

1 UNITED STATES COURT OF APPEALS
2 FOR THE DISTRICT OF COLUMBIA CIRCUIT

3
4 JOHN F. BANZHAF, EXECUTIVE
5 DIRECTOR OF ACTION ON SMOKING
6 AND HEALTH (ASH) AND SOTTERA,
7 INC., DOING BUSINESS AS NJOY,

No. 10-5032

8 Appellees,

9 v.

10 FOOD AND DRUG ADMINISTRATION,
11 ET AL.,

12 Appellants.

13 Thursday, September 23, 2010

14 Washington, D.C.

15 The above-entitled matter came on for oral
16 argument pursuant to notice.

17 BEFORE:

18 CIRCUIT JUDGES GARLAND AND KAVANAUGH AND
19 SENIOR CIRCUIT JUDGE WILLIAMS

20 APPEARANCES:

21 ON BEHALF OF THE APPELLANTS:

22 ALISA B. KLEIN, ESQ.

23 ON BEHALF OF THE APPELLEES:

24 GREGORY G. GARRE, ESQ.

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C O N T E N T S

ORAL ARGUMENT OF:

PAGE

Alisa B. Klein, Esq.
On Behalf of the Appellants

3; 43

Gregory G. Garre, Esq.
On Behalf of the Appellees

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P R O C E E D I N G S

THE CLERK: Case number 10-5032, John F. Banzhaf, Executive Director of Action on Smoking and Health, (ASH) and Sottera, Inc., doing business as Njoy v. Food and Drug Administration, et al., Appellants. Ms. Klein for Appellants; Mr. Garre for Appellees.

ORAL ARGUMENT OF ALISA B. KLEIN, ESQ.

ON BEHALF OF THE APPELLANTS

MS. KLEIN: May it please the Court, Alisa Klein for the Food and Drug Administration.

The District Court held that an electronic cigarette cannot be regulated as a drug or device unless it is intended for a therapeutic use. As we have explained in our briefs, the ruling rests on a misunderstanding of the Supreme Court's decision in *Brown & Williamson*. The *Brown & Williamson* decision rested on three related reasons when the Supreme Court rejected the assertion of jurisdiction over cigarettes and smokeless tobacco, and none of those reasons is applicable to a product like an electronic cigarette.

The first reason was that cigarettes and smokeless tobacco because of their inherent physical properties are necessarily an unsafe means of producing any pharmacological effect, and therefore would have to be banned if regulated as a drug or device. The Supreme Court held that other six specific federal statues that specifically regulated

1 cigarettes and smokeless tobacco showed the Congress did not
2 intend to have these products removed from the market, and the
3 Supreme Court explicitly also invoked a common sense
4 understanding that there was a major domestic tobacco
5 industry, and that Congress had not delegated to the Food and
6 Drug Administration authority to remove these products from
7 the market.

8 And then the third reason was that those specific
9 statutes were in turn ratifying FDA's consistent position that
10 it did not have authority to regulate cigarettes and smokeless
11 tobacco.

12 JUDGE KAVANAUGH: Well, the way the court phrased
13 it, however, was that FDA's long-standing position was that it
14 doesn't have to, it didn't have authority to regulate its
15 drugs, tobacco products absent therapeutic claims, use the
16 phrase tobacco products throughout the opinion in all the key
17 parts, and so it didn't use cigarettes --

18 JUDGE WILLIAMS: And it also used the phrase
19 therapeutic claims throughout. I counted eight in just a
20 casual not using electronic search, just the old fashioned
21 way.

22 MS. KLEIN: Yes.

23 JUDGE KAVANAUGH: I counted 88 tobacco products,
24 too.

25 MS. KLEIN: Well, trying to answer, you know, both

1 questions, again, actually, most of them the Supreme Court
2 said tobacco, and as that term was used by FDA, tobacco,
3 tobacco products, they were talking about products that really
4 have tobacco in them, they were talking about cigarettes and
5 smokeless tobacco, which were the products that were the
6 subject of the '96 rule before the Supreme Court. And
7 until -- I'll discuss the new legislation, but until 2010
8 tobacco products wasn't a defined term, and it's only now that
9 it's both defined to include products derived from tobacco,
10 but then explicitly to exclude products that are drugs and
11 devices. So, the Supreme Court wasn't using a term of art, it
12 was using a colloquial phrase.

