IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, v. PURDUE PHARMA L.P., *et al.*, Defendants.	Case No. CJ-2017-816 Judge Thad Balkman William C. Hetherington Special Discovery Master

DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON & JOHNSON'S MOTION *IN LIMINE* NO. 11 TO EXCLUDE EVIDENCE ASSERTING FRAUD ON THE DEA

REDACTED VERSION

THIS DOCUMENT WAS FILED IN ITS ENTIRETY APRIL 26, 2019,
UNDER SEAL
PER COURT ORDER DATED APRIL 16, 2018

Defendants Janssen Pharmaceuticals, Inc. ("Janssen")[1] and Johnson & Johnson ("J&J") move this Court for an order excluding from trial all evidence and argument contending that Janssen, J&J, or Noramco, Inc. ("Noramco") defrauded, misled, or wrongfully influenced the DEA, FDA, or any other federal agency regulating opioid pain medication. This includes any claim concerning the DEA's establishment of production or procurement quotas for active pharmaceutical ingredients of opioid medications. The Controlled Substances Act and the Supremacy Clause of the United States Constitution preempt any such claims. Accordingly, the evidence and argument are irrelevant to the issues to be decided at trial and therefore inadmissible under Oklahoma Rules of Evidence 2401 and 2402. *See* 12 O.S. §§ 2401, 2402. Janssen and J&J respectfully request that the Court grant this Motion *in Limine* and award such other relief as the Court deems just and proper.

BRIEF IN SUPPORT

In support of this Motion *in Limine*, Janssen and J&J show the following:

I. INTRODUCTION

Federal law, not state law, governs the tightly regulated business of supplying the potent raw materials used to manufacture prescription opioid medications. The State's questioning of employees of J&J's former subsidiary Noramco suggests that the State may contend that Noramco gave the DEA false or misleading information intended to increase the DEA's production and procurement quotas for Noramco's products—the active pharmaceutical ingredients in opioid

[1] "Janssen" also refers to Janssen Pharmaceuticals, Inc.'s predecessors, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.

medications.[2] The DEA itself has never made any such allegations of wrongdoing by Noramco. And federal law preempts any state-law tort claim predicated on an assertion that a party defrauded a public agency in the course of federally regulated interactions with that agency. The Court should therefore exclude as irrelevant any evidence or argument that Janssen or Noramco defrauded, misled, or wrongfully influenced the DEA.[3]

II. ARGUMENT

The State's allegation that Noramco defrauded the DEA cannot serve as a basis for its state-law public-nuisance claim. Federal law preempts state-law claims based on just this type of allegation. Evidence is admissible only if it is "relevant"—that is, it "tend[s] to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." 12 O.S. §§ 2401, 2402. Because the State cannot base its claims on preempted fraud-on-the-DEA allegations, any related evidence and argument bears no connection to any fact that matters.

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[2] The State's questioning of several current and former Noramco employees at recent depositions suggests that the State intends to assert this theory at trial. *See, e.g.*, Ex. A, Feb. 20, 2019 Deposition Tr. of Matthew Martin at 119:16-121:21 ([redacted]; Ex. B, Deposition Tr. of William Grubb (Grubb Dep.) at 97:25-99:5 (questioning about Noramco's efforts to "advocate" for more quota from the DEA); *id.* at 91:4-100:3 [redacted] Ex. C, Feb. 27, 2019 Deposition Tr. of Matthew Minardi at 60:25-63:3 [redacted]; Ex. B, Grubb Dep. at 223:16-226:13 [redacted]

[3] Noramco is a separate company from Janssen and J&J. Neither Janssen nor J&J were involved in any discussions with the DEA about Noramco's quotas. And since 2016, Noramco has no longer been affiliated with J&J. However, the State apparently intends to assert that Janssen, J&J, or both are somehow responsible for the conduct of Noramco (which itself was lawful, as detailed below). Accordingly, Janssen and J&J seek an order that applies to any evidence or argument offered by the State on these subjects regardless of whether the State styles the evidence as applying to Noramco, Janssen, or J&J.

In *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 350 (2001), the Supreme Court held that state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, the Food, Drug, and Cosmetic Act ("FDCA") and its Medical Devices Amendment ("MDA"). The Court explained that "[t]he FDA is empowered to investigate suspected fraud" and pursue criminal prosecutions or injunctive relief, *id.* at 349, and that allowing state-law liability for misleading the FDA would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's objectives." *Id.* at 350. State tort liability would "dramatically increase the burdens facing potential applicants," who "may be discouraged from seeking ... approval of devices with potentially beneficial uses for fear that such use might expose the manufacturer ... to unpredictable civil liability." *Id.* It "would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court," creating "an incentive to submit a deluge of information that the [FDA] neither wants nor needs." *Id.* at 351.

Courts across the country have since recognized that the holding in *Buckman* applies equally to state-law claims for fraud on other federal agencies. *See, e.g., Murray v. Motorola, Inc.*, 982 A.2d 764, 770 n.6 (D.C. 2009) (fraud on the FCC); *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002) (fraud on the EPA); *Transmission Agency of Northern California v. Sierra Pacific Power Co.*, 295 F.3d 918, 932 n.10 (9th Cir. 2002) (fraud-on-the-ERC); *Offshore Serv. Vessels, L.L.C. v. Surf Subsea, Inc.*, 2012 WL 8021738 (E.D. La. Oct. 17, 2012) (fraud on the Coast Guard); *Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 722 (E.D. Tenn. 2001) (fraud on the Department of Energy).

Buckman likewise bars the state-law fraud-on-the-DEA theories that the State asserts here. All of Janssen, J&J, and Noramco's interactions with the DEA—most notably Noramco's representations about production and procurement quotas for opioid medication ingredients—were dictated by the federal Controlled Substances Act ("CSA"). That statute amply "empower[s] [the agency] to investigate suspected fraud," *Buckman*, 531 U.S. at 347, permitting the Attorney General to suspend or revoke a manufacturer's registration to manufacture, distribute, or dispense a controlled substance upon a finding that the manufacturer "has materially falsified any application filed pursuant to or required by" the CSA. 21 U.S.C.A. §§ 811, 824. The Attorney General has delegated this enforcement authority to the DEA, *see Touby v. United States*, 500 U.S. 160, 169 (1991), which has implemented a robust regulatory scheme that it has ample authority to enforce. *See* 21 C.F.R. § 1301.36(a) (permitting DEA Administrator to suspend or revoke registration for violation of section 824 for any period of time); *id.* § 1315.21-.27 (regulation of active pharmaceutical ingredient quotas). And the CSA—like the statutes at issue in *Buckman*—does not provide a private right of action. *McKesson Corp. v. Hembree*, No. 17-CV-323-TCK-FHM, 2018 WL 340042, at *5 (N.D. Okla. Jan. 9, 2018) ("Instead, [the CSA] delegates the power of enforcement of federal drug policy to the federal government . . . [and] courts have rejected private attempts to enforce the CSA through other vehicles.").

Just like the claims rejected in *Buckman*, the State's bid to second-guess Noramco's representations to the CSA would "dramatically increase the burdens facing [manufacturers]—burdens not contemplated by Congress in enacting the [CSA]." *Buckman*, 531 U.S. at 350-51. These additional burdens could, in turn, discourage would-be manufacturers from procuring or manufacturing controlled substances—which all parties agree serve a vital, medically necessary role—for fear of "unpredictable civil liability." *Id.* Additionally, the State's fraud-on-the-DEA claims

would "cause applicants to fear that their disclosures to the [DEA], although deemed appropriate by the [DEA], will later be judged insufficient in state court." *Id.* And manufacturers "would then have an incentive to . . . deluge" the DEA with information it "neither wants nor needs." *Id.* Finally, the State's fraud-on-the-DEA theory would, if permitted to proceed, create the possibility of significant liability for Janssen and J&J—without *any* indication from the DEA that Janssen, J&J, or Noramco did anything wrong.

Court after court has recognized that, under *Buckman*, federal law preempts claims alleging fraud on a federal agency, be it the FDA, the Coast Guard, or the Environmental Protection Agency. *See supra* at 3. The same is true for the State's unfounded claim that Janssen defrauded the DEA. Because the State cannot seek liability on that theory, evidence that Janssen allegedly misled the DEA or any other federal agency regulating opioid pain medications should be excluded as irrelevant.

III. CONCLUSION

For all these reasons, the Court should grant Janssen and J&J's Motion *in Limine* and issue an order barring the State from introducing any evidence or argument that Janssen, J&J, or Noramco defrauded, misled, or wrongfully influenced the DEA or any other federal agency.

Dated: April 26, 2019

Respectfully submitted,

By:_____

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CERTIFICATE OF MAILING

Pursuant to Okla. Stat. tit. 12, § 2005(D), and by agreement of the parties, this is to certify on April 26, 2019, a true and correct copy of the above and foregoing has been served via electronic mail, to the following:

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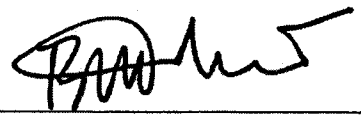

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EXHIBIT A

[FILED UNDER SEAL]

IN THE DISTRICT CIRCUIT OF CLEVELAND COUNTY
STATE OF OKLAHOMA
CASE NO.: CJ-2017-816

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,

Plaintiff,

vs.

(1) PURDUE PHARMA, L.P.;
(2) PURDUE PHARMA, INC.,
(3) THE PURDUE FREDERICK COMPANY;
(4) TEVA PHARMACEUTICALS USA, INC.,;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC.;
(8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC.;
(9) JANSSEN PHARMACEUTICA, INC.; n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS, LLC; and
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.
_____/

