No, not that I'm aware of.

20 MR. CHARNAS: I never asked him about
21 Anatomage and that question at the previous
22 deposition.

23 MR. FUMOSA: You are wasting time.

24 Q. I am sorry, Doctor?

25 MR. CHARNAS: Could the court

1 S. Galella, D.D.S.

2 reporter read his answer back, please.

3 (Record read.)

4 Q. Now, Doctor, let me show you
5 Exhibit 23. I am just going to ask you
6 generally speaking.

7 (Document marked Exhibit 23.)

8 Q. Do you see that, Doctor, Facial
9 Beauty Institute?

10 A. Yes.

11 Q. Exhibit 23, and I am going to
12 represent to you that Exhibit 23 is the A-3
13 attachment to your counsel's original response
14 to our request for production of documents.

15 Just scroll through the first few
16 pages of A-3. You will see the Facial Beauty
17 Institute logo there on the top left, down to
18 the third page -- it actually extends past
19 that, but I am just going to ask you, what is
20 this generally we are looking at?

21 A. That's the radiology report produced
22 by Dental Radiology Diagnostics and signed by
23 the radiologist, Dr. Heidi Kohltfarber.

24 Q. If I scroll down, do you recognize
25 that there are certain images, radiological

1 S. Galella, D.D.S.

2 images?

3 A. Yes. They are screenshots from the
4 cone beam.

5 Q. You recognize that Anatomage is the
6 software used to show these images?

7 A. Most of the images, yes.

8 Q. This is the 47th page of Exhibit 23.
9 What are we looking at here, doctor?

10 A. A screenshot of the tracing done by
11 Anatomage.

12 Q. Do you recognize the setting --

13 MR. CHARNAS: Strike that. Let me
14 ask a different question.

15 Q. If we go back to the first page of
16 Exhibit 23, which, again, was A-3, you will see
17 there are a number of pages as I scroll through
18 which appear to be part of the FBI report from
19 Heidi Kohlthfarber. Do you agree?

20 A. That was the radiology report from
21 Dr. Heidi Kohlthfarber.

22 Q. Right. And then when we get to
23 page 14, we get to a treatment plan, correct?

24 A. Suggested treatment plan, yes.

25 Q. Let's keep going, and there appears

1 S. Galella, D.D.S.

2 to be another treatment plan. It may be the
3 same as the one that came before it. I don't
4 know.

5 Then we are scrolling through and we
6 are coming down to Image 34.

7 Again, this folder came from you, or
8 from your counsel.

9 This Anatomage image that we are
10 looking at in the 34th page, is that part of
11 Heidi Kohltfarber's report? Is that part of
12 one of the treatment plans, or something else?

13 A. That's a screenshot that -- Anatomage
14 does our tracings, and that's a screenshot of
15 one of the tracings. I'm not sure which shot
16 that is because I can only see half the image.

17 Okay.

18 Q. I guess my question is, is this part
19 of Heidi Kohltfarber's report, if you know?

20 A. No. That's the Anatomage screenshot.
21 They do eight or ten screenshots of the
22 tracings that they do.

23 Q. But Anatomage is just a company. Are
24 you saying the company Anatomage --

25 A. We hire them to do our tracings

1 S. Galella, D.D.S.

2 because they contend they're pretty accurate.

3 Q. Was this done in conjunction with the
4 FBI report which I showed you on the first
5 page, was it done in conjunction with one of
6 the treatment plans, or something else?

7 A. It had nothing to do with Dr.
8 Kohltfarber's report other than what their
9 values were that are submitted to the Dental
10 Diagnostics.

11 It's done, the tracings, and we give
12 the doctor the tracings so they can see what
13 numbers and values there are.

14 It's done as part of the treatment
15 plan report primarily. Secondarily, certain
16 values and numbers are not the numbers but --
17 the prognathic mandible, retrognathic maxilla,
18 et cetera, posted on the dental radiology
19 report.

20 Q. So you can see my client's name on
21 the top left?

22 A. Yes.

23 Q. And then there is a date which is
24 February 12, 2020, right?

25 A. Right. That's the date the image was

1 S. Galella, D.D.S.

2 taken.

3 Q. Are you saying that this was made as
4 part of a treatment plan that you created,
5 meaning a treatment plan you created?

6 MR. FELD: Objection to form.

7 MR. FUMOSA: Object to form.

8 A. It was a screenshot of the tracing
9 that was done after we received the tracing and
10 the values and the numbers, and the radiology
11 report. Then we suggest a treatment plan.

12 Q. Maybe my question isn't clear, and if
13 so, I apologize.

14 You've told us that you asked
15 Anatomage to create an image like this,
16 correct?

17 A. Yes. It's a screenshot of a tracing,
18 yes.

19 Q. And is it fair to say that you
20 provided a CBCT scan or scans to Anatomage for
21 the purpose of them creating this image?

22 A. Yes.

23 Q. And is that something that you
24 regularly did in 2018/2019/2020 in connection
25 with OrthoMatrix treatment plans?

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2 MR. FELD: Objection to form.

3 A. Yes.

4 Q. Why did you use Anatomage for this
5 purpose? Why didn't you have someone at FBI,
6 either yourself or Heidi Kohltfarber or
7 Dr. Bouchara or something like that do it? Why
8 did you go to Anatomage directly?

9 MR. FELD: Objection to form.

10 MR. FUMOSA: Objection. You can
11 answer over objection.

12 A. Dr. Kohltfarber and Dr. Bouchara
13 don't trace images. They don't do that as part
14 of their specialty.

15 Anatomage uses a tracing module, and
16 they trace it, and they claim it's very
17 accurate, and according to our spot checks of
18 their tracings, they seem to be very accurate.

19 It's very time consuming, and
20 it's -- it's very time consuming, so we don't
21 have staff that will be able to trace it. We
22 let the pros do it, Anatomage. That's what
23 they do. They have a tracing service, and we
24 pay them for their tracings.

25 Q. Doctor, is it fair to say if you look

1 S. Galella, D.D.S.

2 at the top right here, you see the word
3 analysis?

4 A. Yes.

5 Q. I think you told us you have the 3D
6 view program or module from Anatomage, or you
7 have access to it, right?

8 A. I don't have it on my computer.
9 Dr. Abernathy has it on his computer because he
10 checks the tracings.

11 Q. Sorry. Who is Dr. Abernathy?

12 A. He is the diagnostician that puts
13 everything together.

14 Q. So he works for FBI?

15 A. He is a 1099 contractor.

16 MR. FELD: Object to the form of the
17 question.

18 Q. Just so it's clear, when you say he
19 is a 1099 contractor, are you saying he is a
20 person that is not employed by OrthoMatrix, but
21 OrthoMatrix hires for certain projects; is that
22 correct?

23 A. Yes.

24 Q. So he has the 3D view analysis module
25 at his disposal, correct?

1 S. Galella, D.D.S.

2 A. Yes. On his computer, yes.

3 Q. And is it fair to say that this image
4 that we are looking at, page 34 of Exhibit 23,
5 was done in the 3D view analysis?

6 A. Yes.

7 Q. Do you regard the 3D view analysis as
8 an accurate means of measuring bone
9 enlargement, and particularly maxilla
10 enlargement?

11 A. Would you repeat that, please? I
12 didn't hear you.

13 Q. I am sorry. Do you regard the use of
14 Anatomage in the 3D view analysis mode as an
15 accurate means of measuring bone enlargement,
16 in particular maxilla enlargement?

17 A. In the 3D tracing mode?

18 Q. The 3D -- the mode that is depicted
19 on the screen in front of us, page 34.

20 A. No.

21 Q. What is the basis of your answer?

22 A. Because the adjustments are not
23 available to the precision that is done in the
24 volume render mode with the bone.

25 These are screenshots of 3D mode.

1 S. Galella, D.D.S.

2 It's a different module than the standard
3 Anatomage.

4 You can see by the listing on the
5 right, it's limited space, plus -- battery is
6 running low. We have a low battery.