13 JUDGE KAVANAUGH: All right. Well, do you agree
14 that e-cigarettes were tobacco products as the phrase was used
15 in *Brown & Williamson*?

16 MS. KLEIN: No. No. Absolutely not.

17 JUDGE KAVANAUGH: Yes.

18 MS. KLEIN: Electronic cigarettes are instead like
19 the Favor smokeless cigarette that FDA regulated in 1987, or
20 if you want to scroll farther to 2008 after *Brown & Williamson*
21 Nicogel, which was a hand gel that was meant to satisfy a
22 nicotine craving while you were on an airplane, or in a
23 restaurant, or bar, a place where you're not allowed to smoke.
24 So, no therapeutic use, just delivering nicotine for
25 pharmacological effects, and what FDA said is no, you're not

1 within the holding of *Brown & Williamson*, you concede that
2 you're not a cigarette or a smokeless tobacco which are
3 defined terms, and those products were subject to the specific
4 alternative regulatory scheme that was crucial to the holding
5 of *Brown & Williamson*. The Supreme Court -- nothing suggested
6 that all of these isolated nicotine products were totally
7 unregulated by anyone unless therapeutic claims were made.

8 JUDGE WILLIAMS: There were too many negatives in
9 that sentence.

10 MS. KLEIN: Okay. The products like the Favor
11 smokeless cigarette --

12 JUDGE WILLIAMS: Now, Favor is the one that they
13 didn't talk about, is that correct?

14 MS. KLEIN: Correct, they didn't talk about --

15 JUDGE WILLIAMS: There's one famous episode that it
16 not discussed in *Brown & Williamson*, although historically
17 before it, and --

18 MS. KLEIN: But --

19 JUDGE WILLIAMS: -- I think if you're focusing on
20 that that's not a good move for interpretation of *Brown &*
21 *Williamson*.

22 MS. KLEIN: But what we know is if the Favor
23 smokeless cigarette was not covered by any of those six
24 statutes that the Supreme Court was relying on in saying that
25 it doesn't make sense, Congress specifically addressed

1 cigarettes and smokeless tobacco. And, you know, it may have
2 used the shorthand tobacco products, but those statutes, it's
3 the Federal Cigarette and Labeling and Advertising Act, the
4 Comprehensive Smokeless Tobacco-something Act.

5 JUDGE WILLIAMS: But if you put so much stress on
6 the six particular statutes, if that's what was really driving
7 *Brown & Williamson*, why did the court in *Brown & Williamson*
8 never recite the precise coverage of each of the six statutes?
9 In other words, what it seems to, it talks about tobacco
10 products as customarily marketed, it uses that, or therapeutic
11 goals constantly. So, it seems to be a reasoned, a principle
12 decision by the FDA that the court was latching onto, namely
13 tobacco products marketed with therapeutic claims, and so it
14 naturally had no interest in the specifics of the statutory
15 coverage.

16 MS. KLEIN: No, again --

17 JUDGE WILLIAMS: Your theory requires it, I would
18 think, to enumerate particular items covered and not covered.

19 MS. KLEIN: No, because there was no question that
20 the formal name of the FDA rule was assertion of jurisdiction
21 over cigarettes and smokeless tobacco, there was no question
22 that those products --

23 JUDGE WILLIAMS: I see. I see --

24 MS. KLEIN: -- were covered --

25 JUDGE WILLIAMS: -- what you're saying. By all.

1 MS. KLEIN: -- by all six of the --

2 JUDGE WILLIAMS: Yes.

3 MS. KLEIN: -- federal statutes. And that's why I'm
4 saying tobacco products --

5 JUDGE WILLIAMS: Right.

6 MS. KLEIN: -- was a shorthand colloquial reference
7 to the very products that were the subject of the assertion of
8 jurisdiction, and --

9 JUDGE WILLIAMS: That would still leave the
10 references to therapeutic claims and as customarily marketed
11 as complete and utter surplusage.