VIDEOTAPE DEPOSITION OF MATTHEW MARTIN

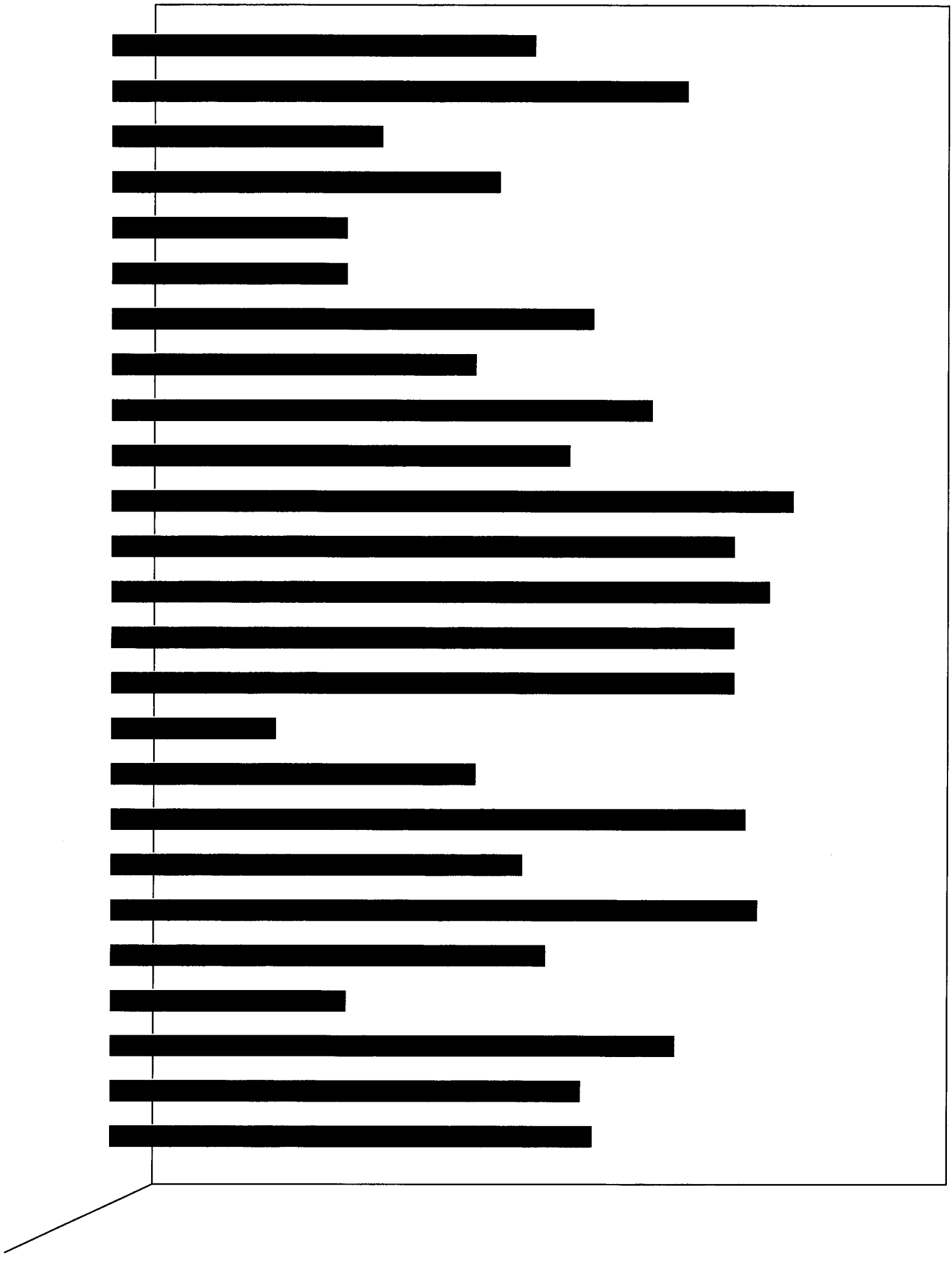
TAKEN OF BEHALF OF THE PLAINTIFF

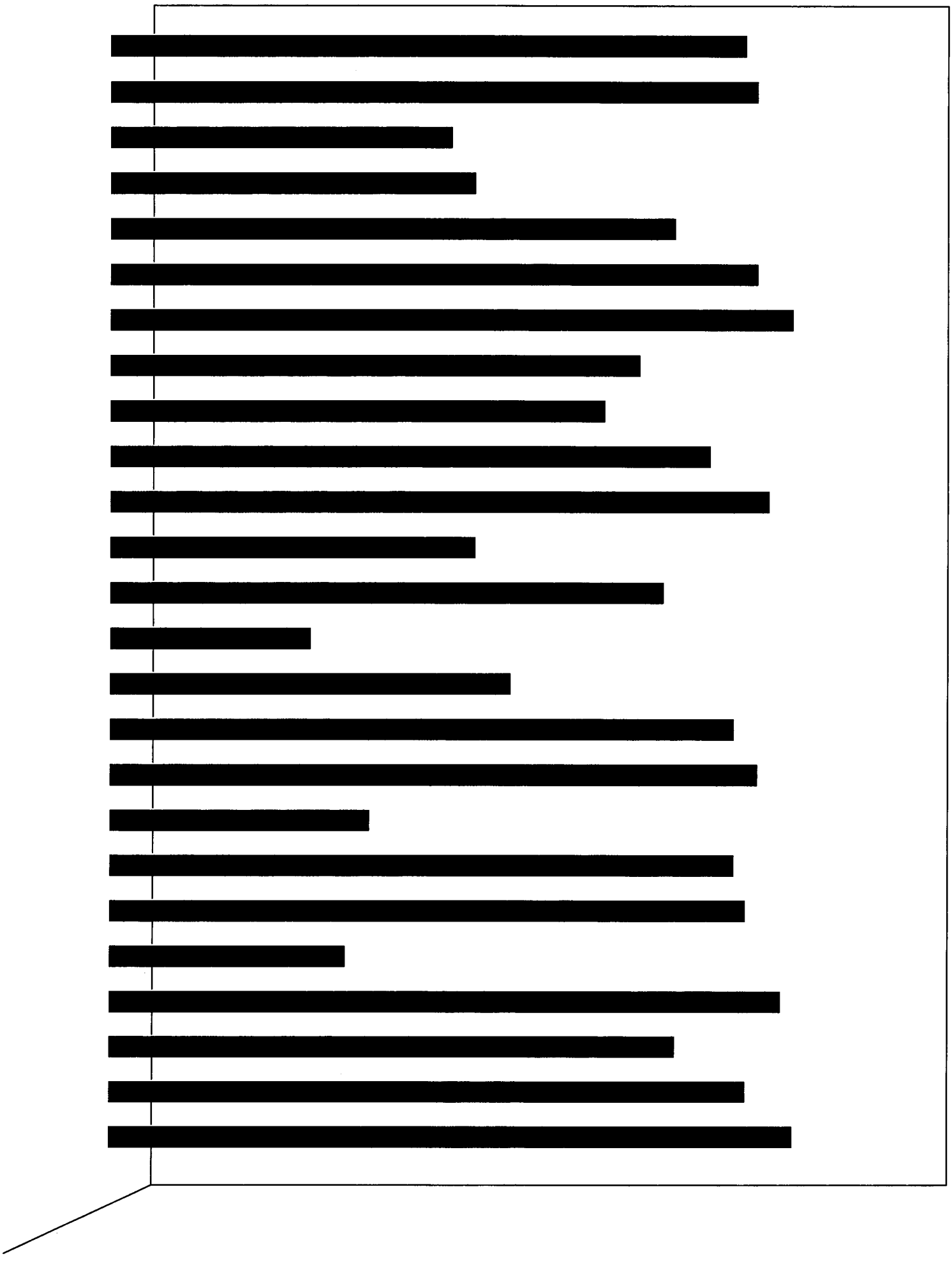
ON FEBRUARY 20, 2019, BEGINNING AT 9:07 A.M.

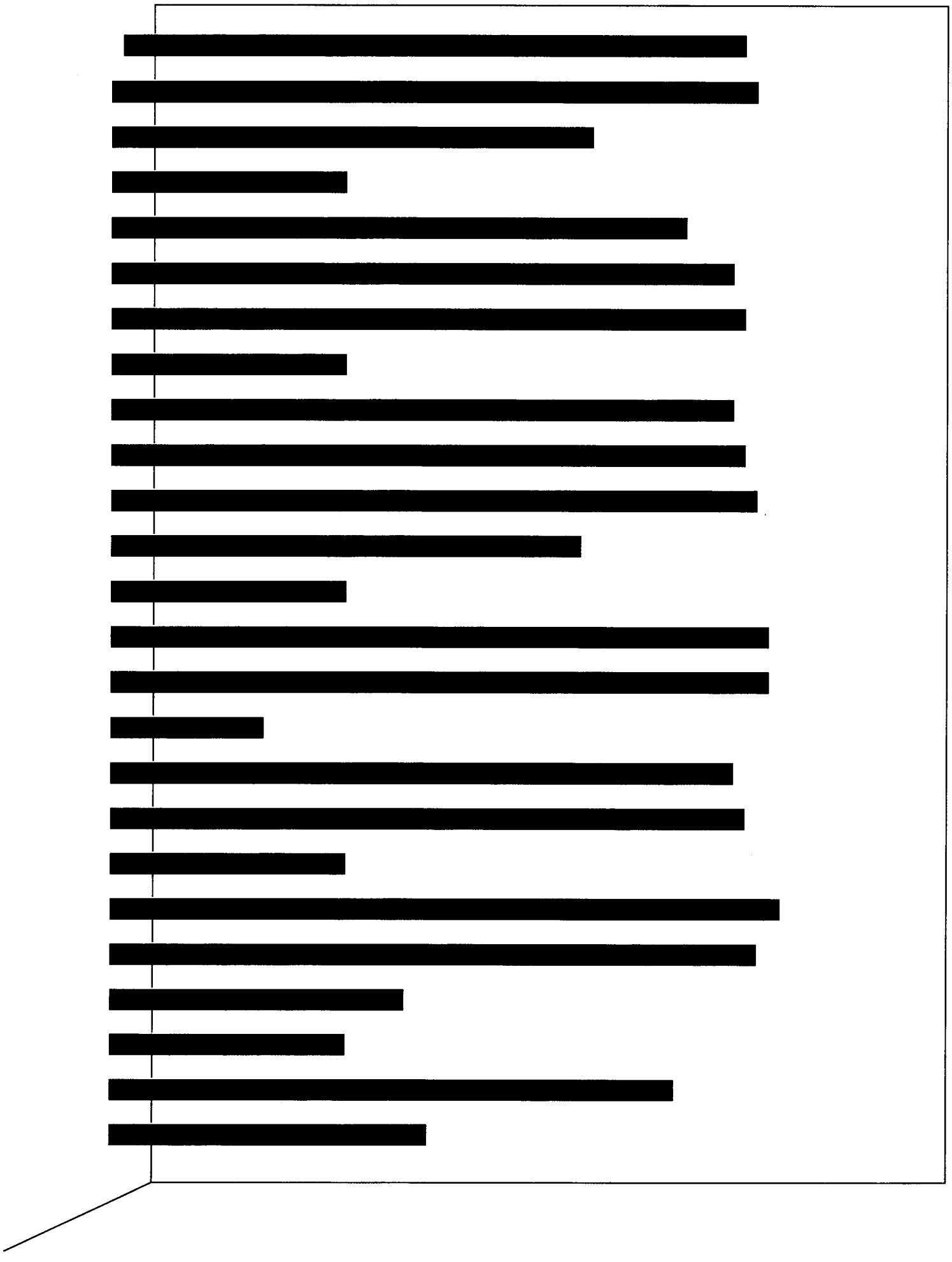
IN SARASOTA, FLORIDA

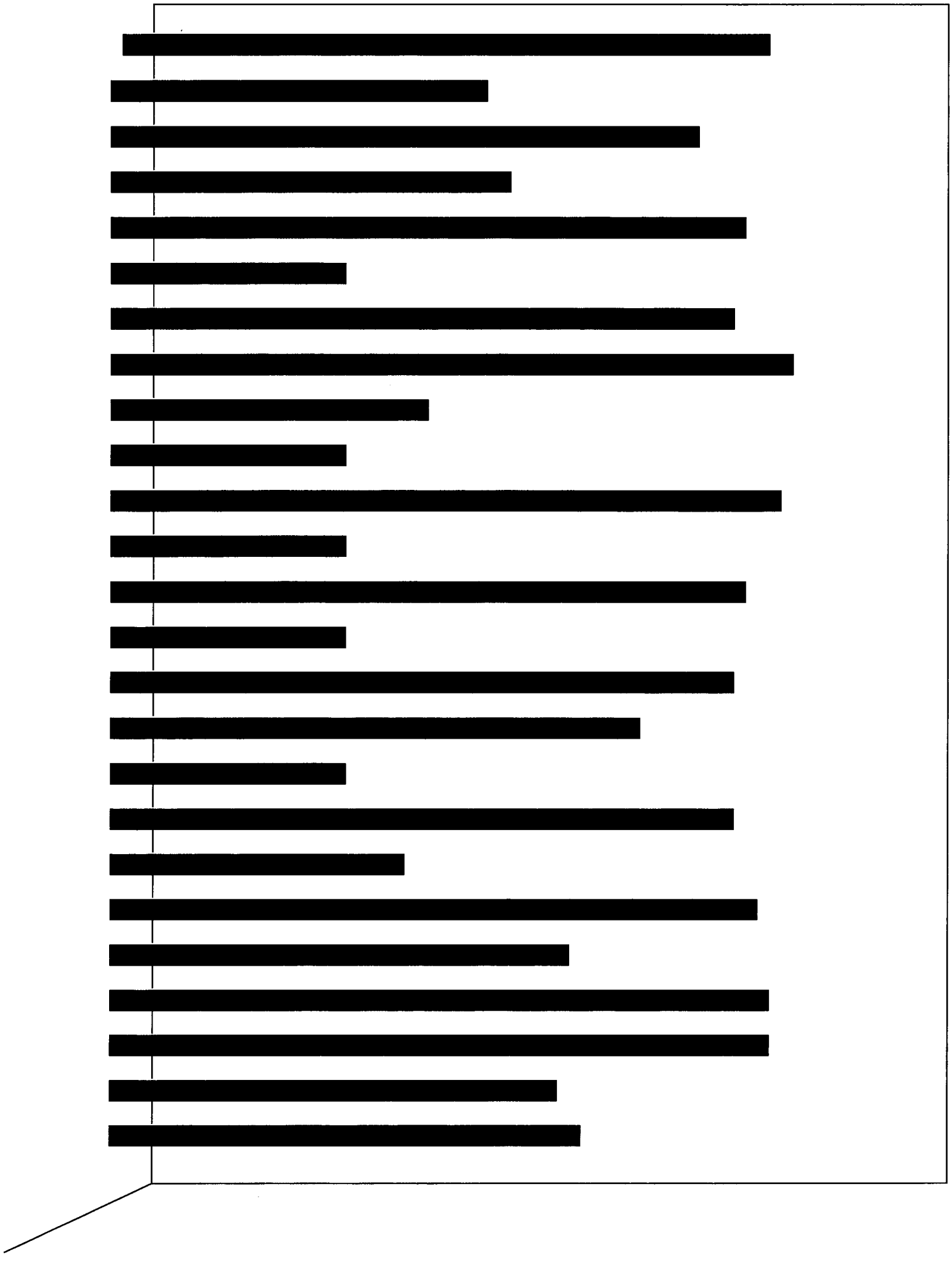
VIDEOTAPED BY: Joel Freedman

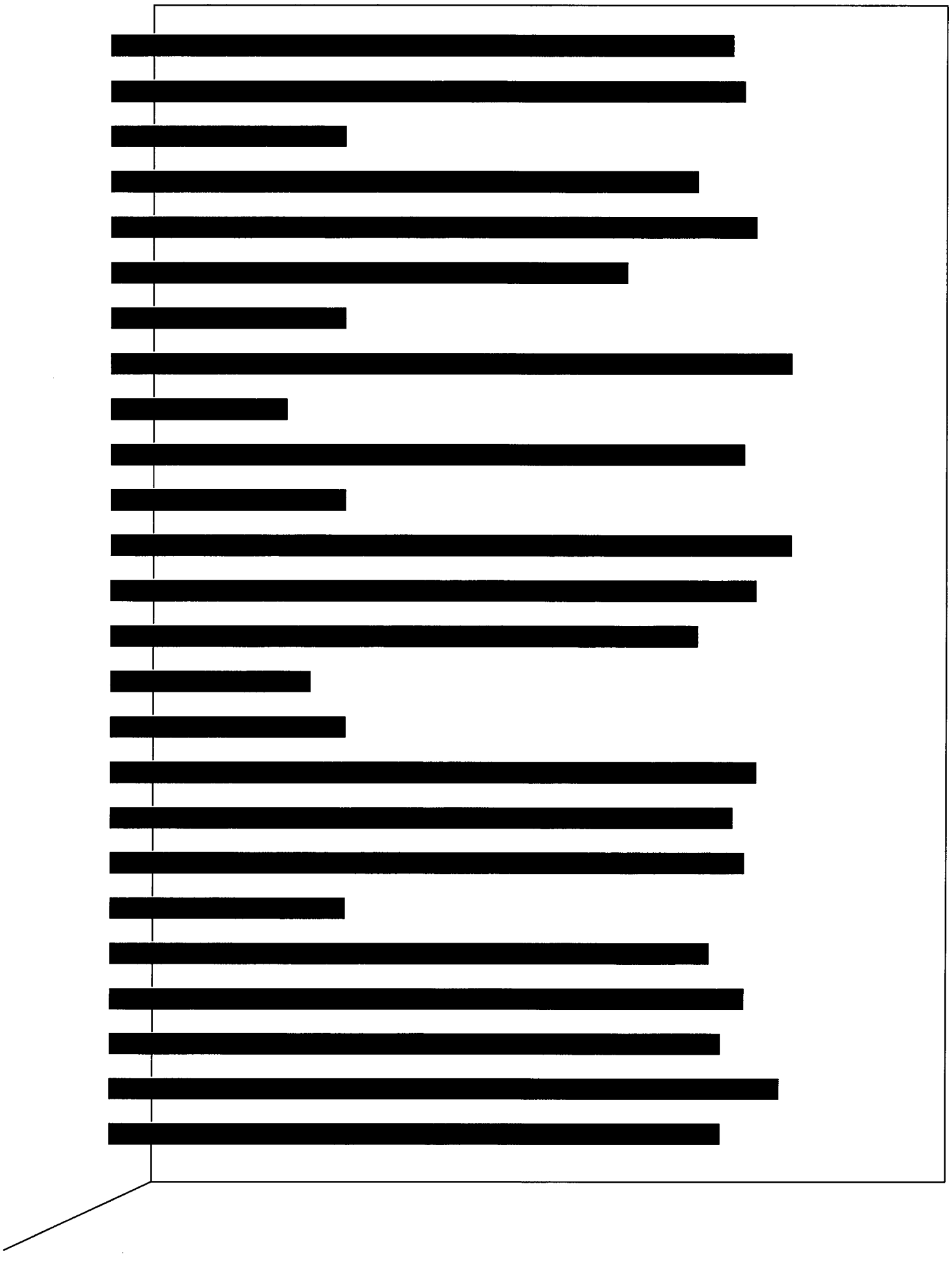
REPORTED BY: Denise Sankary, RPR, RMR, CRR











CERTIFICATE OF OATH

STATE OF FLORIDA

COUNTY OF SARASOTA

I, the undersigned authority, certify that MATTHEW MARTIN personally appeared before me and was duly sworn on the 20th day of February, 2019.

Signed this 22nd day of February, 2019.

DENISE SANKARY, RPR, RMR, CRR
Notary Public, State of Florida
My Commission No. FF 950775
Expires: 1/27/20

EXHIBIT B

[FILED UNDER SEAL]

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	)	
Plaintiff,	)	CASE NO.
vs.	)	CJ-2017-816
PURDUE PHARMA L.P., et al.,	)	
Defendants.	)	

Videotaped Deposition of WILLIAM B. GRUBB, III, taken on behalf of the Plaintiff, pursuant to notice and agreement, before Judith L. Leitz Moran, Certified Court Reporter, at Alston & Bird LLP, One Atlantic Center, 1201 West Peachtree Street, Suite 4200, Atlanta, Georgia, on the 4th day of December 2018, commencing at the hour of 9:10 a.m.