7 Q. Low battery for what?

8 A. Sorry. It just got unplugged.

9 MR. FUMOSA: We're good.

10 Q. Could you finish your answer, Doctor?

11 A. Plus the adjustments to the -- that's
12 not a bone view. That's a teeth view, and so
13 you can't clearly see the bone in that
14 particular image.

15 Q. Are you aware as to whether the
16 Anatomage user manual approves the use of
17 Anatomage in the 3D view analysis mode for
18 measuring bone enlargement?

19 A. No, not aware of that.

20 Q. Do you know that that's not true?

21 A. I'm not aware of if it has that in it
22 or not, in the 3D mode. I don't have the 3D
23 mode on my computer.

24 Q. When you are measuring enlargements
25 of bone for your patients --

1 S. Galella, D.D.S.

2 MR. CHARNAS: Strike that.

3 Q. Do you ever measure enlargement of
4 bone in the nasomaxillary complex as part of
5 your dental practice or ask it to be analyzed
6 for purposes of your dental practice?

7 MR. FUMOSA: Object to the form.
8 That's two questions in one.

9 A. Rephrase it. I am a little confused.

10 Q. I don't blame you. In the course of
11 your dental practice, do you either personally
12 or have someone make efforts to measure
13 nasomaxillary enlargement for use --

14 MR. CHARNAS: Strike that.

15 Q. In the course of your dental
16 practice, in particular in regard to
17 Osseo-Restore patients, do you ever attempt
18 yourself or ask someone else to measure bone
19 enlargement?

20 A. I do so occasionally.

21 Q. When you do so occasionally, do you
22 use the vol/ren in Anatomage view, or something
23 else?

24 A. The volume render view in Anatomage.

25 Q. Anything else you use for that

1 S. Galella, D.D.S.

2 purpose?

3 A. To measure? The gap method is a
4 measurement that we use, but it's more for
5 communication than to give you exact numbers.

6 Q. Before you were asked to do so for
7 this case, put together those five patient
8 documents, did you ever attempt to measure
9 through Anatomage bone enlargement in an
10 Osseo-Restore patient?

11 A. Yes.

12 Q. How often or how many times would you
13 do that before this five cases?

14 A. I don't recall. I don't recall.
15 Maybe a dozen.

16 Q. Did you do any of those tasks before
17 January 25th, 2018?

18 A. It's possible. I don't recall the
19 dates that I did it.

20 Q. So you may have and you may not have;
21 you just don't know, is that fair?

22 A. I don't recall the dates or the
23 years. They sort of ran together.

24 Q. By the way, that image I showed you
25 on page 34 of the Anatomage, was that something

1 S. Galella, D.D.S.

2 you would have provided to Dr. Cortes in the
3 normal course of creating a treatment plan?

4 MR. FUMOSA: Can I have that back,
5 please?

6 (Record read.)

7 MR. FUMOSA: Objection.

8 MR. CHARNAS: Let me rephrase that.

9 Q. Do you know whether the image on
10 page 34 -- I can show you again if you want --
11 whether that is something in the normal course
12 you would provide that kind of an image with a
13 treatment plan to the prescribing dentist?

14 MR. FUMOSA: Can we see image 34
15 again, please?

16 MR. CHARNAS: Sure.

17 Q. Do you see that, Doctor?

18 A. Yes.

19 Q. You see Boja Kragulj's name on the
20 left?

21 A. Yes.

22 Q. Is that something you provided to
23 Dr. Cortes in the normal course?

24 A. She was my patient -- I did the
25 records, and she came for a second opinion, so

1 S. Galella, D.D.S.

2 I would not provide that to Dr. Cortes because
3 that was part of my records before we had a
4 consultation.

5 That specific image, that's all.
6 I'm trying to get there.

7 Q. Doctor, are you familiar with a
8 methodology for measuring bone enlargement
9 which involves taking a sagittal view of a CBCT
10 scan and measuring a point from the foramen
11 magnum to the A point?

12 A. Yes. Not very accurate.

13 Q. What's the basis of your statement
14 it's not very accurate?

15 A. Because the foramen magnum changes
16 its size and changes its position on a regular
17 basis.

18 All the foramen in the cranial base
19 are subject to change. It also depends on the
20 cranial strain. It also depends on a lot of
21 things, so that measurement can have a big
22 variance.

23 Q. That measurement from the foramen
24 magnum to the A point view to the sagittal
25 plane of a CBCT scan, were you familiar with

1 S. Galella, D.D.S.

2 that methodology before January of 2018?

3 A. Yes, I've heard about it. I read
4 about it. I saw the literature.

5 Q. Doctor, we are going to change course
6 here. Now I am going to show you a photograph
7 or several photographs, actually, which is
8 marked as Exhibit 7 in Dr. Cortes's deposition,
9 and I represent to you she testified it came
10 from her files, patient files, on my client,
11 Boja Kragulj.

12 Can you see it, Doctor?

13 A. No.

14 Q. Hold on.

15 (Pause in the proceedings.)

16 Q. How about now?

17 A. Yes.

18 Q. So this is, again, Exhibit 7 from Dr.
19 Cortes's deposition. The page was Bates
20 stamped 380, and it reports to be photographs
21 of my client. They were taken, according to
22 the document, on October 23, 2018.

23 I am going to ask you, looking at
24 the bottom two photographs, which are image
25 0080 and 0082, do you see any gingival

1 S. Galella, D.D.S.

2 recession in either of those photos?

3 A. Yes.

4 Q. In both or one of them?

5 A. In both.

6 Q. Do you see root exposure in either of
7 those two photographs?

8 A. Well, gingival recession is root
9 exposure. I'm not quite sure what you are
10 asking.

11 Q. Do you see any flaring of the
12 anterior maxillary teeth in any of these photos
13 starting with 0079? Then I will scroll down.

14 A. 0079, I didn't see the initial
15 pictures. I couldn't tell you. I don't know
16 what she looked like before.

17 Q. Fair enough. This is going to be
18 Exhibit 12 to Dr. Cortes' deposition. Do you
19 see that now, Doctor? Do you see the
20 photographs?

21 A. Yes.

22 Q. And they are dated January 28, 2018,
23 so this is the same set of teeth, essentially.

24 Am I going too fast for you?

25 A. No.

1 S. Galella, D.D.S.

2 Q. Have you had an opportunity to make
3 an observation as to the flaring and
4 non-flaring of the maxillary anterior teeth?

5 A. I don't see apples to apples. The
6 same picture is not present in these pictures,
7 I'm sorry to inform you.

8 Q. That's okay. I just want to make
9 sure that we are clear. Going back to that
10 Exhibit 7 again, it is your testimony that you
11 cannot tell whether in photograph 0079, that
12 Exhibit 7, whether the patient's anterior
13 maxillary teeth are flared; is that correct?

14 MR. FUMOSA: Objection to that.

15 A. There's a lot of factors I would need
16 to see. They may be flared, but I don't have a
17 radiograph, I don't have any kind of image of
18 where she started, so what you are asking . . .

19 Q. I just showed you 0079. I just want
20 to make sure. 0080 and 0082 on Exhibit 7, you
21 can't tell from those photographs whether her
22 teeth are flared?

23 MR. FUMOSA: Please repeat that.

24 Q. I showed you 0079. I just want to
25 make sure it is the same answer for 0080 and

1 S. Galella, D.D.S.

2 0082. You can't tell from those two
3 photographs whether her teeth are flared,
4 correct? You would need to know more?

5 A. Yes, I need to know more.

6 Q. Do you see anything unusual about
7 those teeth in 0080 and 0082 other than the
8 gingival recession that you just discussed?

9 MR. FUMOSA: Object to the form.

10 A. They appear crowded.

11 Q. Anything else?

12 A. Could be a tongue thrust. There's a
13 little opening in the (inaudible).

14 Q. Anything else, sir?

15 A. The picture is sort of -- could be
16 red. The gingiva may be inflamed. I can't
17 tell you from these pictures.

18 MR. FUMOSA: I object to this line of
19 questioning as it relates to the doctor giving
20 testimony about treatment rendered by another
21 doctor in this suit.