12 MS. KLEIN: No. No. Because FDA, and FDA was
13 obviously totally candid about this with the Supreme Court
14 saying yes, before 1996 we disavowed jurisdiction over
15 cigarettes, it would say, you know, tobacco products used for
16 smoking and chewing unless those products were marketed with
17 therapeutic claims. And it's hard to imagine in modern times,
18 but in the '50s sometimes cigarettes would be sold to relieve
19 respiratory illness. So, even the products over which FDA had
20 always disavowed jurisdiction before '96, even those products
21 FDA said in the unusual circumstances in which they're
22 marketed with therapeutic claims we can reach them
23 notwithstanding the specific statutory provisions that
24 regulated cigarettes and smokeless tobacco.

25 JUDGE KAVANAUGH: Even FDA in its submission to the

1 Supreme Court in *Brown & Williamson* used the phrase tobacco
2 products, and at oral argument General Aspen (phonetic sp.)
3 used it. You just tried to define it a little more narrowly,
4 but the quote shorthand was being used by everyone, and as
5 Judge Williams says it always came with the tag line as
6 customarily marketed, or as marketed without therapeutic
7 claims.

8 MS. KLEIN: Yes. But the only subject, the only
9 issue before the Supreme Court was an assertion of
10 jurisdiction over cigarettes and smokeless tobacco. So, it's
11 not surprising that everyone referred to those as tobacco
12 products, it's what the FDA said in its rule, too, it was just
13 the quick way of saying cigarettes and smokeless tobacco.

14 JUDGE GARLAND: Were there any other kind of tobacco
15 products that --

16 MS. KLEIN: I'm sorry?

17 JUDGE GARLAND: Were there any other kind of tobacco
18 products at that time that the FDA didn't regulate?

19 MS. KLEIN: Well, there were cigars, and little
20 cigars, and pipe tobacco, there are all sorts of products
21 that --

22 JUDGE GARLAND: No, no, I'm sorry. Other than the
23 ones referred to in *Brown & Williamson*.

24 MS. KLEIN: Well, *Brown & Williamson* didn't refer --
25 the assertion of jurisdiction was not over cigars --

1 JUDGE GARLAND: I see.

2 MS. KLEIN: -- or pipe tobacco, or little cigars, it
3 was only over cigarettes and smokeless tobacco, because,
4 particularly because of the use by underage smokers.

5 JUDGE WILLIAMS: So, under your theory then *Brown &*
6 *Williamson* left the FDA totally free to regulate under the
7 Food and Drug Act cigars?

8 MS. KLEIN: You can imagine an argument about cigars
9 that would have been analogous to the argument about
10 cigarettes, there's another regulatory scheme, there's a
11 domestic tobacco industry that we're protecting, it's not an
12 argument that could be made about an isolated nicotine
13 product --

14 JUDGE KAVANAUGH: Why not just use the line, the
15 simple line that the Supreme Court used, the line was those
16 products marketed with therapeutic claims and those that were
17 not? You were just proposing, I think, some kind of tradition
18 deeply rooted test for whether a tobacco product is going to
19 come within *Brown & Williamson* or not.