A Factually, yes.

BY MR. DUCK:

Q Explain.

A It would depend on the year you're asking about, but -- but the quota that we're awarded is based on the market for our market. I mean, just to be very clear, Noramco doesn't determine the market size. That's prescriptions, you know, with physicians.

What Noramco is doing is working within a market, but -- so our quota is going down based on a combination of the market share we have and the actual market. So that -- but in absolute terms, the -- the number of kilograms, 2.2 pounds per kilogram have gone down.

Q Do you know which years?

A It's been declining every year since 2011.

Q Before 2011, was it steadily increasing?

MS. DAWSON: Object to the form of the question.

A It actually varied by year, so I wouldn't say that it was steadily increasing. Depending on the amount of procurement quota they were going to give customers, they would then in turn give us the

same amount of manufacturing quota. So Noramco's quota award is not necessarily correlated to what's happening in the overall marketplace, it's based on our customer's forecast that the DEA's reviewed.

BY MR. DUCK:

Q The manufacturing quota that Noramco receives for various APIs is the result of a negotiation process with the DEA, right?

MS. DAWSON: Object to the form of the question.

A It's not -- no, that's not correct. It's not a negotiation. There's a comment process where the DEA posts what the aggregate for the United States is going to be. They also solicit input from the registrants.

So in the case of oxycodone that you mentioned, Johnson Matthey, Mallinckrodt, Rhodes Technologies, Siegfried, Noramco, are the major producers. And they also purchase customer data. So I don't think it's -- I wouldn't characterize it as a negotiation.

BY MR. DUCK:

Q Well, Noramco is given an opportunity to advocate to DEA why its quota or its slice of the annual pie should be larger, right?

MS. DAWSON: Object to the form of the question.

A I would say -- I would not use the word "advocate". I would say what Noramco does is we provide information to the DEA that our customers have supplied to us from a forecast standpoint.

We also point out to the DEA some things that they can't see. For example, you mentioned exports. So the DEA is looking using their ARCOS system at inventories and transactions in the U.S.

Materials that were exporting outside the U.S., we -- that's something that we do as part of the federal register comment process.

We also highlight to them customer development programs for drugs that are undergoing the approval process, they're not actually in the market yet. So that -- there's a provision to supply material for development. The drugs never get approved, the material gets destroyed.

But that -- through that comment process -- that's why I'm saying it's not an advocacy, it's more of a comment process that's part of the federal register.

I'm sorry, can I clarify one thing?

BY MR. DUCK:

Q Sure.

A Or if the DEA were to submit a question to us to say how much specifically are you going to export, we would ask and answer, but it's not an advocacy.

Q Okay, I want to cover a different area real quick and then we'll -- we'll take a break.

A Okay.

Q Is this the first deposition you've ever given?

A It is.

Q And when we first started this deposition, your lawyer said that they were here on behalf of the witness, that's you. So I just have some questions about, you know, who you're here on behalf of and who is paying your legal fees.

So first, are you here at all on behalf of Noramco or are you here just as Bill Grubb?

MS. DAWSON: Object to the form of the question. I'm going to instruct the witness not to answer.

BY MR. DUCK:

Q And are you paying for your own legal fees today?

MS. DAWSON: Object to the form of the

question. I'm going to instruct the witness not to answer.

BY MR. DUCK:

Q Are you going to follow your lawyer's advice and not answer that question?

A I am, yeah.

MR. DUCK: What's the basis for instructing him not to answer who's paying his legal fees?

MS. DAWSON: At this point I'm registering my objection. And, you know, we're here voluntarily. And as I've said in my communications with you, we've agreed to voluntarily make Mr. Grubb available for deposition. You subpoenaed Bill Grubb in your subpoena.

BY MR. DUCK:

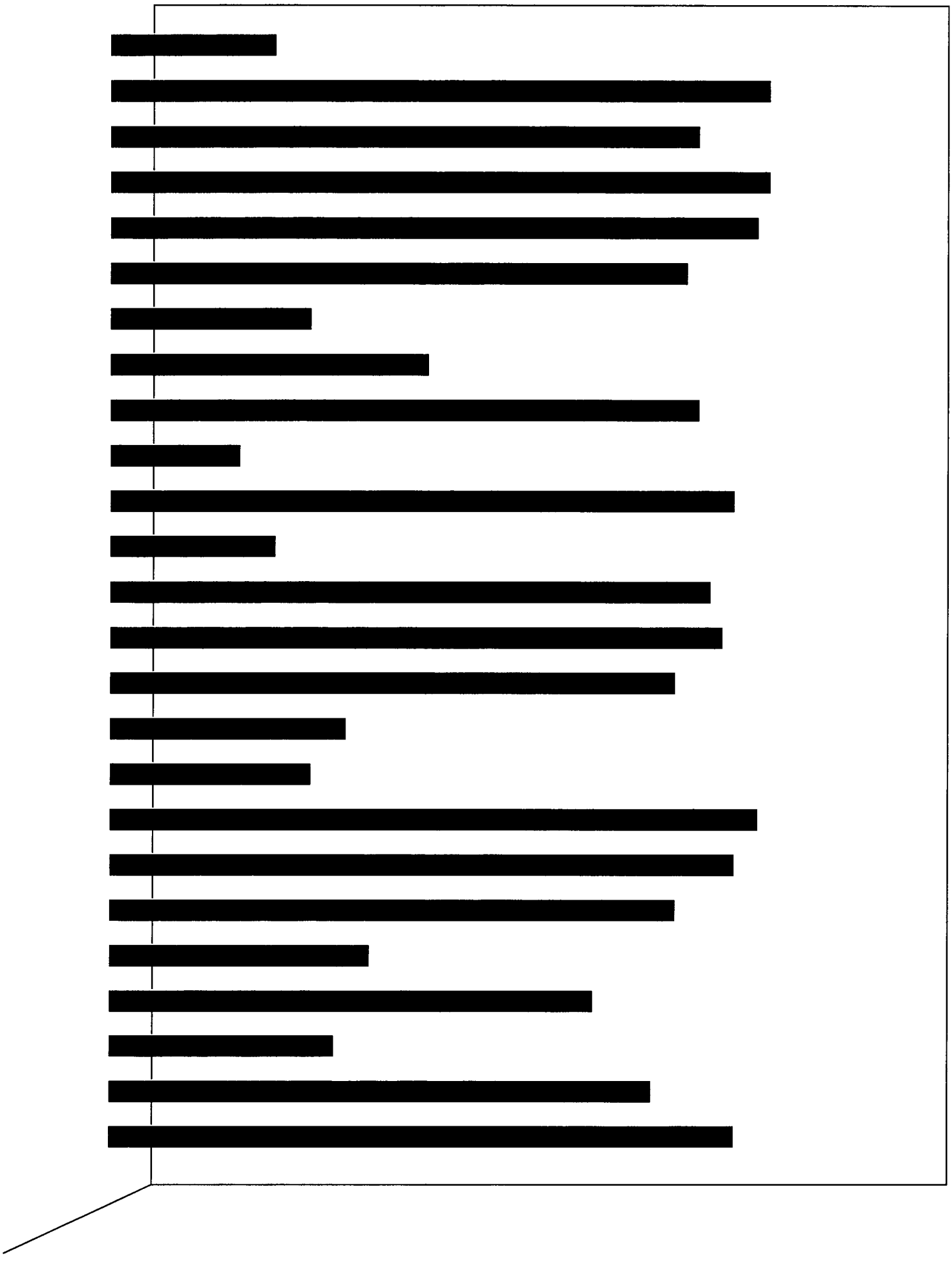
Q How did you first get in touch with the lawyers that are representing you here today?

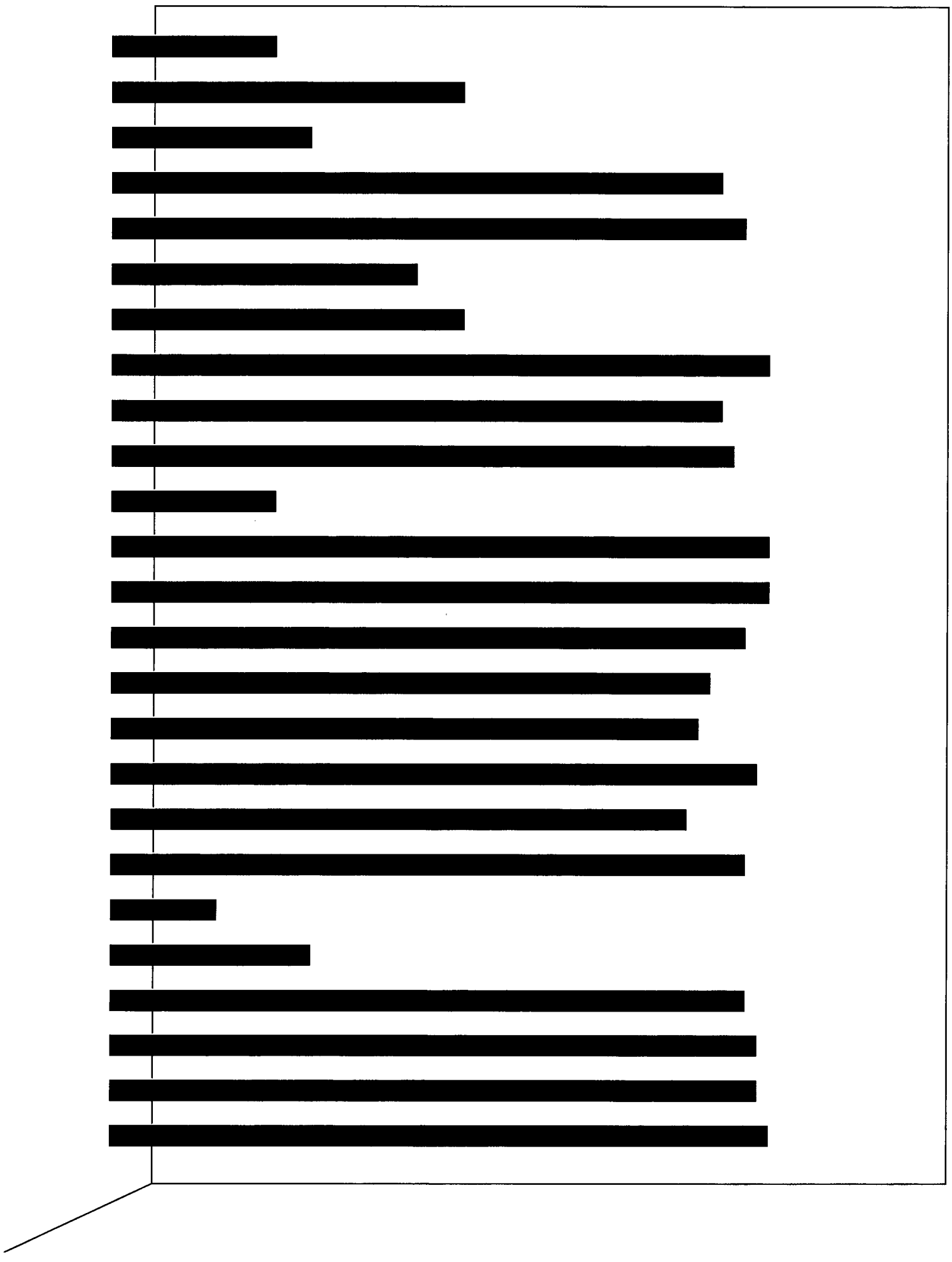
MS. DAWSON: Object to the form of the question. Instruct the witness not to answer.

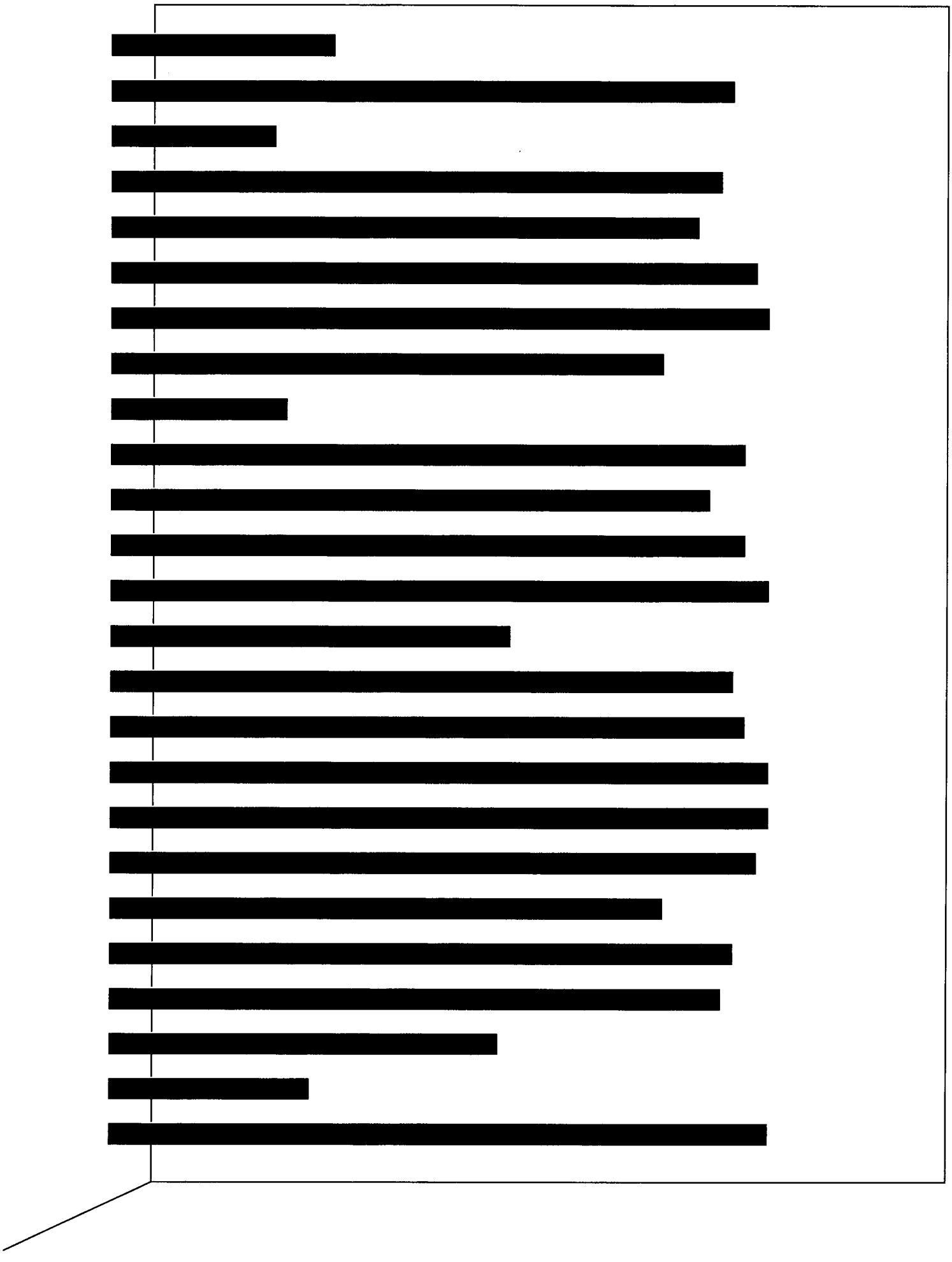
BY MR. DUCK:

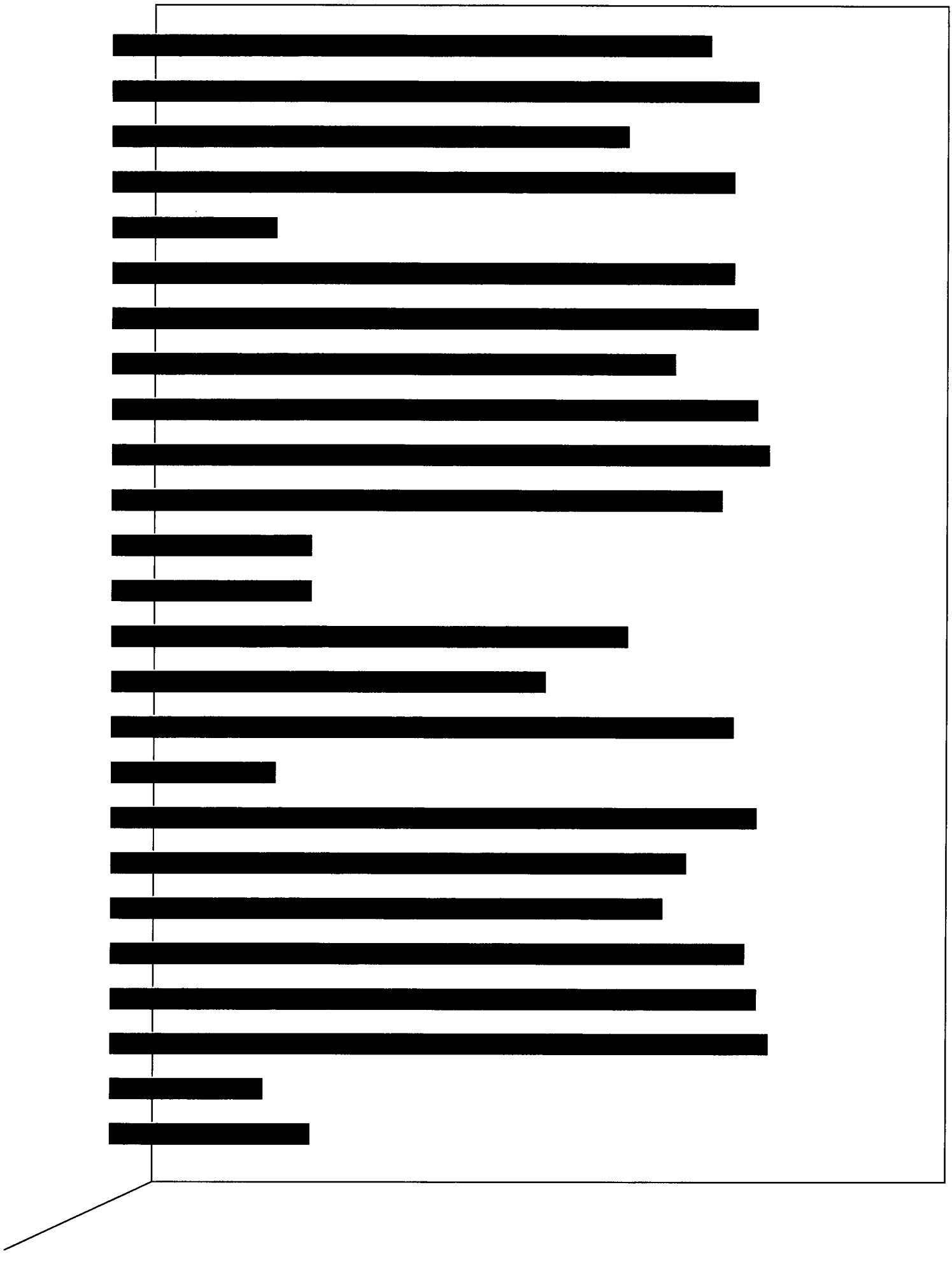
Q Are you going to follow your -- your lawyer's advice?

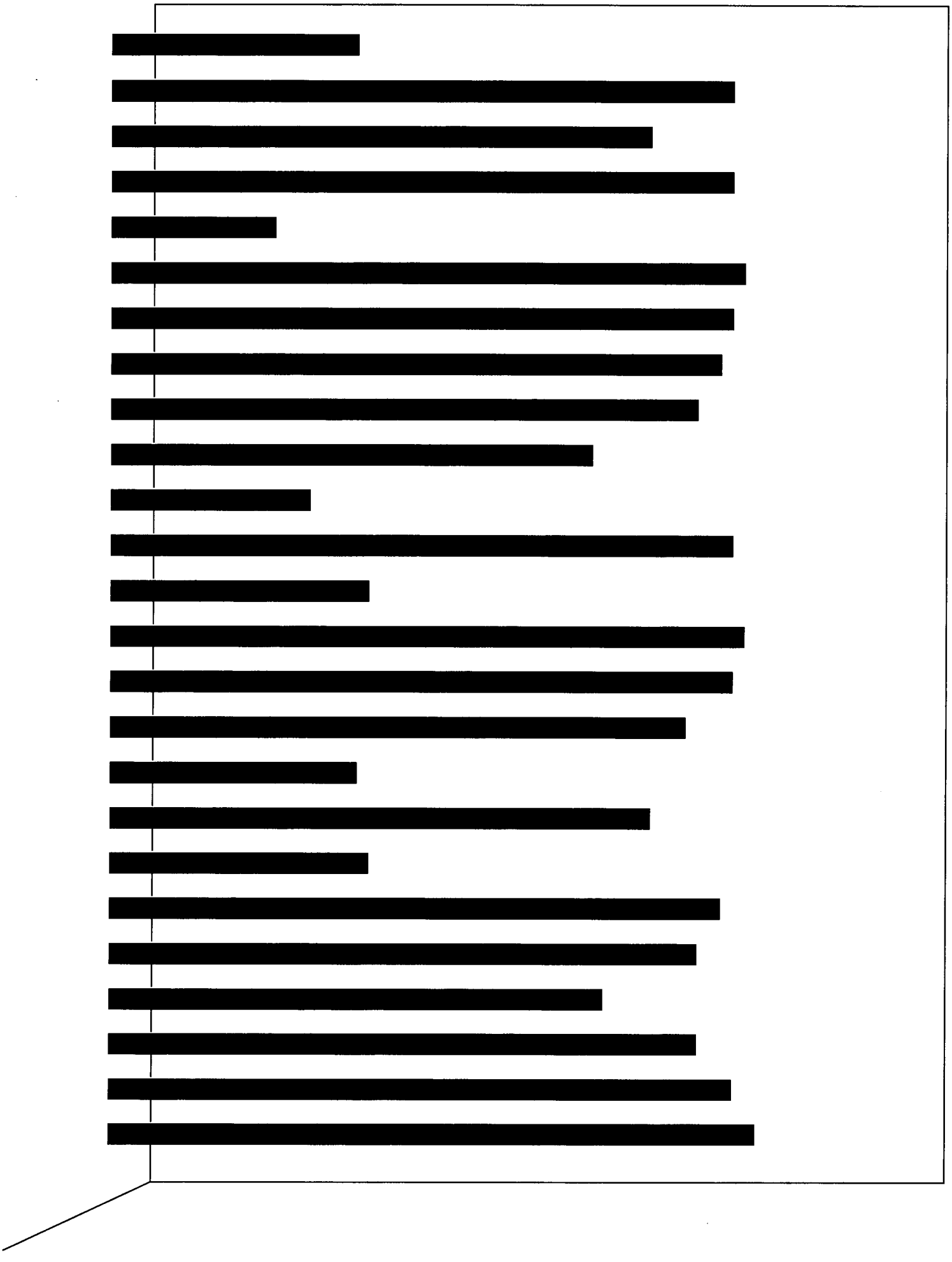
A I am.