22 Please continue.

23 Q. Doctor, I want you to assume that
24 this patient depicted in Exhibit 7 was in a
25 Fixed Osseo-Restore or AGGA appliance for

1 S. Galella, D.D.S.
2 approximately ten months before this photo was
3 taken. As she appears in that photo, do you
4 see any contraindications for continued use of
5 the Osseo-Restore device? That's the Fixed
6 Osseo-Restore device in this patient.

7 MR. FUMOSA: Objection under
8 Carvalho, C-a-r-v-a-l-h-o, versus New Rochelle
9 Hospital.

10 MR. SCHWARTZ: I join in that
11 objection, and that's a standing objection.

12 MR. FUMOSA: That's a standing
13 objection to this entire line of questioning.

14 MR. CHARNAS: Understood.
15 Do you want the question read back?

16 A. The pictures 80 and 82?

17 Q. And also 78 and 79.

18 MR. FUMOSA: I lost the question.
19 Please repeat the question.

20 (Record read.)

21 MR. CHARNAS: I am going to withdraw
22 that question.

23 Q. Doctor, looking at Exhibit 7, the
24 four photographs, and I am glad to scroll
25 through them as much as you want, I want you to

1 S. Galella, D.D.S.

2 assume that that patient had worn a Fixed
3 Osseo-Restore device for approximately ten
4 months before these photographs were taken.

5 As she appears in these photos, do
6 you see any contraindications for continued
7 use of a Fixed Osseo-Restore device?

8 MR. FUMOSA: You can answer over
9 objection.

10 A. Yes.

11 Q. What are those contraindications?

12 A. On picture 0078, do you see the
13 redness of the palatal issue around the pad?

14 Q. Yes.

15 A. That means it has been debonded, and
16 you can look at the bonding and see it has been
17 repaired or patched, so the acrylic pad has
18 moved down the implant plane of the palatal
19 vault or tissue, I guess you'd say, and it's
20 going to start getting more inflamed and
21 possibly dig in.

22 So at this point it says the pad has
23 moved and it's in the wrong place, so the
24 indication at this point would be to remove
25 the appliance.

1 S. Galella, D.D.S.

2 Q. You told me that there are
3 contraindications for continued use of this
4 appliance that appears in 78, correct?

5 A. That's what we are talking about,
6 yes.

7 Q. Well, actually, perhaps my question
8 wasn't clear. I would like to know if there is
9 anything in these photographs which would
10 contraindicate to you that a new Fixed
11 Osseo-Restore device be used in this patient?

12 MR. FUMOSA: Objection. You can
13 answer over objection.

14 A. I'm a little confused. Please phrase
15 it so I can understand.

16 Q. I want you to assume for a moment
17 that this patient's dentist removes the
18 Osseo-Restore device that you see in photograph
19 78, all right? Do you understand that?

20 A. Yes.

21 Q. Now, I'm asking you whether the
22 condition -- anything you see in the condition
23 of this patient in any of the photographs in
24 Exhibit 7 would contraindicate to you that she
25 should continue with another Fixed

1 S. Galella, D.D.S.

2 Osseo-Restore device?

3 MR. FUMOSA: You can answer over
4 objection.

5 A. Wearing the appliance more than three
6 to four months, and then in older adults five
7 to six months, is pretty much -- the body has
8 already made its changes, its remodeling
9 changes. There is not an indication to make
10 two appliances.

11 Q. Specifically, is there anything about
12 the condition of this patient that would
13 contraindicate to you that she should not have
14 another Fixed Osseo-Restore device inserted in
15 her?

16 MR. FUMOSA: Objection to the form.

17 A. The redness around the pad indicates
18 that there has been some damage, and you would
19 have to remove the device, wait a period of
20 time for it to heal, which could take several
21 months, and then reapply the appliance. At
22 that point the teeth would drift, and it would
23 not be a good thing.

24 Q. Why do you say the teeth would drift?

25 A. Because they are crowded, and you

1 S. Galella, D.D.S.

2 created a gap, and the teeth will uncrowd on
3 their own because of that gap.

4 Q. Anything else you see in these
5 photographs that would contraindicate to you
6 that this patient should have another Fixed
7 Osseo-Restore Appliance installed or inserted?

8 MR. FUMOSA: Same objection.

9 A. It could be the recession of the
10 teeth. I don't recall -- I don't know how much
11 was there prior to, but that would be of
12 concern to me.

13 If it was like that before, then
14 there is no change, and that would be an
15 issue.

16 Scroll to the 78, please.

17 Q. Sure.

18 A. The anterior open bite would indicate
19 there is uncontrolled tongue thrust. That
20 would probably be an indication that that needs
21 to be taken care of at this point.

22 The bands are on incorrectly on the
23 molars and the bicuspid.

24 Q. What is incorrect about how the bands
25 are on, sir?

1 S. Galella, D.D.S.

2 A. They are seated unevenly.

3 Q. Before making a determination as to
4 whether this patient should have --

5 MR. CHARNAS: Strike that.

6 Q. Before making a determination whether
7 it was appropriate for this patient to have
8 another Fixed Osseo-Restore device installed,
9 was there any other information you would want
10 to have in terms of a periodontal examination?

11 MR. FUMOSA: Objection. You could
12 answer.

13 A. I think that would probably be good
14 because any time you wear it longer than six
15 months, there's always a possibility that
16 periodontal issues could develop because it's
17 not very easy to keep clean because of the
18 bonding and the pad, et cetera.

19 Q. Thank you. Would you agree that root
20 exposure is evidence of possible root
21 resorption?

22 MR. FUMOSA: What was that question?

23 Q. Would you agree that root exposure is
24 evidence of possible root resorption?

25 A. No.

1 S. Galella, D.D.S.

2 Q. Before determining whether this
3 patient should have another Fixed Osseo-Restore
4 device installed, would you want to determine
5 whether the patient was suffering from any root
6 resorption?

7 A. I would, yes.

8 Q. How would you do that?

9 A. Take a cone beam and check for root
10 resorption.

11 Q. Anything else you would want to know
12 other than what we talked about before you
13 would think it appropriate to put another Fixed
14 Osseo-Restore device on that patient?

15 A. I would not see it appropriate to use
16 two appliances, so if you are talking about me,
17 I have never done two appliances.

18 Q. Thank you.

19 MR. FUMOSA: Same objection to the
20 line of questioning.

21 MR. SCHWARTZ: My objection stands
22 throughout that questioning.

23 MR. CHARNAS: Understood.

24 Q. Doctor, this was Exhibit 14 to Dr.
25 Cortes's deposition. You can see it, right,

1 S. Galella, D.D.S.

2 Doctor?

3 A. I can see it, yes.

4 Q. And you can see my client's name in
5 the date of the scan on the top left?

6 A. Yes.

7 Q. What type of image are we looking at?

8 A. It looks like a cephalometric. It
9 may be a 3D. I have no idea. It's a
10 cephalometric showing soft tissue and hard
11 tissue. Facing the patient, the patient -- the
12 right-hand side is the most visible. This
13 patient is facing to the left profile.

14 Q. Can you see that the patient is
15 apparently wearing some hardware?

16 A. It looks like braces.

17 Q. Can you tell whether it's a
18 controlled arch?

19 A. No.

20 Q. Now I am going to represent to you
21 that this was from Exhibit 2 --

22 MR. CHARNAS: Strike that.

23 Q. This document is Bates stamped 481 at
24 the bottom. Do you see that, at the bottom?

25 MR. FUMOSA: I got it.

1 S. Galella, D.D.S.

2 Q. I want to make sure we are talking
3 about the same thing. Doctor, in this X-ray,
4 do you observe any flaring of the anterior
5 maxillary teeth?

6 A. Yes, there appears to be.

7 Q. How do you know there's flaring of
8 the teeth without having seen prior similar
9 films?

10 A. Say that one more time. I'm sorry.
11 Your voice is tapering off. You must be
12 getting tired.

13 Q. I am getting tired, but I'm getting
14 near the end. Sorry. Let me try it again.

15 You have not seen any cephalometric
16 X-rays of this same patient at a prior time,
17 correct?

18 A. Correct.

19 Q. Without having seen the prior
20 condition of the patient's anterior maxillary
21 teeth, how do you know that this patient's
22 teeth in this film are flared?