20 MS. KLEIN: No, it's not that, it's that if you look
21 at these isolated nicotine products they weren't subject to
22 any other regulatory scheme. So, the theory would have to be
23 you could sell a nicotine lollipop unregulated unless you made
24 therapeutic claims, and no one thought that. FDA, again,
25 Favor, 1987 --

1 JUDGE KAVANAUGH: Those were marketed with
2 therapeutic --

3 JUDGE WILLIAMS: Favor is really not before us --

4 JUDGE KAVANAUGH: Yes.

5 JUDGE WILLIAMS: -- because it was not before the
6 Supreme Court in *Brown & Williamson*.

7 MS. KLEIN: Yes, but the Supreme Court was talking
8 about how Congress ratified FDA's position, and FDA's position
9 didn't treat a product like Favor the way FDA itself had
10 treated cigarettes. And then again in 2008 when Nicogel said
11 I'm also a customarily marketed tobacco product, I don't make
12 therapeutic claims, FDA said no, no, that's like way over-
13 reading *Brown & Williamson*, you're not subject --

14 JUDGE WILLIAMS: But that --

15 MS. KLEIN: -- to us --

16 JUDGE WILLIAMS: -- but we don't own any deference
17 to the FDA's reading of *Brown & Williamson*, do we?

18 MS. KLEIN: That is correct. However, the Supreme
19 Court relief in part on FDA's own understanding of its
20 authority.

21 JUDGE WILLIAMS: But that was its prior statements
22 of its authority, not -- it didn't incorporate a sort of
23 rolling adoption of the FDA future positions.

24 MS. KLEIN: From a straight common sense perspective
25 the rule in *Brown & Williamson* made some sense, because the

1 Supreme Court said look, Congress has regulated -- I'm just
2 going to use cigarettes as the shorthand for cigarettes and
3 smokeless tobacco, but Congress has regulated cigarettes; we
4 know Congress meant for cigarettes to stay on the market; we
5 have six specific statutes that regulate them, or five if you
6 don't count the smokeless; and they have to bear warnings,
7 they can't be sold to children, they can't be advertised by
8 the FCC. None of that would have been true of electronic
9 cigarettes, or Favor, or Nicogel, that just -- and so that
10 would require the Supreme Court to say nobody regulates those
11 products, and there's nothing in *Brown & Williamson* to suggest
12 that it meant to leave totally unregulated products that just
13 deliver nicotine. And the other conclusion of the Supreme
14 Court --

15 JUDGE KAVANAUGH: Well, there was discussion in the
16 briefs about the nicotine inhaler, I think, right? So --

17 MS. KLEIN: Well, there's a --

18 JUDGE KAVANAUGH: -- at least it was before the
19 court, the reply brief footnote discusses that.

20 MS. KLEIN: That was --

21 JUDGE KAVANAUGH: I realize it's not in the opinion,
22 that's a thin read, but at least there was some awareness of
23 other things.

24 MS. KLEIN: And the Supreme Court certainly didn't
25 call into question FDA's long-standing regulation of nicotine

1 delivery devices, like the inhaler, the patches, the gums, the
2 lozenges. I mean, Pfizer sells a prescription nicotine
3 inhaler. If the Plaintiff were right anyone could just sell
4 that same inhaler, not go through the clinical studies, not
5 have to demonstrate safety and effectiveness, just don't
6 explicitly say this is to help you reduce your dependence on
7 cigarettes.

8 JUDGE KAVANAUGH: You invoked --

9 MS. KLEIN: And it just doesn't make any sense.

10 JUDGE KAVANAUGH: -- common sense, so taking a step
11 back here, your position would mean that FDA could ban
12 electronic cigarettes but not cigarettes, and does that make
13 much sense to attribute that intent to Congress?

14 MS. KLEIN: Well, to be a little more precise, the
15 question for FDA for electronic cigarettes like for other
16 nicotine products, pure nicotine products, is is this safe for
17 any use? So, for example, if it could be shown that an
18 electronic cigarette is a safe method of nicotine maintenance,
19 so instead of cigarettes you use an electronic cigarette for
20 nicotine maintenance, that could be approved if the science
21 supports it. And in fact, in the new legislation that --

22 JUDGE KAVANAUGH: But what I've said is correct,
23 right? FDA would have the authority to ban electronic
24 cigarettes, but not cigarettes?