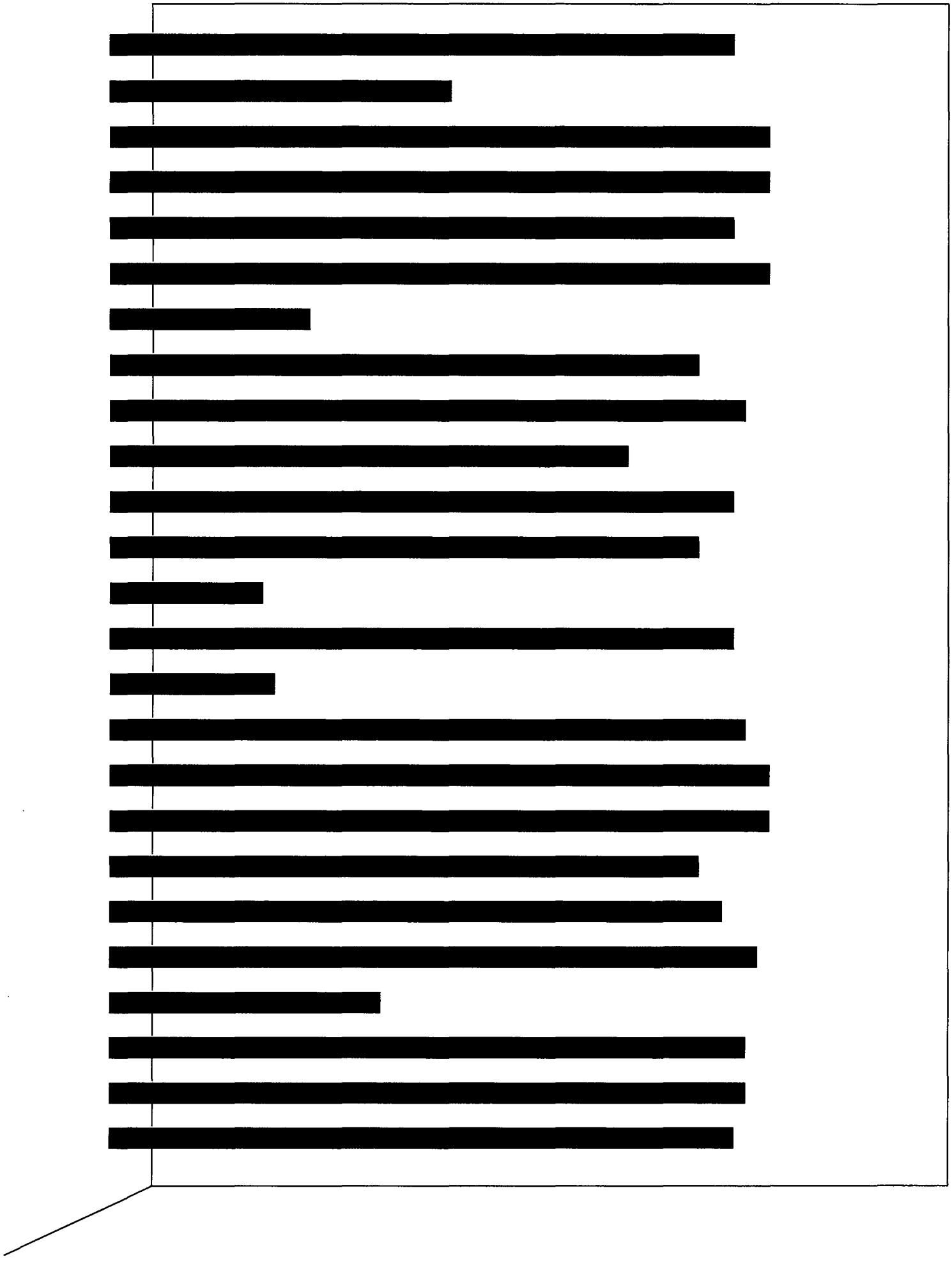


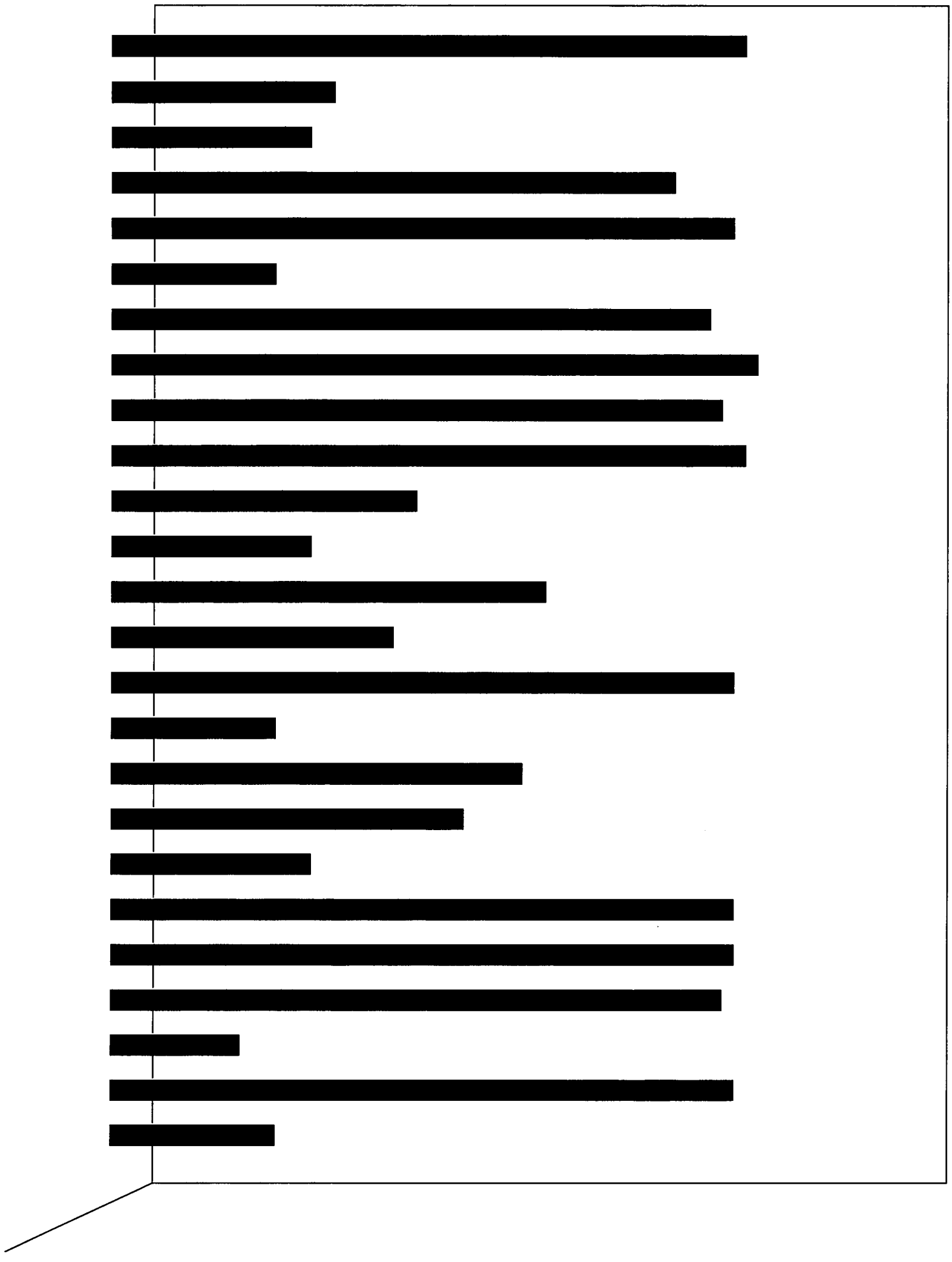


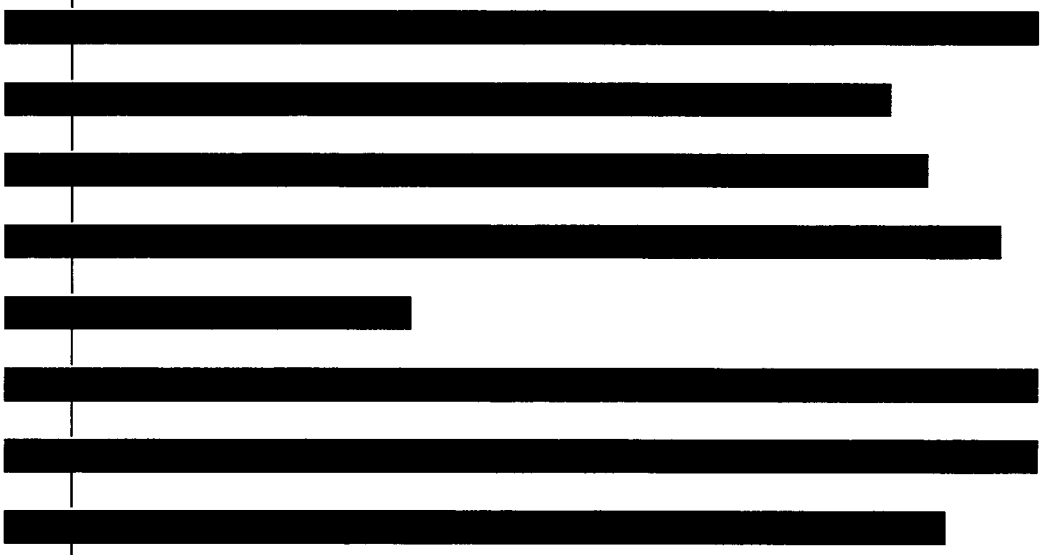












BY MR. DUCK:

Q Well, Noramco works on the supply side of this market, correct?

MS. DAWSON: Object to the form of the question.

A Noramco is a supplier of API that is subject to quota that's issued by the DEA, and the customers have to have quota to procure, so that's correct.

BY MR. DUCK:

Q And supply can drive market growth?

MS. DAWSON: Object to the form of the question.

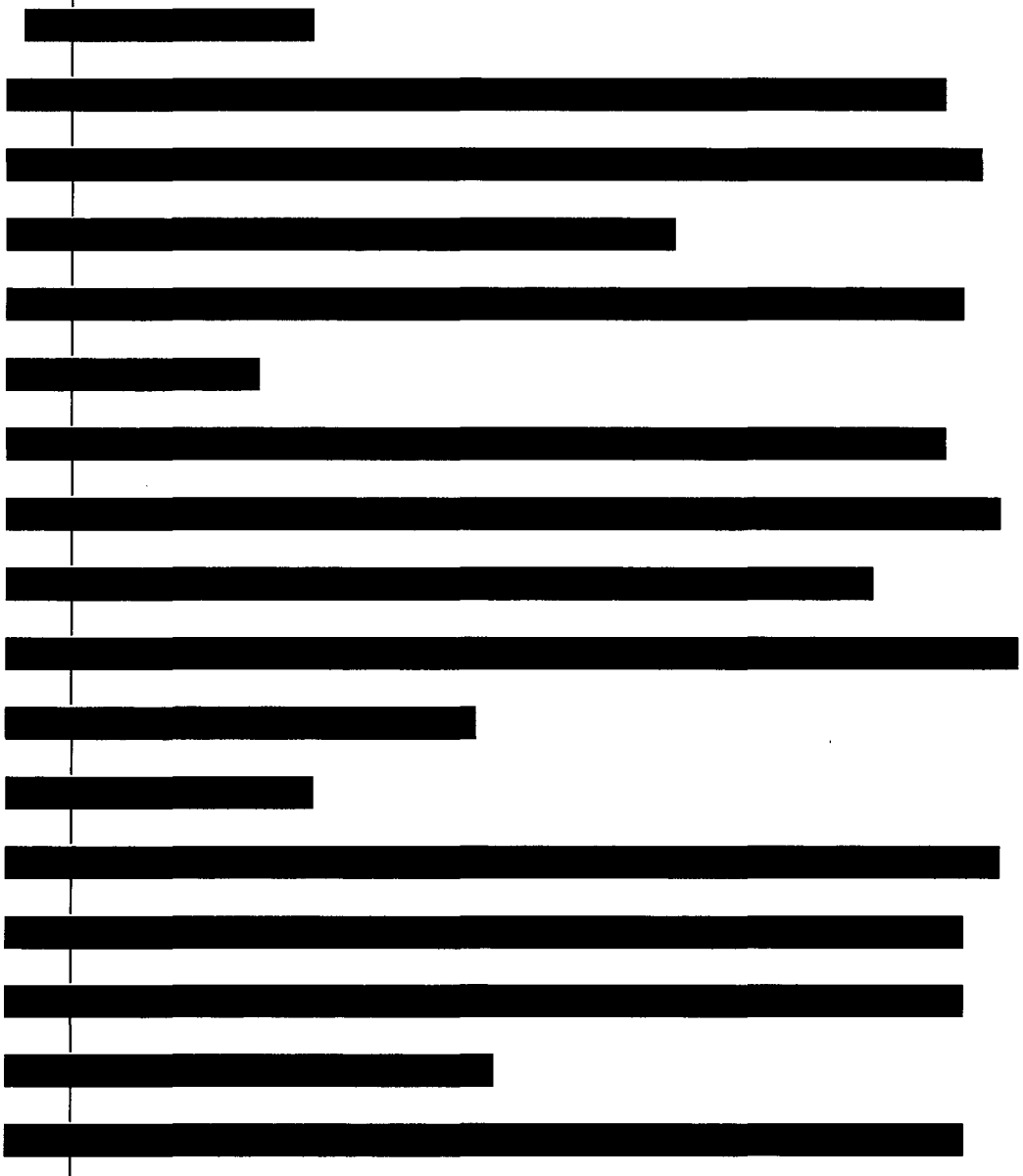
A I -- I disagree with that.

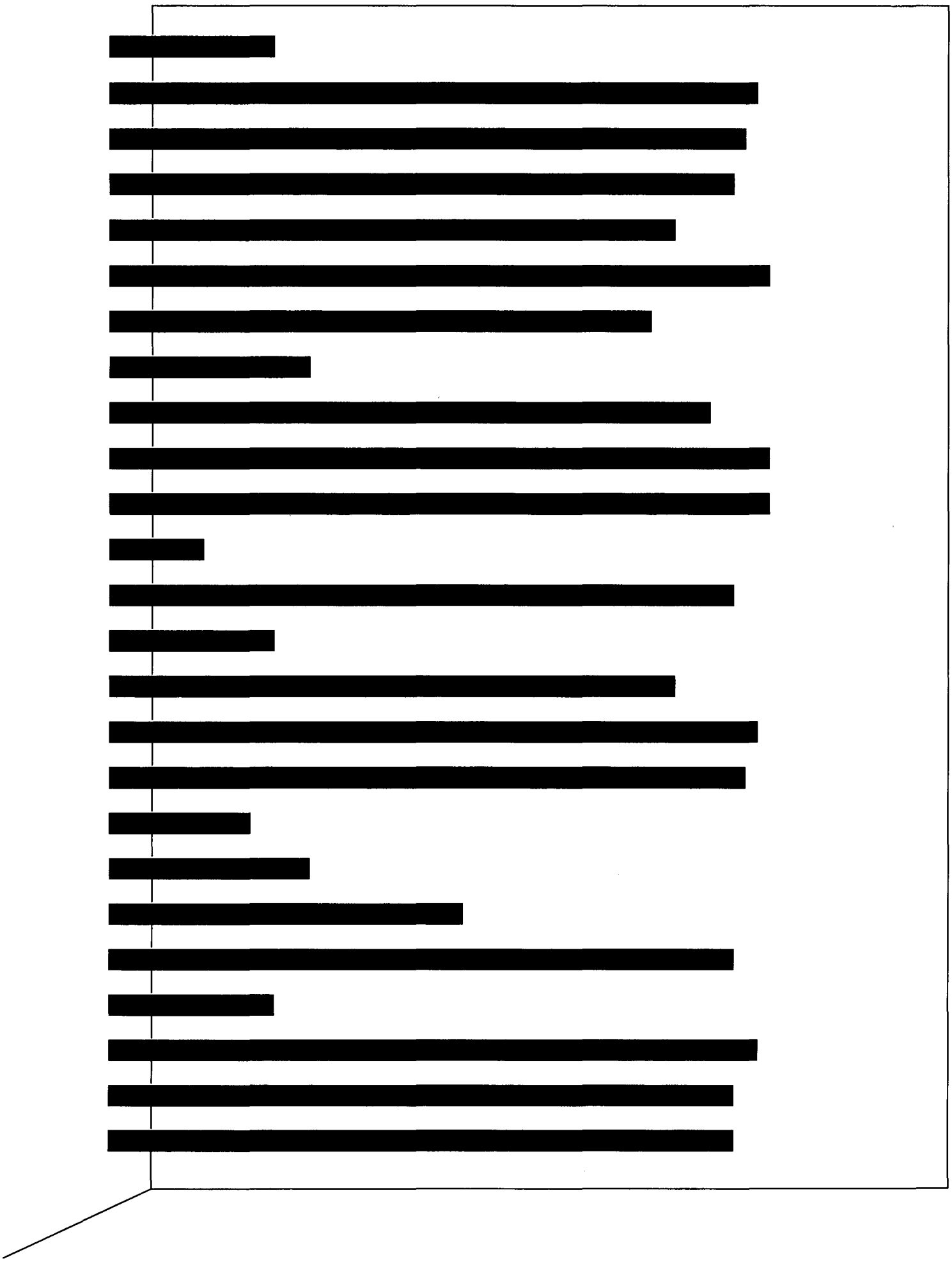
BY MR. DUCK:

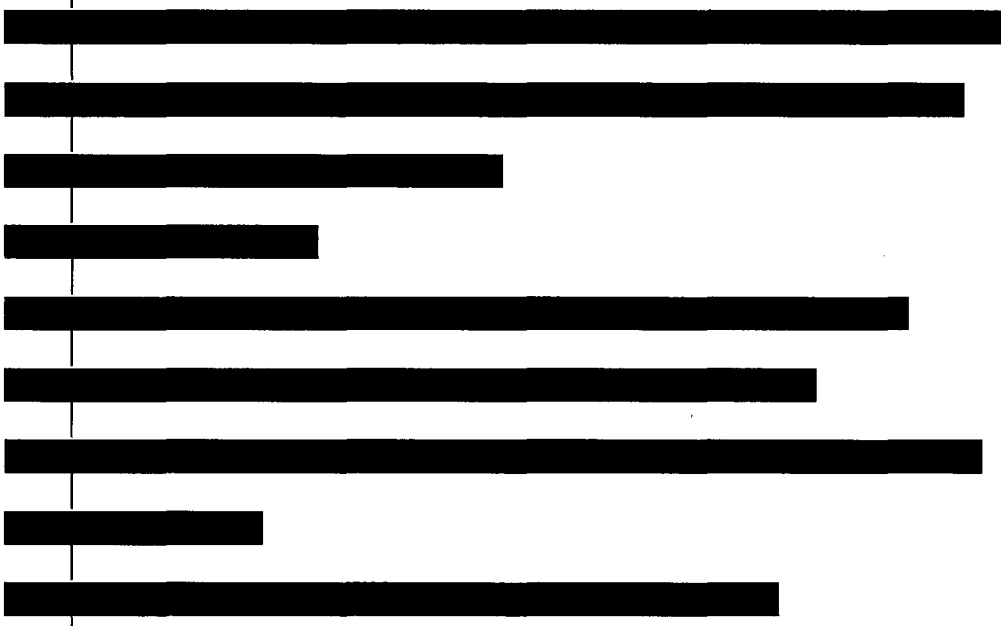
Q You think that only demand can drive market growth?

MS. DAWSON: Object to the form of the question. I don't think he was finished with his answer to your prior question. If you could please let him finish his answers.

A I feel like that that would be the tail wagging the dog. I mean, this -- ultimately, the demand for our products is generated based on the doctor writing a prescription.







BY MR. DUCK:

Q You're aware that in the United States as determined by the White House Commission on Opioid Abuse there has for years now been an oversupply of opioids in the United States?

MS. DAWSON: Object to the form of the question.

A I'm actually not aware of that from where I sit. We're supplying an active ingredient that the DEA has given us quota for. And then our customers request procurement quota to buy the product that we've been granted permission to make.

And I was going to go further to say that that process has to happen annually. So, you know, I -- I'm not commenting on is it over or under, I'm just saying that I'm really working in a super

highly regulated system here, and what I make actually every year is not up to me. I can provide data to the agency, but that doesn't mean I'm going to be granted quota to do that.

BY MR. DUCK:

Q Noramco doesn't have to manufacture the entirety of its quota, does it?

MS. DAWSON: Object to the form of the question.

A That's hypothetically -- I -- I guess you're correct.

BY MR. DUCK:

Q And Noramco receives orders from its customers for API, right?

A That's correct.

MS. DAWSON: Object to the form of the question.

A When you say "orders," you're -- I assume you mean a purchase order?