23 A. You look at A point and B point, and
24 you project occlusal plane line, and if A point
25 is behind B point and the anterior -- maxillary

1 S. Galella, D.D.S.

2 anterior teeth are in front of the mandibular
3 incisors, and the mandibular incisors are not
4 retroclined in a negative position, then
5 generally the maxillary anterior teeth are
6 flared.

7 I have looked at thousands of
8 cephalometrics, and that's sort of what you
9 determine.

10 Q. The position of the anterior
11 maxillary teeth in this X-ray, is that
12 consistent with the design goals of the
13 Osseo-Restore device?

14 A. No.

15 MR. FUMOSA: Can I have that question
16 back?

17 MR. CHARNAS: Can the court reporter
18 read it back?

19 (Record read.)

20 MR. FUMOSA: Objection to form and
21 also Carvalho.

22 A. The position you are talking about --
23 I am not sure what you mean.

24 Q. The flare, Doctor.

25 MR. FUMOSA: Do you understand the

1 S. Galella, D.D.S.

2 question? Object to the form of the question.

3 A. I don't understand what you are
4 asking.

5 Q. You have told us that the anterior
6 maxillary teeth are flared, correct?

7 A. Yes.

8 Q. Is that flaring of the anterior
9 maxillary teeth consistent with the design
10 goals of the Osseo-Restore device?

11 MR. FUMOSA: Objection to the form.
12 Also no foundation.

13 A. No.

14 Q. What is the basis for your answer?

15 A. Because the A point is not moved
16 forward -- I'm assuming it's after growth
17 appliance, because there's a gap, so the teeth
18 appeared somewhat flared.

19 Q. Why is that inconsistent with the
20 design goals of AGGA?

21 A. Because the Osseo-Restore Appliance,
22 if inserted or placed properly and monitored
23 properly, you get minimal flaring.

24 Q. Do you see anything else in that
25 cephalometric X-ray that in your opinion you

1 S. Galella, D.D.S.

2 find inconsistent with the design goals of AGGA
3 -- of the Osseo-Restore device?

4 A. I don't see -- other than that, no.

5 Q. How about the position of the molars;
6 anything about that that you find inconsistent
7 with the design goals of the Osseo-Restore
8 device?

9 A. I don't know what they looked like
10 before.

11 Q. Do you agree that the molars are
12 tipped backwards?

13 A. The second molar appears to be tipped
14 somewhat. The first molar appears to be
15 normal.

16 Q. Is a tipped molar consistent with the
17 design goals of AGGA?

18 MR. CHARNAS: Let me rephrase that.

19 Q. Is a tipped molar consistent with the
20 design goals of the Osseo-Restore device?

21 MR. FUMOSA: Objection to the form,
22 and also no foundation.

23 A. The second molar occasionally will be
24 somewhat tipped posteriorly because it's not
25 banded or part of the anchorage system that's

1 S. Galella, D.D.S.

2 banded, so it will vary in its position, so
3 tipping is not unusual of that.

4 Q. Thank you, Doctor. What is Ortho
5 Assist?

6 A. It's the old name of what is now
7 called Orthologic. It's a diagnostic service
8 provided by OrthoMatrix to doctors.

9 Q. When did Ortho Assist become
10 Orthologic?

11 A. There was somebody that had
12 trademarked the name Ortho Assist in another
13 field, and there was a trademark issue, so we
14 changed our name to preclude any issues.

15 Q. The type of service that you provided
16 stayed essentially the same, correct?

17 A. Remained the same, yes.

18 Q. I want to get back to 2018 for a
19 moment. Can you tell us what services you
20 provided to John's Dental in regard to
21 Osseo-Restore in 2018?

22 MR. FELD: Objection to form. Vague.

23 MR. FUMOSA: You can answer over
24 objection.

25 Q. Let me withdraw that question. First

1 S. Galella, D.D.S.

2 I want to ask you about you personally. What
3 service did you perform for Osseo --

4 MR. CHARNAS: Strike that.

5 Q. What services did you perform in 2018
6 personally for John's Dental?

7 A. Personally?

8 Q. Yes.

9 A. I used them as a dentist to make my
10 appliances. They were my laboratory. I
11 provided them services under my Steve Galella
12 D.D.S. Practitioner. Personally, no.

13 Q. Steve Galella D.D.S. Practitioner, is
14 that the name of a company, or you are talking
15 about just yourself?

16 A. I am talking about myself. You are
17 asking me personally, not as a principal, not
18 as an employee. Me personally, that's what I'm
19 answering.

20 Q. Got you. Thank you. In your role as
21 an officer or employee of OrthoMatrix, what
22 services in 2018 did you provide to John's
23 Dental in regard to the Osseo-Restore device
24 generally?

25 MR. FELD: Objection to form.

1 S. Galella, D.D.S.

2 MR. FUMOSA: You can answer over
3 objection.

4 A. I would check. They would show me
5 models with the appliances constructed on the
6 models, and I was to check the appliances and
7 make sure they were built or constructed in
8 line with the parameters that the appliances
9 should have.

10 It was the Osseo-Restore appliances,
11 the tongue habit appliances, the FRLAs, the
12 removable appliances.

13 Q. In 2018 from time to time would
14 John's Dental also ask your advice for how to
15 deal with unusual or possibly problematic
16 Osseo-Restore prescriptions?

17 MR. FELD: Note my objection.

18 MR. FUMOSA: Objection.

19 A. Yes. "We are having trouble with
20 this. How do we design a case?"

21 They were missing teeth that they
22 weren't used to be missing, or we had one case
23 that was missing four anterior teeth, you
24 know, so we had to deal with it.

25 Q. And you provided that service as part

1 S. Galella, D.D.S.

2 of your position with OrthoMatrix, correct?

3 A. Yes.

4 Q. In 2018, how often did you provide
5 that service, that advisory service?

6 A. Monday through Friday. They were
7 open Monday through Friday.

8 Q. I guess what I'm getting at is how
9 often did you respond to inquiries from John's
10 Dental about problematic or unusual
11 prescriptions with regards to the Osseo-Restore
12 device?

13 A. It varied from month-to-month. I
14 would say probably did a thousand cases a year.

15 Q. It is it fair to say it was multiple
16 times a week that you would respond to these
17 kinds of inquiries from John's Dental?

18 A. I'm sorry. Maybe I am confused.
19 Checking the --

20 Q. No. I apologize. In regards to this
21 advisory service that you just discussed where
22 John's Dental would inquire when they had
23 issues, unusual issues, problematic issues,
24 would Osseo-Restore -- let's call that the
25 advisory capacity -- how often would you

1 S. Galella, D.D.S.

2 interact with John's Dental in 2018 in this
3 advisory capacity?

4 A. Maybe a couple of times a month.

5 Q. Was there an extra fee paid to you or
6 OrthoMatrix, to your knowledge, for this
7 advisory capacity work, or was that part of the
8 royalty fee?

9 A. No extra fee.

10 Q. I am going to show you Exhibit 21.
11 Can you see that, Doctor, on the screen?

12 A. Yes.

13 Q. So this was premarked as Exhibit 21.
14 (Document premarked Exhibit 21.)

15 Q. Have you ever seen -- it is a
16 three-page exhibit. Have you ever seen the
17 first page on this? Let me scroll through
18 slowly. When I say the first page, now I am
19 talking about just the form, not what is
20 written on it.

21 A. Yes. Go up to the top. Let me read
22 it.

23 I think the lab used this to send to
24 doctors that used this type of an appliance so
25 it would make the prescription writing easier.

1 S. Galella, D.D.S.

2 Q. This document -- let me go through
3 it. There is actually three pages here.

4 Is this one of the documents that
5 you reviewed, this three-page document, in
6 preparation for the deposition?

7 A. I don't recall, but go ahead. I'll
8 look at it.

9 Q. Tell me if this first page looks
10 familiar to you. I am going to scroll through,
11 but let me know if I am going too fast for you.