25 MS. KLEIN: Yes, assuming that there's no scientific

1 evidence to show that an electronic cigarette could be a safe
2 nicotine maintenance therapy. And just, I want to finish what
3 I was saying that in the new legislation one of Congress'
4 concerns was to encourage more and better nicotine replacement
5 therapies, and it's directed FDA to fast-track those
6 applications, and particular what we're talking about extended
7 use nicotine replacement products, because the ones that are
8 currently approved are designed for short-term, 12-week use,
9 and so there's, you know, a workshop that's being convened,
10 and this is why FDA has written to the Electronic Cigarette
11 Manufacturer's Association encouraging the firms to come to
12 FDA to work with FDA to see if these products could be used
13 for nicotine maintenance, just like methadone maintenance for
14 heroin addicts. Is this a safe means of instead of smoking
15 cigarettes, which, you know, the harms are well-known, would
16 this be a safe and effective substitute? But that's all drug
17 regulation. And so, this is the reason discussed in the
18 Public Health Amicus brief why it is so important why Congress
19 carved out from the definition of tobacco product any product
20 that's regulated as a drug or a device.

21 JUDGE WILLIAMS: Yes. What about cigars, again?
22 Because although evidently not covered, is that correct? Not
23 covered in the 1996 rule, they're explicitly covered in the
24 later statute. Of course that doesn't tell us what the
25 Supreme Court meant, but it's perhaps a congressional view as

1 to what the Supreme Court meant. And they have, cigars have
2 certainly the first two of the characteristics that you
3 mentioned, right? That on a health basis they would have to
4 be banned at least as much as cigarettes, right? And they're
5 part of a great American industry.

6 MS. KLEIN: I want to be careful not to get out
7 ahead of the Food and Drug Administration, which hasn't
8 addressed cigars.

9 JUDGE WILLIAMS: But it has explicit authority to?

10 MS. KLEIN: Well, the way the new --

11 JUDGE WILLIAMS: Under the Tobacco Act.

12 MS. KLEIN: -- legislation works, FDA is given
13 explicit authority over cigarettes, smokeless tobacco,
14 cigarette tobacco, and roll your own tobacco, and any other
15 tobacco products that the Agency deems by regulation --

16 JUDGE WILLIAMS: Right.

17 MS. KLEIN: -- to be tobacco products. And a
18 different provision provides that FDA can't ban certain
19 products --

20 JUDGE WILLIAMS: Right.

21 MS. KLEIN: -- including cigars. FDA has not yet
22 deemed any -- it hasn't yet completed its regulatory process,
23 and it hasn't yet deemed any product to be a tobacco product.
24 So, I'm just -- the analysis of cigars is different.

25 JUDGE WILLIAMS: I see. So, the statute says they

1 can't ban cigarettes, which seems to pre-suppose that they
2 could on the deeming provision deem them tobacco products, or
3 deem them --

4 MS. KLEIN: I think Your Honor meant --

5 JUDGE WILLIAMS: -- worthy of --

6 MS. KLEIN: -- cigars.

7 JUDGE WILLIAMS: -- regulation. Cigars.

8 MS. KLEIN: Yes.

9 JUDGE WILLIAMS: I'm sorry.

10 MS. KLEIN: Yes.

11 JUDGE WILLIAMS: Yes.

12 MS. KLEIN: Exactly.

13 JUDGE WILLIAMS: Okay.

14 MS. KLEIN: Yes.

15 JUDGE GARLAND: Could you talk about the Tobacco
16 Control Act?

17 MS. KLEIN: Yes, Your Honor. It was agreed in
18 District Court I think correctly that the Tobacco Control Act
19 doesn't change the answer to the question that's before the
20 Court. And in fact, these products were detained before the
21 Tobacco Control Act was even passed. And the Tobacco Control
22 Act while defining tobacco product in a way that is expansive,
23 specifically and repeatedly says a product that meets the
24 definition of a drug or device or a combination product is not
25 a tobacco product, the drugs and devices are regulated under

1 the drug and device authority, and nothing shall alter or
2 constrict that authority. So, the answer to the Tobacco
3 Control Act question is the same as the answer to the question
4 of can these products be regulated as drugs or devices.