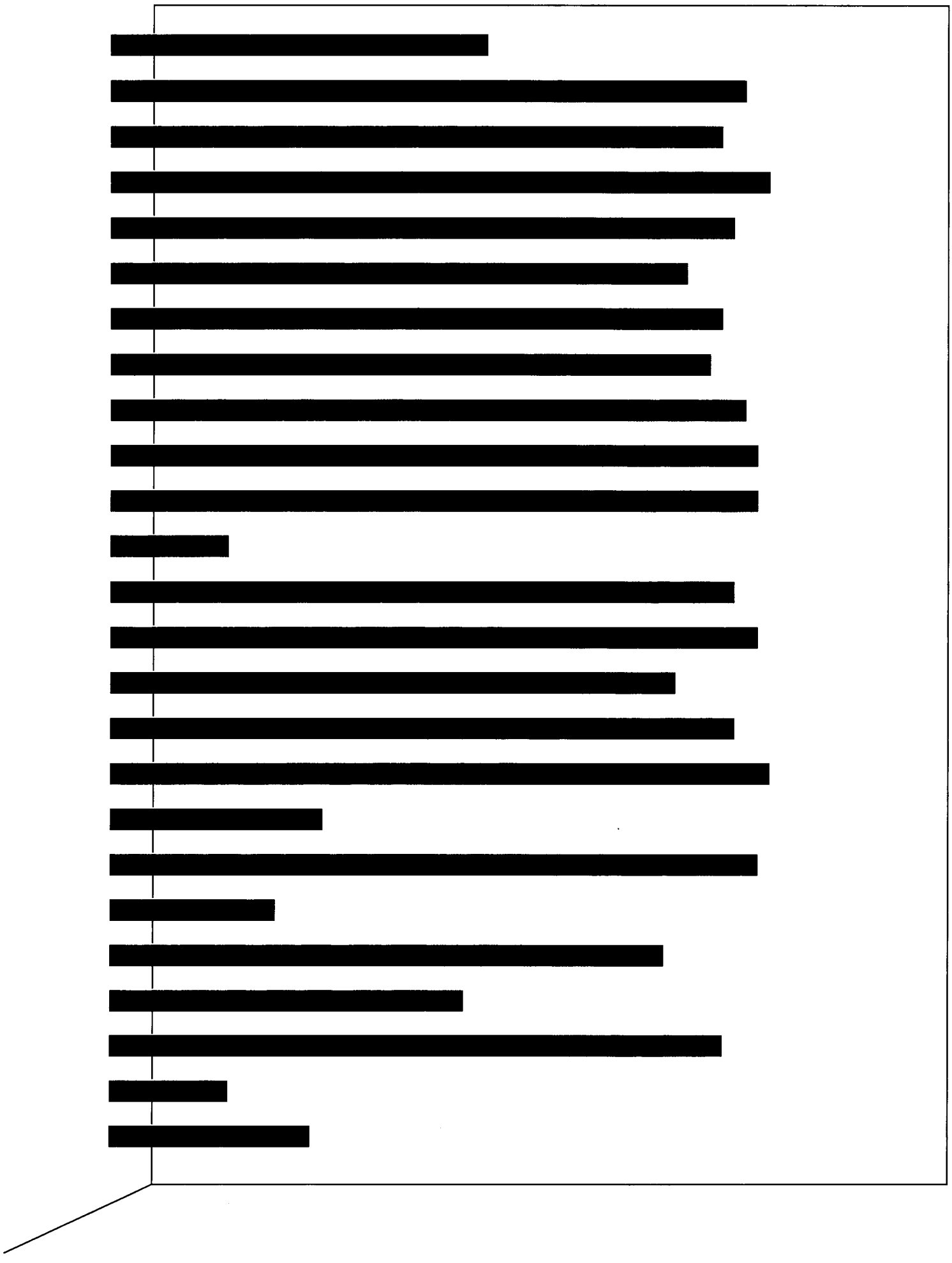
BY MR. DUCK:

Q Right.

A That's correct.

Q And Noramco's job is to fill those orders?

MS. DAWSON: Object to the form of the



[redacted]

A Oxycodone is a highly addictive, prescription narcotic-strength opioid used to treat -- to treat severe and chronic pain conditions.

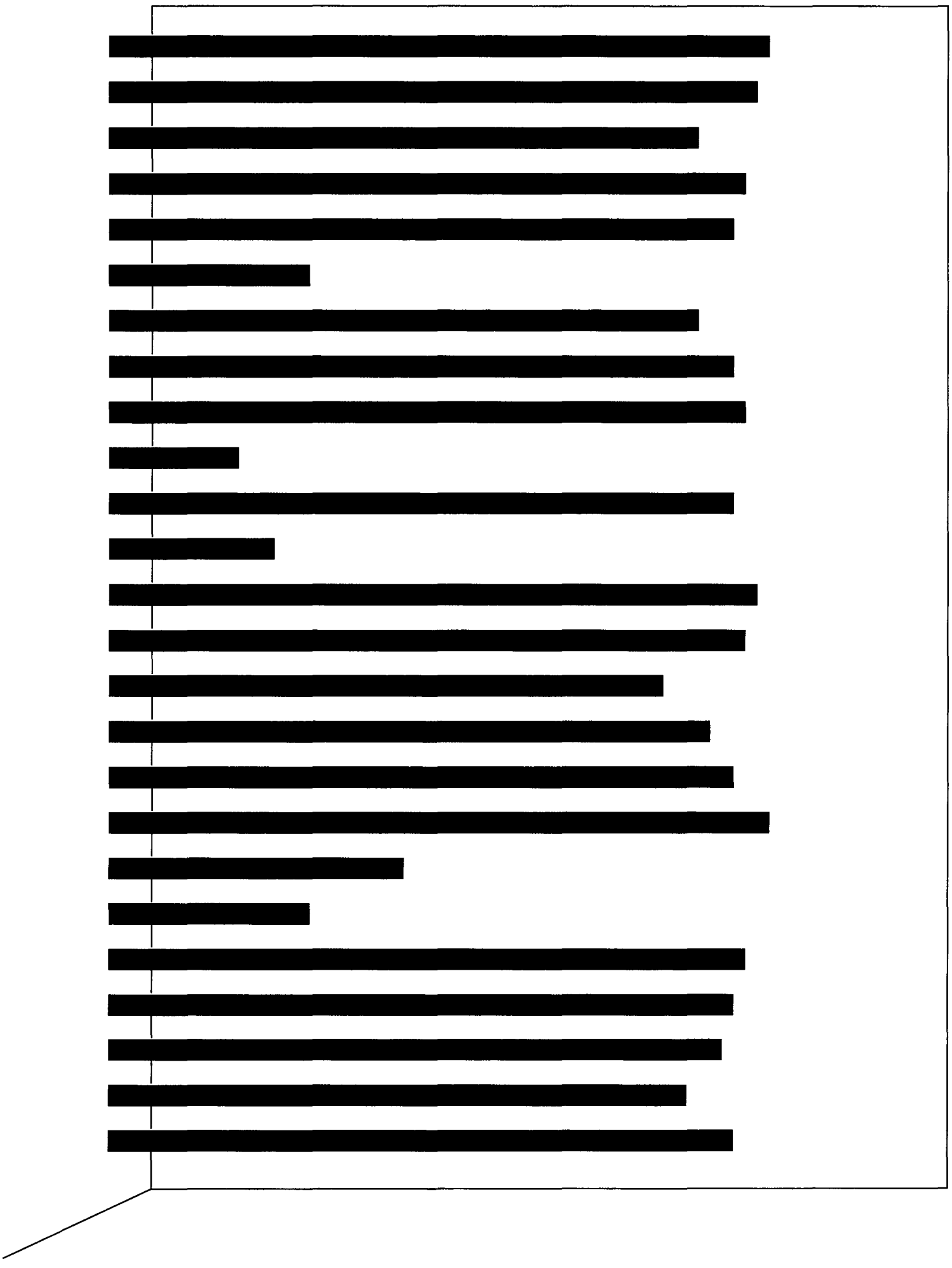
BY MR. DUCK:

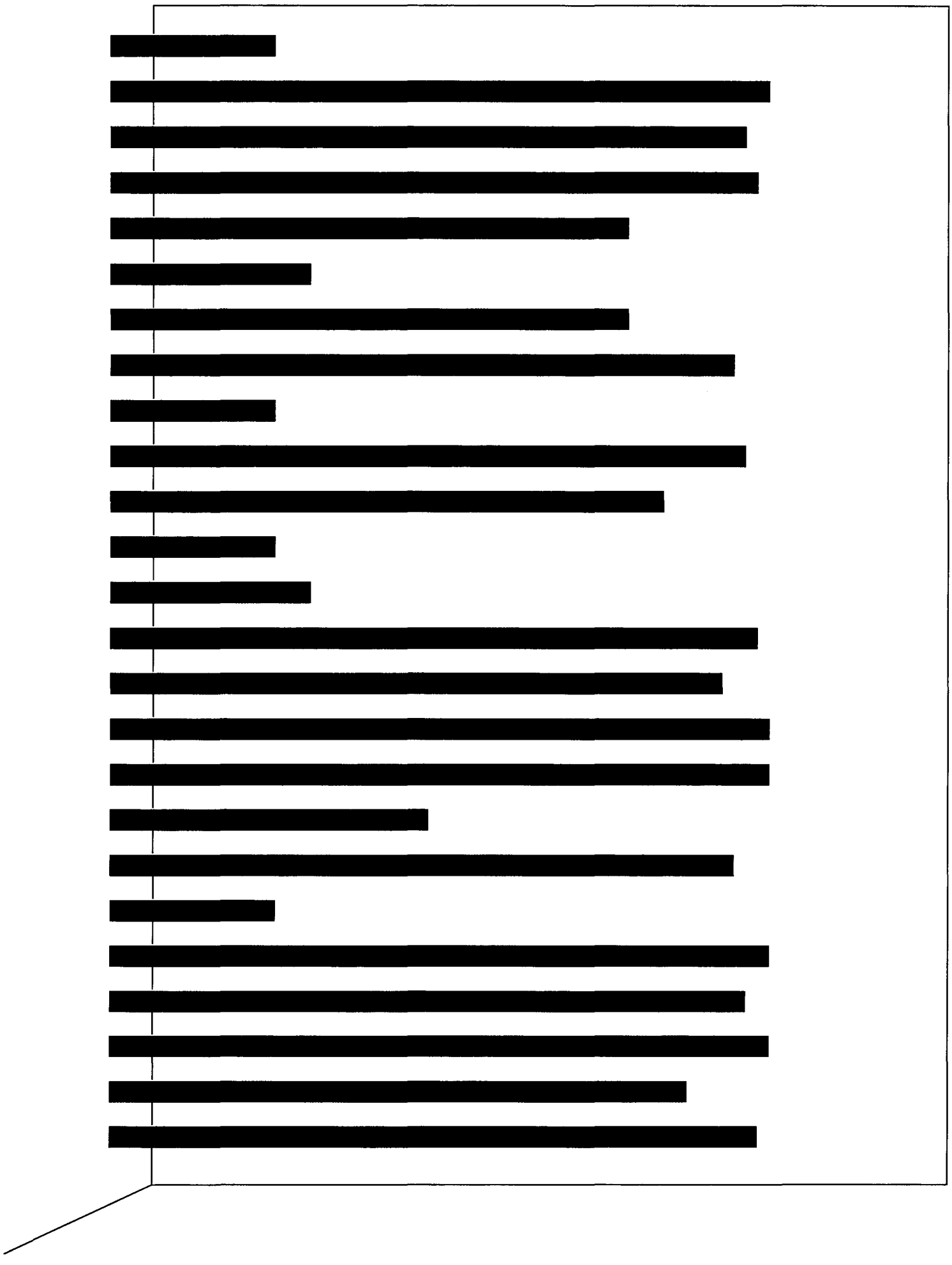
Q That's just true, right? Oxycodone is a highly addictive, prescription narcotic-strength opioid?

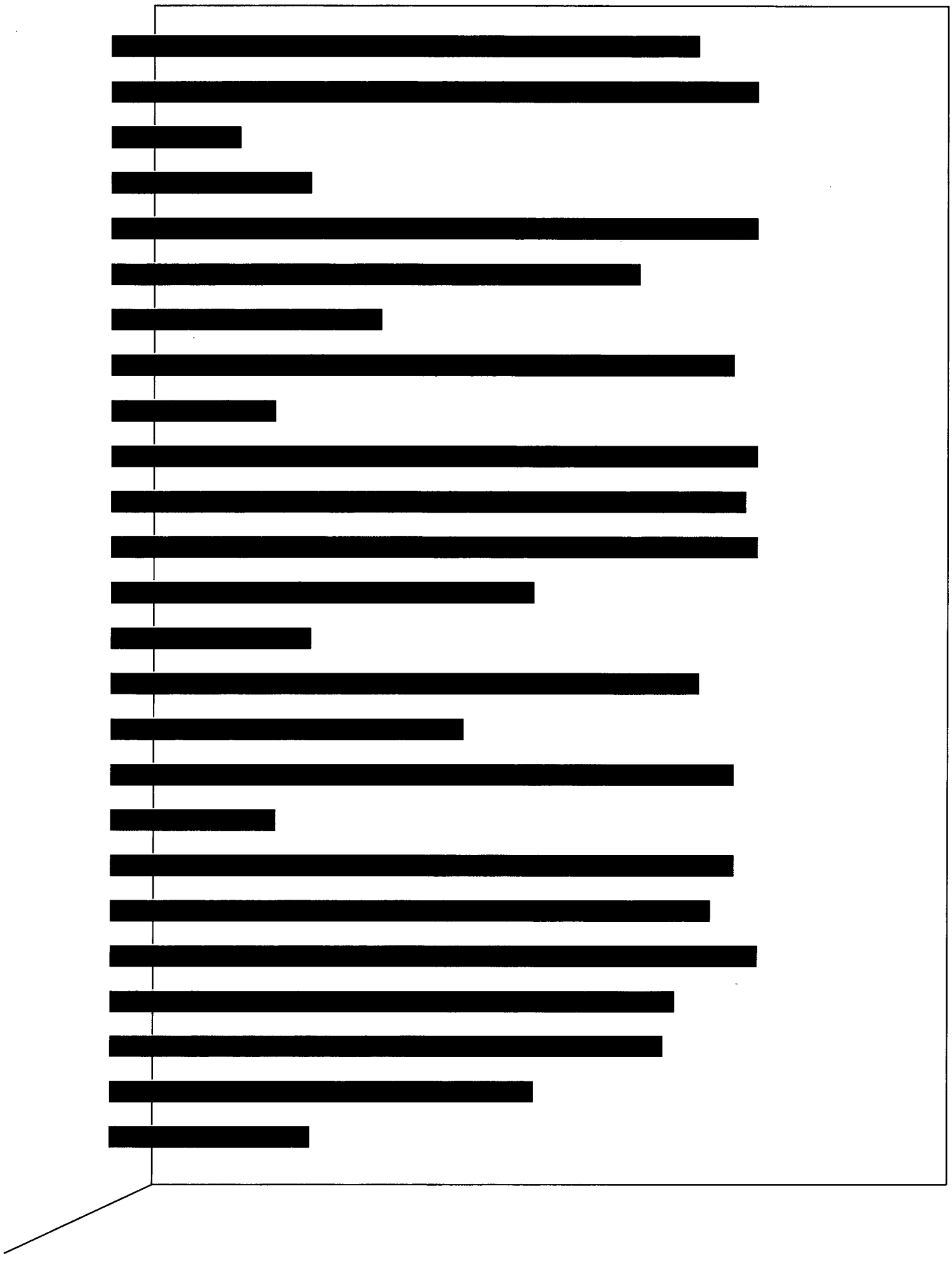
MS. DAWSON: Object to the form of the question.