12 Just that first page, does it look
13 familiar to you?

14 A. No.

15 Q. I am going to draw your attention to
16 a few things on the first page. It says doctor
17 name, Martha Cortes D.D.S. Do you see that
18 there?

19 A. Yes.

20 Q. And the date 8/11/2016, do you see
21 that?

22 A. Yes.

23 Q. It says attention Glenda. Do you
24 know a Glenda at John's Dental?

25 A. She used to work for John's Dental,

1 S. Galella, D.D.S.

2 yes.

3 Q. Was that one of the people you spoke
4 to at John's Dental when you were talking to
5 them in your advisory capacity?

6 A. Sometimes.

7 Q. Anyone else?

8 A. Presently it's Mariah.

9 Q. Before Glenda left the company,
10 anyone else you spoke to?

11 A. Yes, but I don't recall the names.

12 Q. I am going to represent to you that
13 Jerry Neuenschwander at his deposition on
14 Wednesday was asked to read sections of this
15 document, and he read that as Glenda call Dr.
16 Galella. Do you recall receiving a phone call
17 from Glenda in November of 2018 about either my
18 client, Boja Kragulj, or about a prescription
19 from Dr. Martha Cortes?

20 A. I don't have a recollection of that.
21 That was many years ago.

22 Q. Let me go down to the second page.
23 Do you recognize this form, generally speaking,
24 on the second page of Exhibit 21?

25 A. It looks like some kind of internal

1 S. Galella, D.D.S.

2 form.

3 Q. Have you ever seen the form before?

4 A. I don't recall seeing it.

5 Q. Do you see towards the bottom it says
6 per Dr. G. proceed with case?

7 A. I see that.

8 Q. Was that the type of judgment that
9 you would make from time to time in your
10 advisory capacity for John's Dental in terms of
11 whether to proceed or not to proceed with an
12 Osseo-Restore case?

13 A. I would see an appliance on the
14 model; an advisory thing. They would show me a
15 model and say how do we design this appliance,
16 and I would give them the answer and tell them
17 that either the design was fine or make these
18 changes.

19 I have no knowledge of the doctor,
20 no knowledge of the history, no knowledge of
21 anything other than "Here's a set of models
22 with the appliance, and that's what we need to
23 do."

24 Q. Would they send you the models or the
25 photographs of the models?

1 S. Galella, D.D.S.

2 A. The photographs of the models.

3 Q. Based on the photographs of the
4 models, from time to time in this capacity,
5 would you ever tell John's Dental not to
6 proceed with a prescription for an
7 Osseo-Restore device?

8 A. No. I would tell them not to do it
9 if they were missing too many teeth or if they
10 were -- there was no way to construct it, there
11 was no anchorage. Yes, there would be some
12 situations that we would do that.

13 Q. I want to show you this third page,
14 and it says Dr. Martha Cortes on the top left,
15 has my client's name, Kragulj, Bojo. Do you
16 see that?

17 A. Yes.

18 Q. It says ship date 9/26/18. Do you
19 see that?

20 A. Yes.

21 Q. Let me scroll down to the end.

22 I would enlarge it, but I think it
23 is not going to be too visible. Let me read
24 that to you -- strike that.

25 Can you read that yourself?

1 S. Galella, D.D.S.

2 A. No.

3 Q. How about now? Can you read it?

4 A. No.

5 Q. How about now?

6 A. Okay. I can read it now. Thank you.

7 Q. Read that to yourself, at the bottom

8 section under November 19, 2018, 11:22:12.

9 Tell me when you need me to move it over,

10 because I know it's cut off on the right a

11 little bit.

12 A. Well, move it over. Keep moving.

13 Okay. That's good.

14 Okay, I read it.

15 Q. Did you read that in preparation for

16 your deposition today?

17 A. No.

18 Q. Having read that, Doctor, does that

19 refresh your recollection as to whether you

20 ever approved the use of the second

21 Osseo-Restore or AGGA device for my client,

22 Boja Kragulj?

23 MR. FUMOSA: Object to the form.

24 A. Again, generally I don't approve of a

25 second appliance. I have no knowledge,

1 S. Galella, D.D.S.

2 apparently, that this was a second appliance.

3 It was just "Should we make the appliance?"

4 These images, the images you are
5 showing, when the pictures are sent, I have no
6 way of enlarging that or finding out that it
7 wasn't a second appliance.

8 All I know is they want this
9 appliance. Is it made properly? Proceed with
10 case.

11 I usually said, "Great, looks
12 great," something like that, when I approved
13 of an appliance.

14 There was no question to me "Is this
15 a second appliance? How should we make it?"

16 Q. So it's your testimony that no one
17 from John's Dental in November of 2018 told you
18 that the appliance that Dr. Cortes had
19 prescribed at that time was a second appliance;
20 is that correct?

21 A. Not to my recollection.

22 Q. Now, if you knew it was a second
23 appliance, would that have changed your advice
24 to proceed?

25 A. Yes.

1 S. Galella, D.D.S.

2 Q. And why is that, sir?

3 A. I would have wanted to call the
4 doctor and find out what's going on and look at
5 the records.

6 It was her choice to do whatever she
7 wanted, but I would have wanted to talk to
8 her.

9 Q. But it's fair to say you generally
10 would not prescribe the second Osseo-Restore
11 device for a patient, correct?

12 A. Not in my practice.

13 MR. SCHWARTZ: Again, it is a
14 continuing objection. I don't know if I have
15 to keep restating it, but everything to Dr.
16 Cortes.

17 MR. CHARNAS: You don't, Henry.
18 Continuing objection.

19 MR. FUMOSA: I object as well.

20 Q. Dr. Galella, I want to go back to
21 Exhibit 10 for a moment. These, again, are
22 model photographs that were produced in
23 discovery from John's Dental with regard to my
24 client. I want you to take a look -- can you
25 see them?

1 S. Galella, D.D.S.

2 A. Yes.

3 Q. I want you to take a look at the
4 photograph on the sixth page. Do you see any
5 contraindications from that photo of a model
6 for use of an Osseo-Restore device?

7 A. I am looking at a model with a side
8 view. Do you want me to see the rest of them?

9 Q. Let me show you some more. I am
10 going to show you the fourth page.

11 A. That's the occlusal view.

12 Q. We can go back to them as often as
13 you want.

14 A. The occlusal view.

15 Q. Sixth page?

16 A. Side-view.

17 Q. The seventh page?

18 A. Okay.

19 Q. Eighth page?

20 A. Okay.

21 Q. The 23rd page?

22 A. Okay.

23 Q. The 25th page.

24 A. Okay.

25 Q. And the 27th page.

1 S. Galella, D.D.S.

2 A. Okay.

3 Q. Having those photographs in mind, and
4 again I will go back if you want to any of
5 them, do you see any contraindications for the
6 use of an Osseo-Restore device in any of these
7 photographs?

8 MR. FUMOSA: You can answer over
9 objection.

10 A. Go back to the first picture, the
11 occlusal view.

12 Q. Sure. Number 6, right?

13 A. No.

14 Q. I'm sorry. Number 4.

15 A. Yes. They are missing a bicuspid so
16 I have a model, no knowledge of the patient.
17 All I know is they are missing a bicuspid so it
18 could be they wanted to get 2 or 3 millimeters
19 to replace the bicuspid that is missing. There
20 is no contraindication the appliance would be
21 made. Proceed with the case.

22 Q. Dr. Galella, is it fair to say that
23 at some point before the year 2000, you had a
24 theory that you could achieve three-dimensional
25 growth in the nasomaxillary complex of

1 S. Galella, D.D.S.

2 nongrowing adults using an AGGA or
3 Osseo-Restore device?

4 MR. FUMOSA: Could I have that
5 question read back, please?

6 (Record read.)