5 JUDGE KAVANAUGH: You think that the Tobacco Control
6 Act defines tobacco product differently from how *Brown &*
7 *Williamson* used the term?

8 MS. KLEIN: Yes, Your Honor.

9 JUDGE KAVANAUGH: Is that --

10 MS. KLEIN: I mean, *Brown & Williamson* -- again, we
11 just think it was using it as a, really as a shorthand for
12 cigarettes and smokeless tobacco. It wasn't pre-judging one
13 way or another cigars, other products that, you know --

14 JUDGE KAVANAUGH: Well, let me try another theory
15 and tell me why this is wrong, that the Supreme Court said
16 tobacco products that the line they drew was customarily
17 marketed versus not, left a gap, a regulatory gap, Congress
18 comes in and fills the regulatory gap and now provides a
19 different set of authority over those tobacco products as
20 defined here as customarily marketed, isn't that a pretty
21 sensible way to put the pieces together here?

22 MS. KLEIN: Well, I think I'm probably repeating
23 things I've said, but no, not for products that just deliver
24 nicotine which were never subject to any alternative
25 regulatory scheme. That wouldn't have been just a gap, that

1 would have been like a void, unlike cigarettes which were
2 subject to all sorts of regulation, there was no alternative
3 regulation of products like nicotine lollipops, or nicotine
4 patches, or the Favor, I know, the Court doesn't like that,
5 the, you know, inhalers, all of these products, they were not
6 subject to any other scheme. So, we do not think that is --

7 JUDGE KAVANAUGH: But that happens not infrequently
8 that the court rules there's no authority over something, and
9 Congress has to come in and provide authority, that's --

10 MS. KLEIN: But, again, I mean --

11 JUDGE KAVANAUGH: -- part of our daily business.

12 MS. KLEIN: -- it really wasn't before the Court,
13 the question of --

14 JUDGE KAVANAUGH: Yes.

15 MS. KLEIN: -- the nicotine patch, and there's
16 absolutely no reason to think that this court was calling into
17 question FDA's long-standing regulation of that type of
18 nicotine product, where it's --

19 JUDGE KAVANAUGH: Right.

20 MS. KLEIN: -- not, the problem wasn't that it was
21 being nicotine -- the problem in *Brown & Williamson* is if you
22 deliver nicotine through the cigarette device it's inherently
23 unsafe because of the way when the tobacco is lit and you
24 smoke it it causes cancer and all sorts of other harms. Just
25 the same analysis doesn't work when you're talking about just

1 delivering isolated nicotine, and that's why FDA has been able
2 to improve --

3 JUDGE KAVANAUGH: So --

4 MS. KLEIN: -- all sorts, approve all sorts of
5 isolated nicotine products.

6 JUDGE KAVANAUGH: Just so I understand, because I
7 might be confused, what tobacco products were marketed without
8 therapeutic claims as of *Brown & Williamson* that would have
9 been left in a regulation-free zone if the theory I wanted
10 earlier were correct.

11 MS. KLEIN: Well, I mean, the Favor cigarette is the
12 best --

13 JUDGE KAVANAUGH: Okay.

14 MS. KLEIN: -- example --

15 JUDGE KAVANAUGH: Is there any other?

16 MS. KLEIN: -- pre-*Brown & Williamson* that we have.
17 We don't have specific examples, but the theory would have to
18 be --

19 JUDGE KAVANAUGH: Because the other examples you
20 gave are marketed with therapeutic claims, correct?

21 MS. KLEIN: Well, as it happens like nicotine
22 lollipops, nicotine hand gel -- not hand gel, I'm sorry,
23 nicotine water, as it happens, those were marketed both with
24 structure function claims and therapeutic claims, but our
25 point is --

1 JUDGE KAVANAUGH: And therefore were regulatable, so
2 when you were saying the sky would have been falling as of
3 *Brown & Williamson* because there would have been a regulation-
4 free zone it really is just Favor?