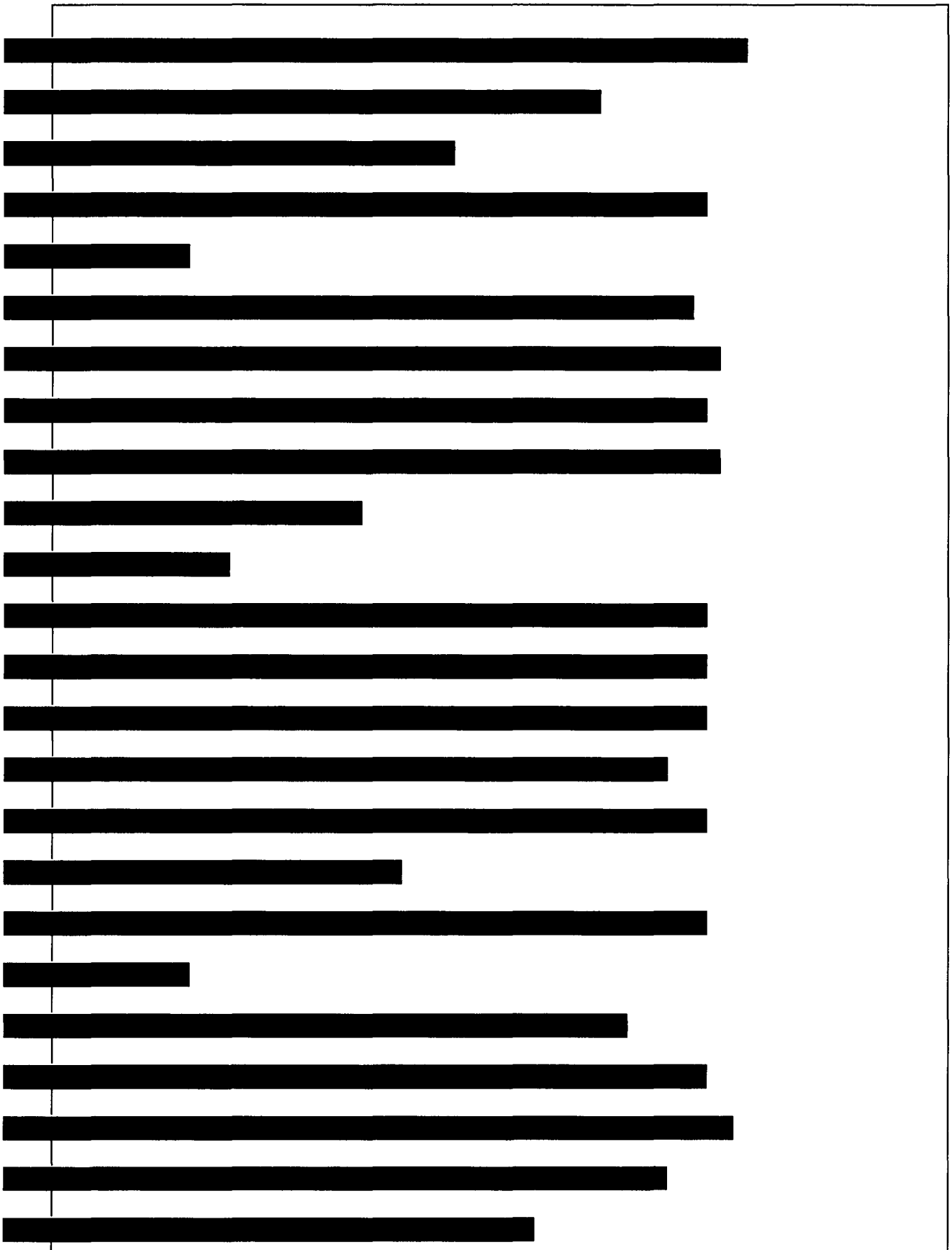
A I am not in a position to say whether that's true or false. I know that in the label for oxycodone-containing products there's a black box warning that hits a few of these points, yes.

[redacted]









BY MR. DUCK:

DISCLOSURE

Pursuant to Article 10.B of the Rules and Regulations of the Board of Court Reporting of the Judicial Council of Georgia, I make the following disclosure:

I am a Georgia Certified Court Reporter. I am here as a representative of U.S. Legal Support.

I am not disqualified for a relationship of interest under the provisions of O.C.G.A. 9-11-28(c).

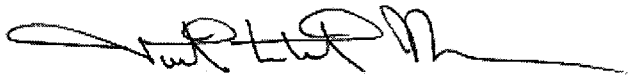
I was contacted by the office of U.S. Legal Support to provide court reporting services for this deposition.

I will not be taking this deposition under any contract that is prohibited by O.C.G.A. Section 15-14-37 (a) and (b).

I have no exclusive contract to provide reporting services with any party to the case, any counsel in the case, or any reporter or reporting agency from whom a referral might have been made to cover this deposition.

I will charge my usual and customary rates to all parties in the case, and a financial discount will not be given to any party to this litigation.

This, the 6th day of December 2018.



Judith L. Leitz Moran, CCR-B-2312
Certified Court Reporter

EXHIBIT C

[FILED UNDER SEAL]

THE DISTRICT COURT OF CLEVELAND COUNTY

STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER, ATTORNEY GENERAL
OF OKLAHOMA,

Plaintiff,

vs. No. CJ-2017-816

(1) PURDUE PHARMA, L.P.,
(2) PURDUE PHARMA, INC.,
(3) THE PURDUE FREDERICK COMPANY;
(4) TEVA PHARMACEUTICALS USA, INC.,;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC.;
(8) ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC., n/k/a
JANSSEN PHARMACEUTICALS, INC.;
(9) JANSSEN PHARMACEUTICA, INC.;
n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,
f/k/a ACTIVIS, INC., f/k/a WATSON
PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS LLC; and
(13) ACTAVIS PHARMA, INC.;
f/k/a WATSON PHARMA, INC.;

Defendants.
_____/

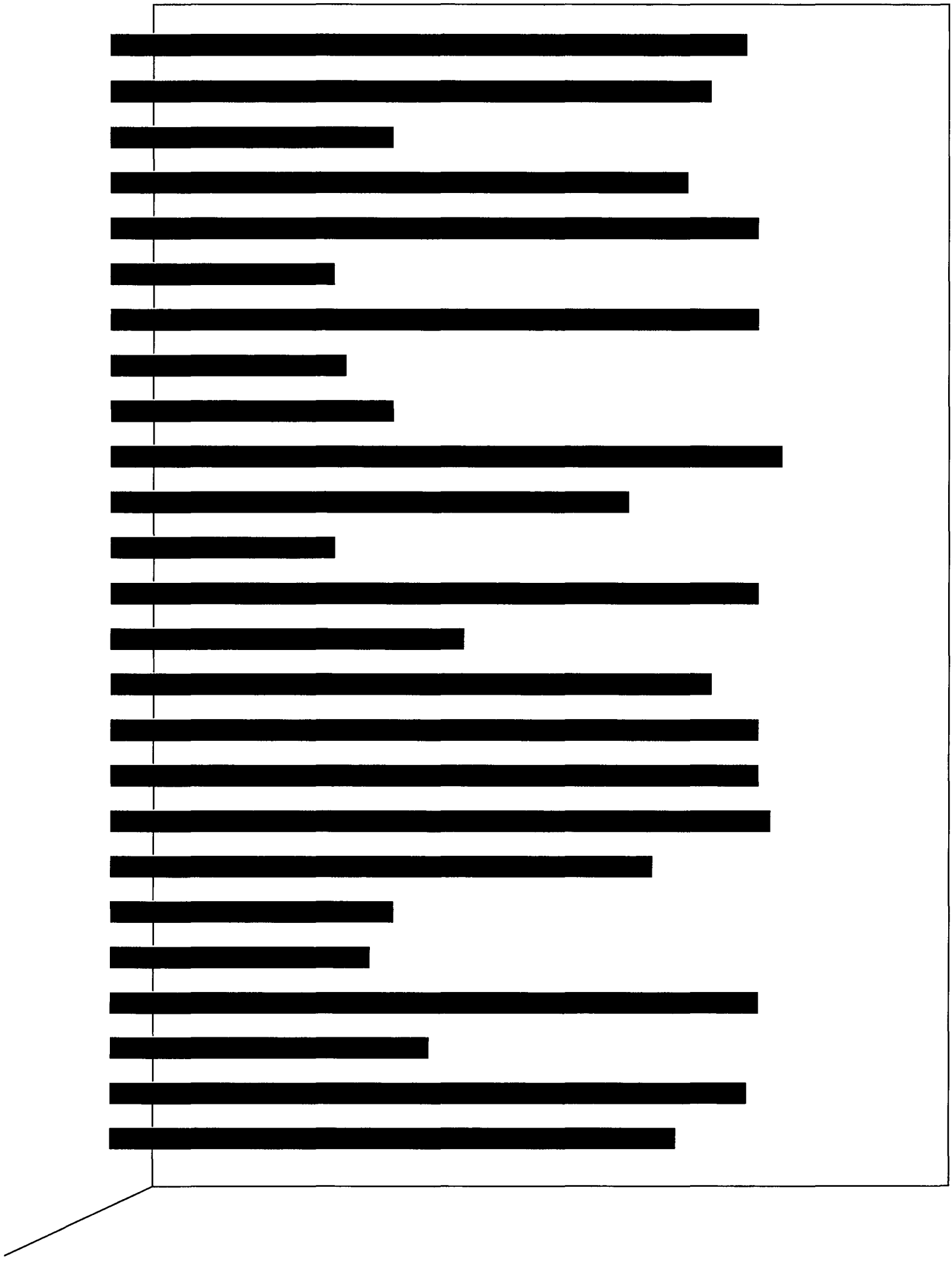
VIDEOTAPED DEPOSITION OF MATTHEW MINARDI

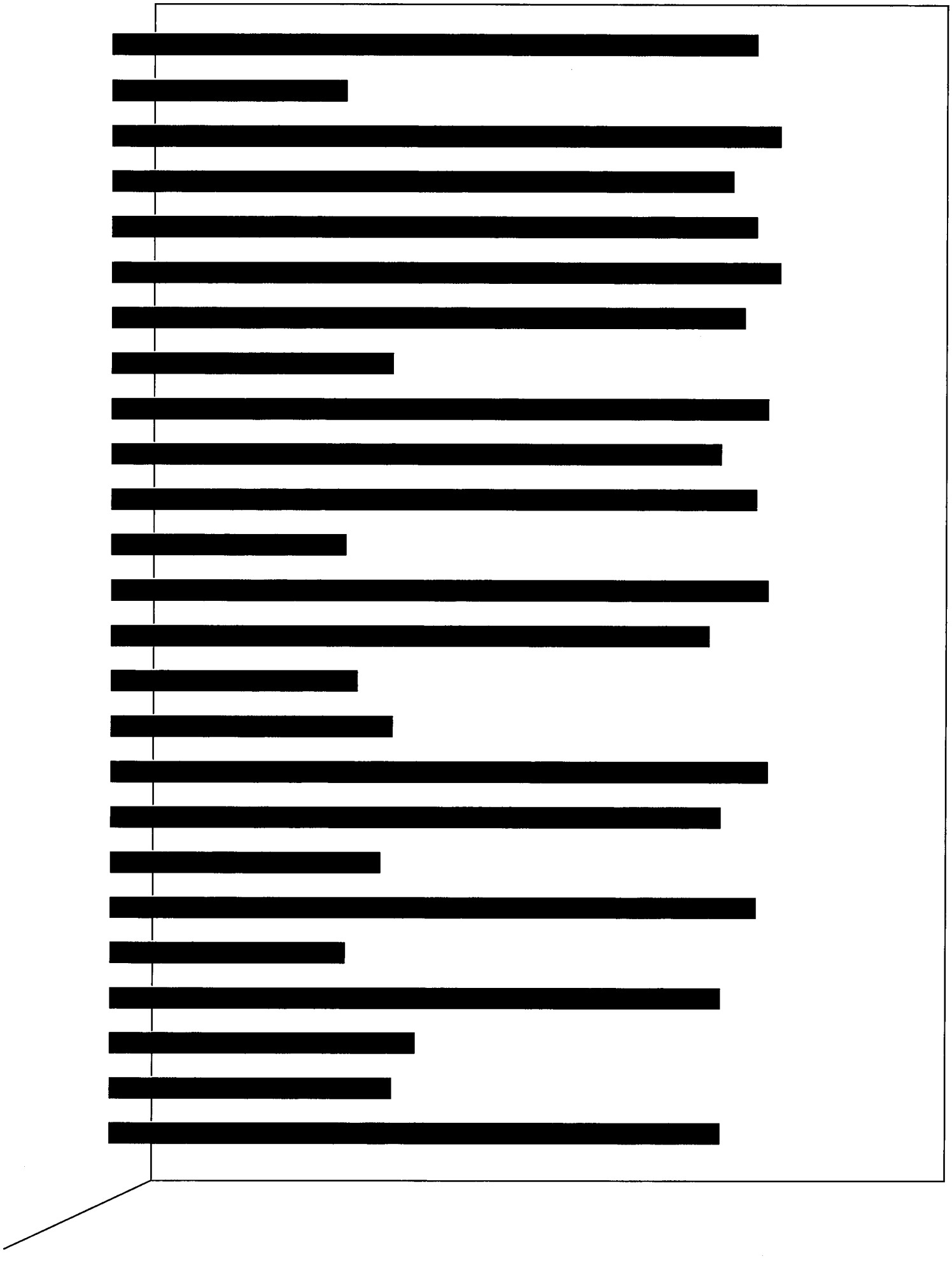
(Taken by Plaintiff)