7 MR. FUMOSA: Objection to the form.

8 A. 3D? Yes.

9 Q. And --

10 A. It's -- the nasomaxillary is a whole
11 complex up in here. Yes.

12 Q. And that would include maxillary
13 enlargement in the sagittal plane, correct?

14 A. Yes.

15 Q. What did you do to test that theory
16 before January 25, 2018?

17 A. What did I do to test the theory?

18 Q. Yes, sir.

19 A. Well, I don't know. I could have
20 done -- you know, there was visual
21 observations, empirical tests of the theory.
22 Enlow's Essentials of Facial Growth indicated
23 that remodeling is a three-dimensional process,
24 and the three-dimensional process, you know, we
25 saw gaps opening up, so it all paralleled the

1 S. Galella, D.D.S.

2 literature. But to prove it, we hadn't
3 published anything to prove it yet.

4 Q. To this day you have not published
5 anything to prove it, correct?

6 A. I have on the removable; just not on
7 the fixed.

8 Q. Other than relying on Enlow's
9 theories --

10 MR. CHARNAS: Strike that.

11 Q. Relying on Enlow's theories is not
12 testing your theory, correct?

13 MR. FUMOSA: Objection.
14 Argumentative.

15 MR. CHARNAS: Strike that.

16 Q. Is relying on Enlow's theories a test
17 of your theory about AGGA?

18 MR. FUMOSA: Object to the form.

19 A. No. His theories, H.M. Frost, the
20 other literature.

21 Q. Other than making visual
22 observations, what else did you do to test your
23 theory about AGGA creating three-dimensional
24 growth in the nasomaxillary complex of
25 non-growing adults, before January 25th, 2018?

1 S. Galella, D.D.S.

2 A. Well, there was what you saw in
3 Patients 1 through 5, I did very similar things
4 to measure, but it didn't prove anything
5 because there was no research done. It just
6 tested my theory.

7 Q. So would you say that your theories
8 about AGGA or Osseo-Restore causing these
9 changes in the nasomaxillary complex of
10 non-growing adults is an unproven theory?

11 MR. FUMOSA: Object to the form.

12 MR. LAIRD: I also join in that.

13 A. Rephrase it. That's -- rephrase,
14 please.

15 Q. You told us it was your theory before
16 the year 2000 sometime that the AGGA device,
17 which we are also calling Osseo-Restore device,
18 can cause three-dimensional changes in the
19 nasomaxillary complex of non-growing adults,
20 including enlarging the maxilla in the sagittal
21 plane, correct?

22 MR. FUMOSA: Object to the form.

23 A. The word "correct" at the end is
24 throwing me. Rephrase it so I understand.

25 Q. Sorry. Is it fair to say, sir, that

1 S. Galella, D.D.S.
2 you had a theory before the year 2000 that the
3 AGGA device could be used to make
4 three-dimensional changes in the nasomaxillary
5 complex of non-growing adults including
6 enlarging the maxilla in the sagittal plane?

7 A. Yes, I did say that.

8 Can we take a break for a second?

9 Q. Can I ask you one more question, sir?

10 A. It's sort of an emergency.

11 Q. That I respect. Five minutes?

12 A. Yes. That would be good. Thank you.

13 (A recess was taken.)

14 BY MR. CHARNAS:

15 Q. Dr. Galella, while we were off the
16 record, did you have any conversation with your
17 attorney?

18 A. Beg pardon?

19 Q. While we were off the record, did you
20 have any conversation with your attorney?

21 MR. FUMOSA: Just answer that yes or
22 no.

23 A. Yes.

24 Q. I don't want to know what your
25 attorney told you or what you said to him, but

1 S. Galella, D.D.S.

2 as a result of that conversation, do you want
3 to change any of your answers to this
4 deposition to this point?

5 MR. FUMOSA: Objection. Don't answer
6 that. Don't answer that.

7 MR. CHARNAS: Actually, it's a
8 perfectly proper question.

9 MR. FUMOSA: I don't think it's a
10 proper question. Don't answer that question.
11 This is privileged. Don't answer that.

12 MR. CHARNAS: Madam court reporter,
13 could you read the last question back before we
14 took a break?

15 (Record read.)

16 MR. FUMOSA: You can answer.

17 MR. CHARNAS: He answered that.
18 Before the break.

19 MR. FELD: I just want to make clear,
20 I am representing Dr. Galella with respect to
21 his 30(b)(6) testimony today, and I did not
22 speak to Dr. Galella during that last break.
23 You asked if he spoke to counsel. Just for the
24 record, I did not speak to Dr. Galella.

25 MR. FUMOSA: And I am going to move

1 S. Galella, D.D.S.

2 to strike the question and answer as to whether
3 or not I spoke to Dr. Galella on a break.

4 To have that in a deposition is
5 totally inappropriate, as far as I am
6 concerned, and I will move to strike that
7 question and answer.

8 MR. CHARNAS: Brian, I just want some
9 clarification. Did you say you are
10 representing OrthoMatrix and Dr. Galella?

11 MR. FELD: No. Dr. Galella is being
12 produced today, as you said, as a 30(b)(6)
13 witness as well. I am representing Dr. Galella
14 with that in mind because I am representing
15 OrthoMatrix, so I did not speak to Dr. Galella
16 during the break in my capacity as his attorney
17 on behalf of OrthoMatrix.

18 MR. CHARNAS: Since there has been
19 much time gone by since the question, I am
20 sorry, madam court reporter, I have to ask you
21 to read it one more time for context.

22 (Record read.)

23 Q. Dr. Galella, when did you start using
24 CBCT scans in your practice, approximately?

25 A. Maybe eight years ago. I can't

1 S. Galella, D.D.S.

2 recall the year, but maybe eight years ago.

3 Q. And when -- sorry. I didn't mean to
4 interrupt you. Did you finish your answer?

5 A. Maybe seven, maybe eight. I can't
6 recall exact dates.

7 Q. When did you start using Anatomage?

8 A. Probably about the same time.

9 Q. I just want to make sure that I
10 understand. In terms of proving that theory
11 that we just discussed about AGGA making
12 three-dimensional changes in the nasomaxillary
13 complex, before January of 2018, other than
14 visual observations, what did you do to prove
15 that theory?

16 A. Well, clinical experience. I saw it
17 clinically, which is -- and then I did -- I
18 took the 3D imaging, and I did pretty much what
19 I did on the Patient 1 through 5 that you saw.
20 I did those observations and measurements.

21 It proved it to me, but for the rest
22 of the world I hadn't posted anything. Sorry.

23 I knew that the removable appliance
24 works because there's a long history of use of
25 that, you know, probably over 20, 30 years of

1 S. Galella, D.D.S.

2 that, and that worked.

3 Q. When you say 3D imaging, are you
4 talking about CBCT scans, or are you talking
5 about Anatomage?

6 A. 3D imaging is your cone-beam scans,
7 yes, and Anatomage is what I've always used to
8 interpret the cone beams.

9 Q. In a vol/ren setting?

10 A. Well, there's many settings, but the
11 volume rendering is the most common one I used.

12 Q. Is it your testimony that you have
13 used Anatomage in the 3D view analysis setting
14 to measure bone enlargement?

15 A. I can't understand -- I don't know
16 what you are talking about. 3D view analysis
17 setting?

18 Q. It's what we talked about earlier,
19 sir. I think you recognized that Anatomage has
20 a 3D view analysis model.

21 A. Oh, okay. The tracing module. Yes.

22 Q. Have you ever used that 3D view
23 analysis module of Anatomage to confirm your
24 theory about AGGA?

25 A. No. I used pretty much the volume

1 S. Galella, D.D.S.

2 render, and then I would size things, et
3 cetera, just like you saw on Patient 1 through
4 5.

5 Q. And you did that before January of
6 2018?

7 A. Yes.

8 Q. Now, you tried to arrange funding for
9 Dr. Bromage in an attempt to get his overlay
10 system accepted by the dental profession; is
11 that true?

12 MR. FELD: Objection to form.
13 Relevance.

14 MR. FUMOSA: Objection.

15 A. The funding for Dr. Bromage is
16 because New York University was going to close
17 his laboratory down. That was what the funding
18 was for; not to promote his overlay thing or
19 bring it to the world.