5 MS. KLEIN: No. No. Because nicotine lollipops if
6 the manufacturer could just remove the expressed therapeutic
7 claims the theory would be they could just sell them. This
8 doesn't make any sense, you could just sell a nicotine
9 lollipop.

10 JUDGE WILLIAMS: It does make, it makes a lot of
11 sense.

12 MS. KLEIN: That makes --

13 JUDGE WILLIAMS: To the extent that the FDA drew a
14 distinction based on the presence of absence of therapeutic
15 claims would just be an endorsement of that, and if Congress
16 didn't like it, it could modify the statute.

17 MS. KLEIN: It drew that distinction only for
18 cigarettes and smokeless tobacco. I mean, this is -- we've
19 shown at length in our reply brief that therapeutic claims
20 they've never been the only reason that a product is a drug,
21 there are all sorts of products, like No-Doze, and tanning
22 booths, and --

23 JUDGE KAVANAUGH: Well, that's outside the tobacco
24 context, though, and --

25 MS. KLEIN: Well, Favor cigarettes, it's --

1 JUDGE KAVANAUGH: That's the one. Yes, you've got
2 one.

3 MS. KLEIN: No, Favor cigarettes --

4 JUDGE KAVANAUGH: You have one, that's good.

5 MS. KLEIN: -- and Nicogel, I have two.

6 JUDGE KAVANAUGH: Okay.

7 MS. KLEIN: I realize one is after *Brown &*
8 *Williamson* and one is before, so we've now flanked *Brown &*
9 *Williamson* with -- and, but also just why, there would be no
10 reason to think that you could sell a nicotine lollipop for a
11 recreational nicotine hit and nobody could regulate that.
12 That's --

13 JUDGE WILLIAMS: There's a lot of reason to think
14 that. I mean, the presence of subsection B in the statute
15 suggests that Congress cared a lot about the presence or
16 absence of therapeutic claims, right? The presence of C
17 obviously complicates matters, but --

18 MS. KLEIN: Well, it not just complicates it, I
19 mean, that's -- C was added in order to bring within the
20 definition of drug products that are not sold with therapeutic
21 claims.

22 JUDGE WILLIAMS: And it turns out through years of
23 FDA practice that it didn't fully do the job, right?

24 MS. KLEIN: No.

25 JUDGE WILLIAMS: Because the FDA steadfastly

1 insisted on therapeutic claims with respect to the tobacco
2 products that it phased.

3 MS. KLEIN: No, cigarettes and smokeless tobacco,
4 not other nicotine products, and of course, not non-nicotine
5 products like caffeine pills, like No-Doze. Nicotine
6 products, pure nicotine, like the Favor cigarette, it didn't
7 matter whether they were marketed with therapeutic claims or
8 other types of drug claims, FDA concluded those were drugs.
9 It was a special approach to cigarettes and smokeless tobacco
10 because as FDA explicitly said if we regulate those because of
11 their effects of the structure and function of the body we
12 would have to ban them, and we know Congress didn't want to
13 ban them.

14 JUDGE KAVANAUGH: If we --

15 JUDGE GARLAND: Can I ask -- I'm sorry.

16 JUDGE KAVANAUGH: Go ahead. Go ahead.

17 JUDGE GARLAND: Can I ask you about what seems like
18 a relatively unique procedural element of this case. So, the
19 original -- the only piece of paper we have explaining the
20 Government's position as an agency on this is the blocking
21 order, or whatever it's called. What's it called?

22 MS. KLEIN: The detention order --

23 JUDGE GARLAND: The detention order.

24 MS. KLEIN: -- with respect to Njoy, yes.

25 JUDGE GARLAND: Right. That's the only, that's the

1 most formal document we have, is that right?