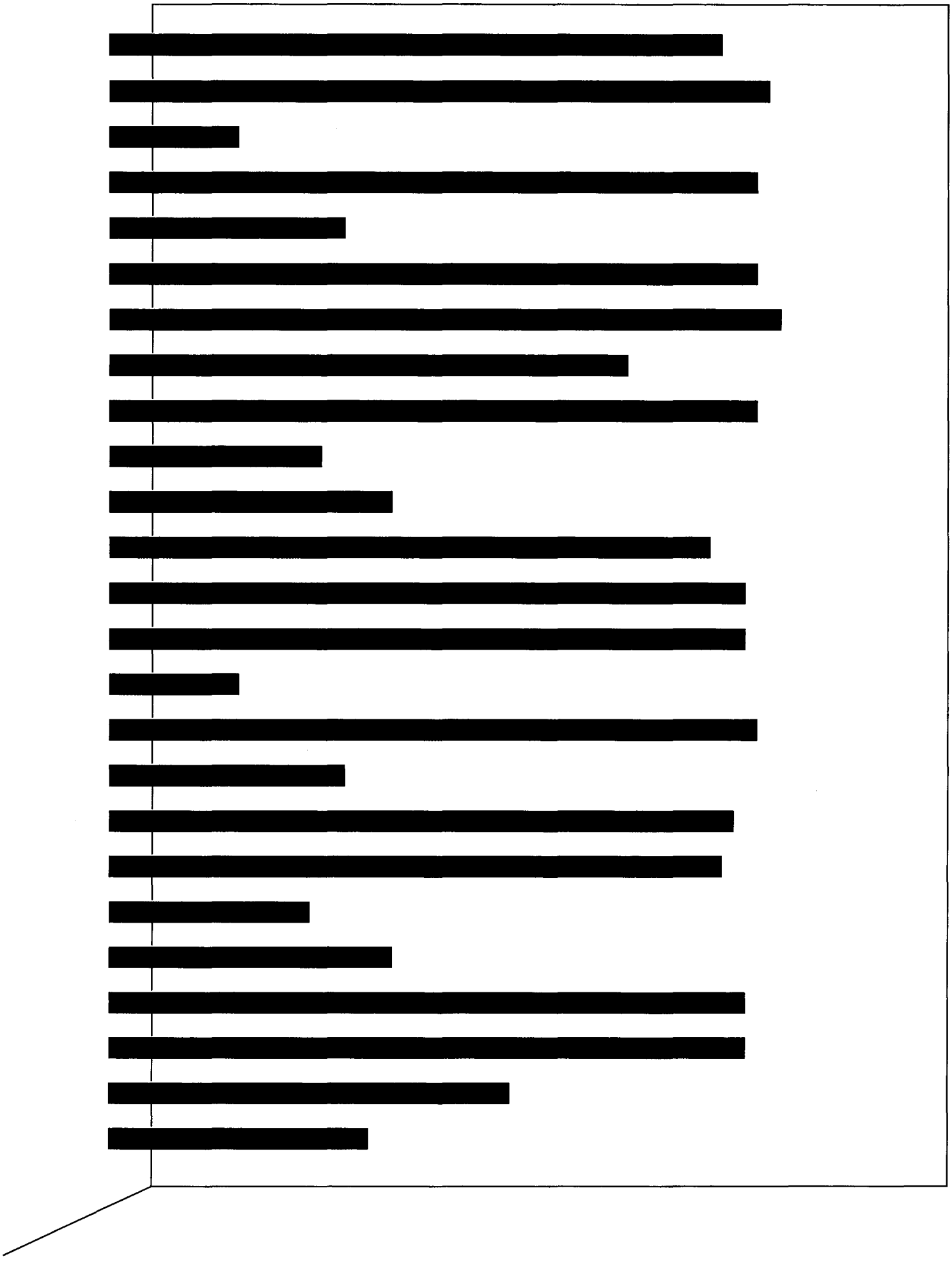
Raleigh, North Carolina

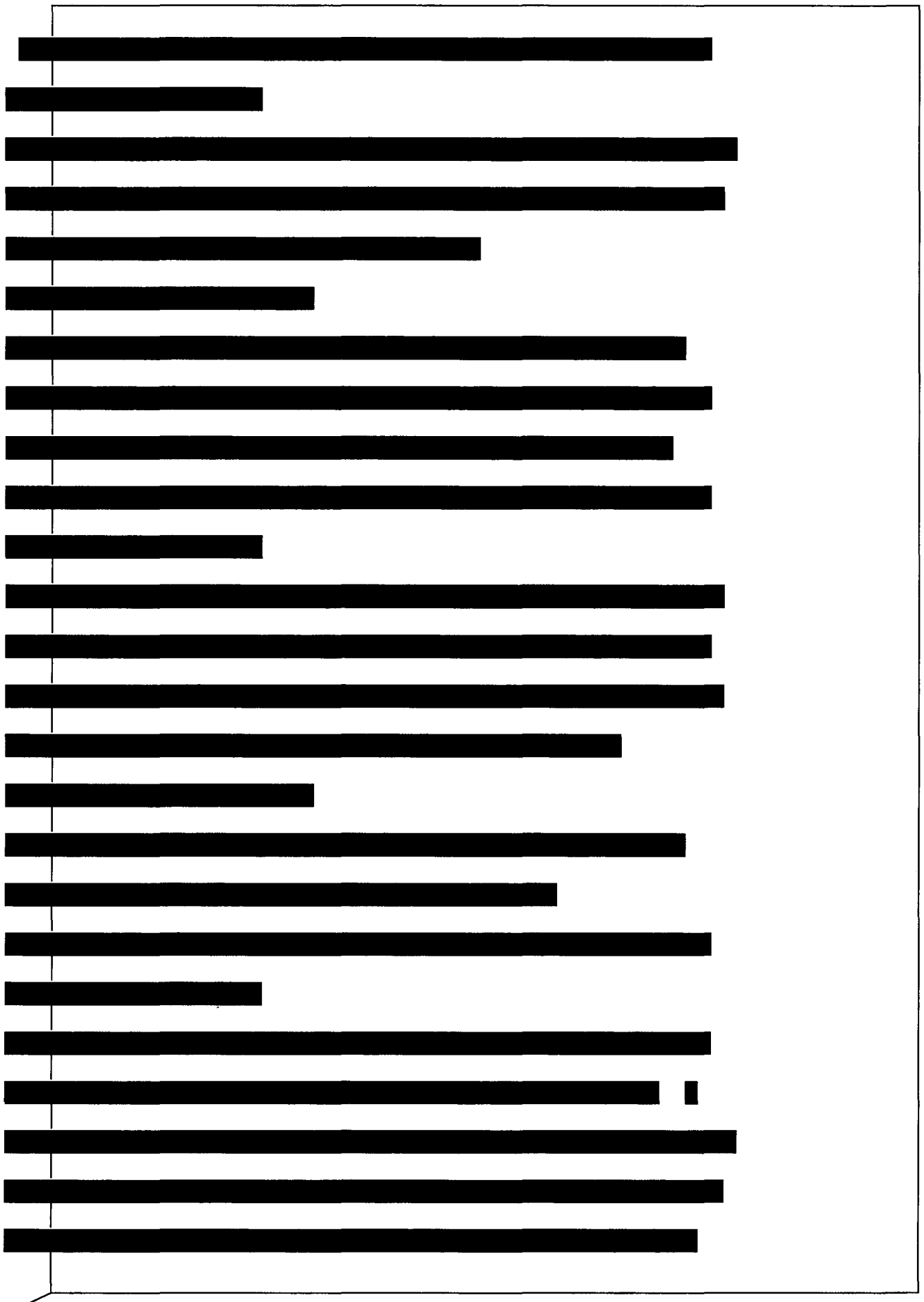
Wednesday, February 27, 2019

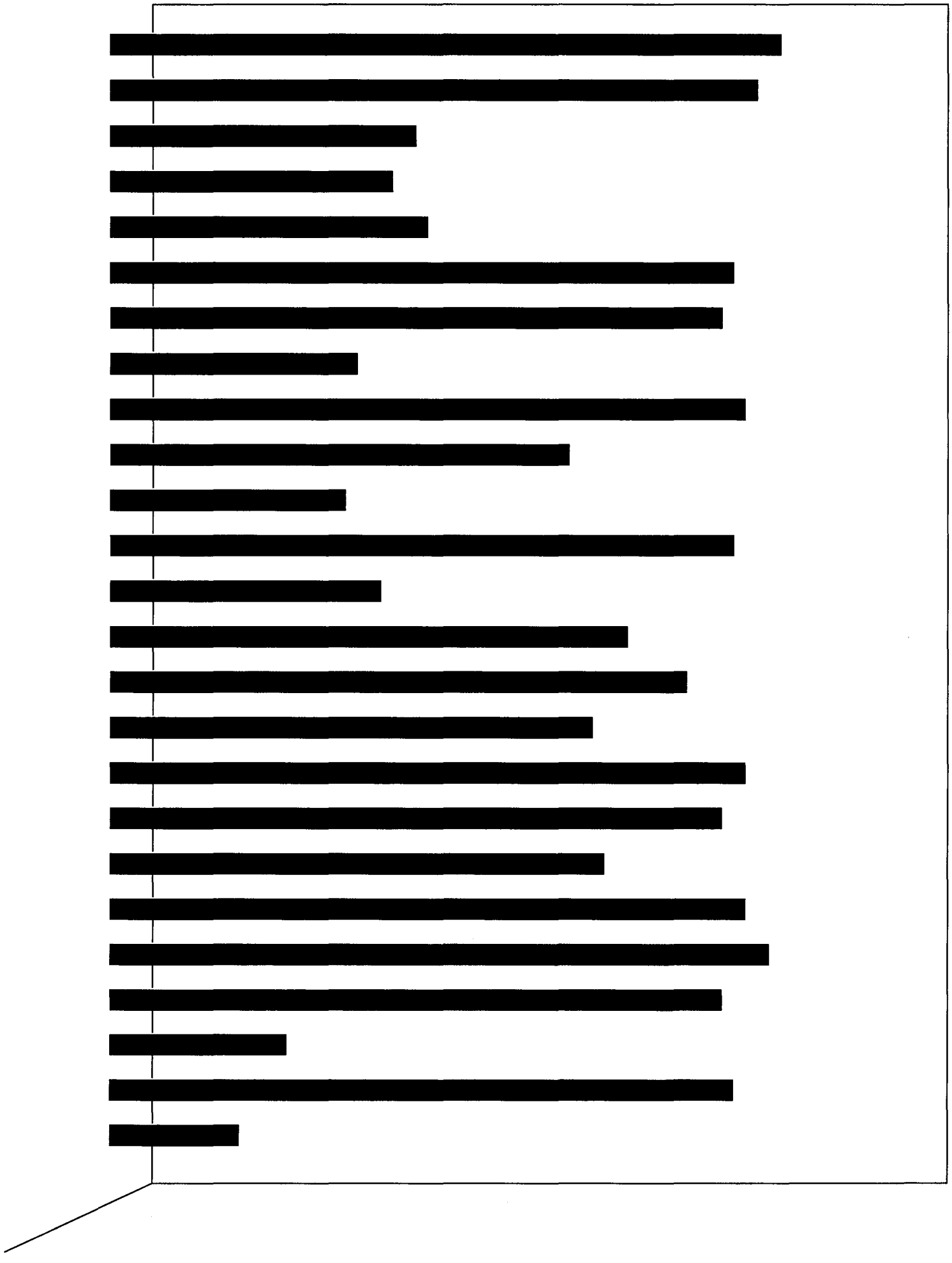
Reported in Stenotype by
Amy A. Brauser, RPR, RMR, CRR

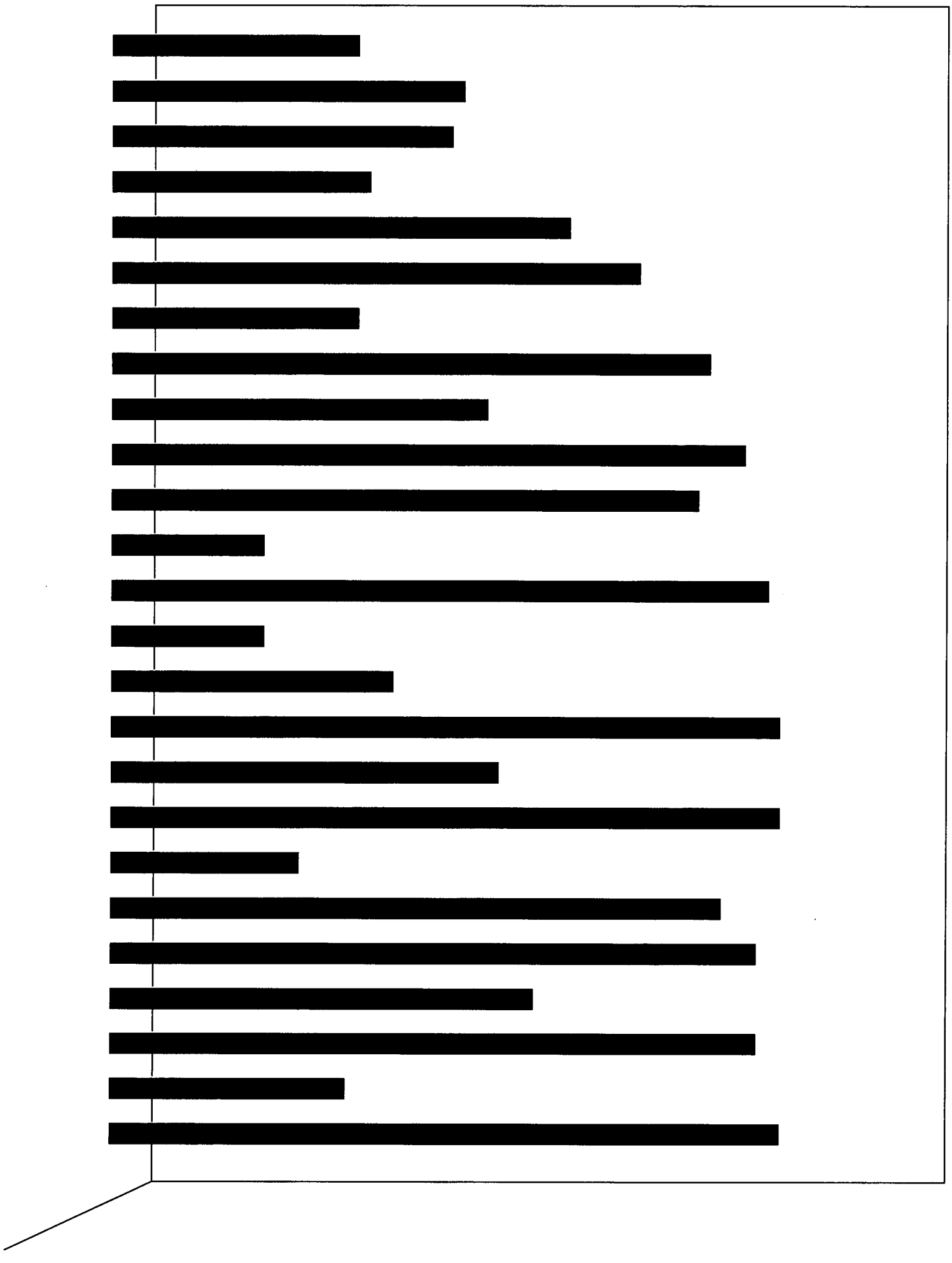












STATE OF NORTH CAROLINA

COUNTY OF DAVIDSON

C E R T I F I C A T E

I, Amy A. Brauser, Registered Merit Reporter/Certified Realtime Reporter, the officer before whom the foregoing deposition was taken, do hereby certify that the witness was duly sworn by me prior to the taking of the foregoing deposition; that the testimony of said witness was taken by me to the best of my ability and thereafter reduced to typewriting under my direction; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken, and further that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interest in the outcome of the action.

This is the 1st day of March, 2019.

Amy A. Brauser, RPR RMR CRR
Notary Public # 20023030055