20 The funding was to ensure he would
21 have his lab still open.

22 Q. And what was your interest in
23 ensuring that Dr. Bromage has his lab still
24 open?

25 A. Because that's his research facility

1 S. Galella, D.D.S.

2 that he uses to do research. He has a big mass
3 spec and some lasers and some electron
4 microscopes, et cetera, et cetera. That's how
5 he proves things.

6 Q. Does that have anything to do, as far
7 as you know, with the Osseo-Restore device?

8 A. His laboratory and the Osseo-Restore
9 are two different entities.

10 Q. What I am asking you, sir, to your
11 knowledge, is Dr. Bromage conducting any
12 research in regard to the efficacy or safety of
13 the Osseo-Restore device?

14 A. He's developing an overlay system
15 but, like I said before, having trouble with
16 the sizing parameters and the imaging.
17 Sometimes parts of the imaging are cut off that
18 preclude us from doing the mammalian
19 boundaries. That's what the whole thing is
20 based on.

21 Q. So it is fair to say that Dr. Bromage
22 is doing research, among other things, I
23 assume, into the use of the overlay system to
24 measure bone enlargement?

25 A. Bone changes, yes, I think that's

1 S. Galella, D.D.S.

2 accurate.

3 Q. And you had an interest in getting
4 funding to keep that kind of research going,
5 correct?

6 A. To keep the laboratory open and other
7 research, because there's other important
8 research he is doing.

9 Q. Is anyone else to your knowledge
10 doing research into the measurement of --

11 MR. CHARNAS: Strike that.

12 Q. Are you doing any research into the
13 efficacy or safety of the Osseo-Restore device
14 currently?

15 A. Rephrase that. Sorry. I got to
16 understand what you are saying.

17 Q. Sure, sure. As to the present time,
18 in the recent past, have you been doing any
19 research in regard to the safety or efficacy of
20 the Osseo-Restore device?

21 A. Clinical research, yes.

22 Q. Any other kind of research?

23 A. That's all I feel like I'm ready to
24 do at this point.

25 Q. Anybody else at OrthoMatrix that you

1 S. Galella, D.D.S.

2 know of who is doing research in regard to the
3 safety or efficacy of the Osseo-Restore device?

4 A. Dr. Deal is doing some research, and
5 doctor -- he has done some research relating it
6 to airway.

7 Q. What is Dr. Deal's --

8 MR. FELD: I just want to place an
9 objection, and counsel, I ask you to clarify
10 what you mean by anyone in OrthoMatrix.

11 Q. Any human being who is employed by or
12 an officer of OrthoMatrix. I think you
13 understood that, didn't you, Doctor?

14 A. Well, employed by is a whole
15 different subject. Dr. Deal is a 1099
16 contractor.

17 Q. Do you know of anyone who is doing
18 research in regard to the safety and efficacy
19 of the Osseo-Restore Appliance who is
20 associated or affiliated with OrthoMatrix?

21 A. Well, Dr. Deal has done some research
22 concerning the airway and the removable
23 appliance.

24 Q. What about concerning the fixed
25 appliance?

1 S. Galella, D.D.S.

2 A. No.

3 Q. Do you know anyone who is doing any
4 research currently into the safety or efficacy
5 of the Osseo-Restore device, whether affiliated
6 or associated with OrthoMatrix or not?

7 A. That would be Dr. Bromage at New York
8 University.

9 Q. His research is in regard to the
10 overlay system, correct?

11 MR. FUMOSA: Objection.
12 Argumentative.

13 A. That would be the efficacy of the
14 appliance, if it works.

15 Q. You would want to have a reliable
16 system of measuring bone enlargement or growth
17 before determining whether the Osseo-Restore
18 Appliance was safe and efficacious; is that
19 fair to say?

20 A. No.

21 MR. FUMOSA: Objection to that last
22 question. Argumentative.

23 Q. Do you continue to teach dentists to
24 this day about the Osseo-Restore device?

25 A. Yes.

1 S. Galella, D.D.S.

2 Q. Do you continue to do that through
3 your role as an officer or employee of
4 OrthoMatrix?

5 MR. FELD: Form.

6 A. Yes.

7 Q. And do you still continue to this day
8 to place Osseo-Restore devices into the mouths
9 of patients?

10 A. Yes.

11 Q. When is the last time you did that?

12 A. Three, four weeks ago.

13 Q. Since 2017, how much money have you
14 made, approximately, annually from your share
15 of royalties from John's Dental for the sale of
16 the Osseo-Restore device or devices?

17 MR. FELD: Objection to form. Vague,
18 ambiguous.

19 MR. LAIRD: I also join as well.

20 MR. FUMOSA: Also join. You can
21 answer over objection if you can answer.

22 MR. SCHWARTZ: I join.

23 A. Spell it out exactly what you're
24 asking. I'm sorry.

25 Q. Sure. You told us that there's a

1 S. Galella, D.D.S.

2 royalty paid by John's Dental for the
3 manufacture and sale of each Osseo-Restore
4 device, correct?

5 A. Yes. Paid to OrthoMatrix.

6 Q. Did you also tell us at your
7 deposition, the first day of your deposition,
8 that Inside Dentistry gets part of that
9 royalty?

10 A. Yes.

11 Q. Is that paid directly from John's
12 Dental to Inside Dentistry?

13 A. No. It is paid from OrthoMatrix to
14 Inside Dentistry.

15 Q. How much money has Inside Dentistry
16 made on an annual basis since 2017 as its share
17 of royalties from John's Dental's sale of
18 Osseo-Restore devices?

19 A. Let me think for a minute.

20 Q. Take your time, sir.

21 MR. FUMOSA: Can I make an inquiry,
22 counsel, for clarification?

23 MR. CHARNAS: After I'm finished my
24 questioning.

25 MR. FUMOSA: In terms of you for

1 S. Galella, D.D.S.

2 clarification. Do you want to know the
3 approximate annual amount?

4 MR. CHARNAS: I think that was the
5 question, since 2017.

6 MR. FUMOSA: Approximate annual
7 amount.

8 A. Fifty, 60,000 was paid by OrthoMatrix
9 to Inside Dentistry.

10 Q. And since 2017, how much money have
11 you made annually from your teaching about the
12 Osseo-Restore Appliance?

13 MR. FUMOSA: Objection. Totally
14 irrelevant. You can answer over objection.

15 MR. FELD: Join.

16 A. Maybe 60, \$70,000 a year.

17 Q. Since 2017, how much money have you
18 made annually from placing AGGA or
19 Osseo-Restore products in your own patients?

20 MR. FUMOSA: I will object to this.
21 Totally irrelevant.

22 MR. FELD: Join.

23 MR. FUMOSA: You can answer over
24 objection.

25 A. Are you asking how much I make in my

1 S. Galella, D.D.S.

2 practice income?

3 Q. Let me ask you a different question.
4 How much do you charge your patients since 2017
5 for the Osseo-Restore device and the treatment
6 associated therewith?

7 MR. FUMOSA: I will object to this
8 entire line of questioning. Totally
9 irrelevant.

10 A. It would be a package of -- it
11 depends on whether it's just the appliance and
12 orthodontics or if it was TMJ and orthodontics.

13 Q. Let's just talk about the appliance
14 itself.

15 A. I have to pull the data on that.

16 Q. Sir, if I came to your office and you
17 determined that it would be in my best interest
18 to have an Osseo-Restore device installed in
19 me, what would you quote me in terms of a fee?

20 MR. FUMOSA: Objection to this.
21 Vague, and form of the question.

22 MR. FELD: Objection.

23 A. I don't charge for just -- for me to
24 just charge for the appliance placement would
25 not be rational to me because you have to

1 S. Galella, D.D.S.

2 finish your case.

3 Q. I mean from placement through the end
4 of the treatment.

5 A. That would require the orthodontics
6 as well.

7 Q. When you say "the orthodontics," you
8 mean the controlled arch?

9 A. That's orthodontic.

10 Q. So what would you charge for the
11 Osseo-Restore device, the controlled arch brace
12 and the treatment program?

13 A. \$7,000.

14 Q. Do you know that some of the dentists
15 charge \$15,000 for that service?

16 MR. FUMOSA: Objection to that.
17 Totally improper.

18 MR. FELD: Irrelevant.

19 MR. FUMOSA: And irrelevant. And
20 also now you are testifying.

21 A. It depends on the part of the country
22 you are in.

23 Q. Do you know of any dentists who
24 charge \$15,000 for that service?

25 A. Yes.

1 S. Galella, D.D.S.

2 MR. FELD: Objection to form.

3 Relevancy.

4 MR. FUMOSA: Join.

5 Q. You said that you would charge about
6 7,000 for that service. How many Osseo-Restore
7 appliances -- again, this is fixed -- have you
8 installed in your patients since and including
9 2017, approximately?

10 MR. FUMOSA: Do you want the question
11 repeated?

12 THE WITNESS: I would love the
13 question repeated. I got interrupted in my
14 thoughts.

15 (Record read.)

16 A. I have no idea, but I would say --
17 let's just guess that -- how many years is
18 that?

19 Q. Well, why don't we make it easier.
20 Up until the pandemic, on an annual basis, in
21 the five years before the pandemic, so that
22 would be five years before, say, March of 2020,
23 on an annual basis, how many fixed
24 Osseo-Restore devices have you installed in
25 your patients?

1 S. Galella, D.D.S.

2 MR. FUMOSA: Objection to this.

3 A. 500, maybe. Maybe 250 to 500. I
4 have no idea.

5 Q. Per year?

6 MR. FELD: Don't guess, Dr. Galella.

7 MR. FUMOSA: Do you understand the
8 question?

9 A. Per year? You said five years, I
10 thought.

11 Q. I'm sorry. I thought I broke it down
12 per year. I'm trying to make it easier for
13 you, so let's start again.

14 In the five years before the
15 pandemic, which is March of 2020,
16 approximately, on an annual basis -- no one
17 wants you to guess -- what is your best
18 estimate as to the number of Osseo-Restore
19 devices that you have installed in your
20 patients?

21 A. I don't know the answer to that.

22 Q. Would you say it's at least 100?

23 MR. FELD: Objection.

24 MR. FUMOSA: Objection.

25 A. I can't answer that.

1 S. Galella, D.D.S.

2 Q. Would you say it's at least ten on an
3 annual basis?

4 MR. FELD: Objection.

5 MR. FUMOSA: Objection.

6 A. Ten would be a guess.

7 Q. We don't want you to guess. You
8 said -- that 500 number you gave before, what
9 did you mean that to be; 500 --

10 A. That is total appliances, not fixed,
11 but removable and -- most of my patient base is
12 young so I do a lot of removable.

13 Q. Is it your testimony that you have no
14 idea how many Osseo-Restore devices you have
15 installed in the last five years?

16 A. No. I don't know.

17 Q. Let's take a five-minute break. I
18 believe I am finished. I just want to review
19 my notes. It's 2:28 so 2:35.

20 (A recess was taken.)

21 Q. Dr. Galella, you mentioned before
22 that in terms of proof of the theory of AGGA
23 that we discussed, that before January of 2018,
24 you relied on, I think you said, clinical
25 evidence or clinical observations; is that

1 S. Galella, D.D.S.

2 right?

3 A. I relied on clinical observations,
4 and I did do measurements, you know, to prove
5 that point, yes. That's the basis.

6 Q. When you say "measurements," you are
7 talking about gap measurements as we discussed
8 earlier?

9 A. Gap measurements and the measurements
10 that you saw in Patients 1 through 5. It's the
11 same measurements.

12 Q. And the same methodology?

13 A. Yes.

14 Q. And analysis in the volume rendering
15 view, correct?

16 A. Yes, that's correct.

17 Q. When you say clinical observations or
18 clinical evidence, that's also basically
19 eyeball people, right? That's included in --

20 A. Well, facial shape and profiles, the
21 health of the joints, the mandible, mandibular
22 position; yes, clinical things. The width, you
23 can measure clinically the width of the molar
24 width, et cetera, et cetera, in your patients.

25 Q. Thank you, sir.

1 S. Galella, D.D.S.

2 MR. CHARNAS: Those are all the
3 questions I have. Thank you very much, Dr.
4 Galella.

5 I don't know if anybody else has any
6 questions.

7 MR. SCHWARTZ: I have no questions.

8 MR. FUMOSA: I have questions.

9 Can you please put up Exhibit 21.

10 (Pause in the proceedings.)

11 EXAMINATION

12 BY MR. FUMOSA:

13 Q. Dr. Galella, you were questioned
14 about this note here with John's Dental, and
15 reference was made to a Mr. Neuenschwander. Do
16 you recall that?

17 A. Yes.

18 Q. And I think reference was made to
19 Mr. Neuenschwander's interpretation of a note
20 which begins "Glenda call." Do you see that on
21 Exhibit 21?

22 A. Yes.

23 Q. I believe Mr. Neuenschwander
24 testified that he didn't make that note, and he
25 was interpreting that note.

1 S. Galella, D.D.S.

2 Take a look at that note, and it
3 says "Glenda call." Do you see the initials
4 next to "call"?

5 A. Yes.

6 Q. What do those two initials appear to
7 say to you?

8 A. MC.

9 Q. Doctor, are the initials MC -- or the
10 name Martha Cortes have the initials M and C?

11 A. Yes, they would.

12 Q. When it says here also on another
13 portion of Exhibit 21, "Dr. G proceed with
14 case," what is your interpretation of that?

15 A. Per Dr. Galella proceed with case,
16 that means that the appliance fit the model and
17 they could go ahead and finish the case.

18 Q. At any time, at this time or at any
19 time prior to when you saw the patient in 2020,
20 were you aware that this patient had, in fact,
21 had applied two Osseo-Restore appliances to her
22 by Dr. Cortes?

23 THE WITNESS: Not until I saw her in
24 2020.

25 MR. CHARNAS: Could you read back the

1 S. Galella, D.D.S.

2 question and answer? I didn't quite catch
3 that.

4 MR. FUMOSA: I will rephrase it.

5 Q. At any time prior to seeing the
6 patient in 2020, were you aware that this
7 patient had, in fact, two Osseo-Restore
8 appliances that were applied to her by Dr.
9 Cortes?

10 A. No.

11 Q. Thank you. Now, you were asked to
12 produce five case studies; am I correct; the
13 five cases we talked about?

14 A. Yes.

15 Q. Now, Mr. Charnas mentioned a number
16 of times that you had 600 patients. Doctor,
17 were there any restrictions placed upon you
18 with respect to the patients that you selected
19 for your case studies?

20 A. Yes.

21 Q. And what were those restrictions?

22 A. It was five patients all over 30 with
23 one being over age 35.

24 Q. If we take approximately 600 patients
25 that you had, approximately how many patients,

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S. Galella, D.D.S.
approximately, would fit those parameters of
over 30 years of age; approximately how many?

A. Fifty -- approximately 50 or 60.

MR. FUMOSA: Thank you. I have
nothing further.

MR. CHARNAS: Anybody else?

MR. FUMOSA: I am ordering a copy.

MR. SCHWARTZ: I am ordering a copy.

MR. LAIRD: I am ordering a copy.

MR. FELD: I am ordering a copy.

(Time noted: 2:42 p.m.)

Subscribed to and sworn _____

To before me this Steve Galella

____ day of _____, 20 .

Notary Public

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CERTIFICATION

I, HELENE GRUBER, a New York State certified shorthand reporter, hereby certify that the foregoing transcript is a complete, true and accurate transcript in the matter of Kragulj v. Cortes, et al held on February 4, 2022.

I further certify that this proceeding was reported by me and that the foregoing transcript was prepared under my direction.

Date: February 14, 2022



HELENE GRUBER

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Our Assignment No. J7887880

Case Caption: Kragulj

vs. Cortes et al

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I declare under penalty of perjury
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except for changes and/or corrections, if
any, as indicated by me on the DEPOSITION
ERRATA SHEET hereof, with the understanding
that I offer these changes as if still under
oath.

Steve Galella

Subscribed and sworn to on the _____ day of
_____, 20____ before me,

Notary Public,

in and for the State of _____

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