2 MS. KLEIN: Yes, although it's applying the same
3 principles that were discussed in the Nicogel proceeding where
4 the principles are set on at much greater length. This is
5 where the --

6 JUDGE GARLAND: Well, it says -- it, actually
7 that -- this order says and, right?

8 MS. KLEIN: Yes.

9 JUDGE GARLAND: It says both --

10 MS. KLEIN: Yes.

11 JUDGE GARLAND: -- you know, it's being detained
12 because it is both intended for effect on the body, and
13 because it's intended for therapeutic, right?

14 MS. KLEIN: Yes, correct.

15 JUDGE GARLAND: So, do we know from that whether the
16 Government's position was that it had to have both, or whether
17 it was one or the other?

18 MS. KLEIN: No, it's -- I mean, it's always been one
19 or the other, and this is -- in the Ninth Circuit in that
20 storage container case in --

21 JUDGE GARLAND: Well, I know what the Government's
22 overall position is, but with respect to this particular item
23 do we know whether the Government was intending to obtain
24 because of both, or because of one or the other?

25 MS. KLEIN: Well, I know that the FDA's position

1 now, consistent with what it said previously is either is a
2 basis for regulating a nicotine product, not a cigarette, but,
3 you know, pure nicotine product as a drug. I don't -- there's
4 no administrative record as Your Honor is pointing out in
5 Njoy's products in particular, so I don't have anything else.

6 JUDGE GARLAND: There's some vague reference in
7 maybe a footnote, is there an issue here as to whether this
8 was, is being marketed with a therapeutic claim?

9 MS. KLEIN: It's really open. We don't have an
10 administrative record on the way these products are being
11 marketed, and it's -- the District Court said well, if you
12 come forward with evidence that it's being marketed for
13 therapeutic use then, you know, even under the District
14 Court's reasoning the products would be unapproved drugs.

15 JUDGE GARLAND: But what proceeding would have
16 gone -- I mean, I take it that there's really no final Agency
17 action here, there's an argument, or a conclusion by the
18 District Court that it would be futile, but I guess one
19 possible consequence of final Agency action might have been a
20 determination about whether or not there were therapeutic
21 claims, is that right or not right?

22 MS. KLEIN: That is correct. But again, the
23 question of how a product is marketed can change over time,
24 and the way these detention orders work it's not literally
25 that FDA is detaining that particular batch, they just get

1 returned and the company disposes of them elsewhere, and so
2 the question, like is FDA limited to regulating cigarette,
3 electronic cigarettes only if they make therapeutic claims --

4 JUDGE GARLAND: Right, but in order --

5 MS. KLEIN: -- is going to be --

6 JUDGE GARLAND: -- to detain these, in other words I
7 guess what I'm asking is whether both sides are asking us for
8 an advisory opinion on what the FDA is limited to when this
9 case itself might be resolved on the facts of the case by
10 therapeutic claim, or does the FDA think there is no
11 therapeutic claim here?

12 MS. KLEIN: Well, again, these products were
13 detained, it was over a year ago.

14 JUDGE GARLAND: I don't mean these specific
15 products, but the way in which this company is marketing the
16 products.

17 MS. KLEIN: I believe Njoy will stand up and
18 represent that they don't make therapeutic --

19 JUDGE GARLAND: Yes.

20 MS. KLEIN: -- claims, and so if the Court is asking
21 whether there should be a remand for development of the
22 evidence we don't actually think that makes sense. I mean,
23 the Court would certainly have discretion, but at this point
24 the District Court has issued a definitive legal ruling that
25 is we believe incorrect, it's denied reconsideration, and we

1 probably would just be back where we started from, and there
2 are lots of other companies that are also distributing
3 electronic cigarettes, so it's a very important principle, we
4 don't think it's advisory in any Article 3 sense, and we are
5 under an injunction --

6 JUDGE GARLAND: And what do you --

7 MS. KLEIN: -- based on a legal ruling.

8 JUDGE GARLAND: And what do you say of the other
9 side, the position that you're not entitled to *Chevron*
10 deference with respect to the Tobacco Control Act because you
11 do not actually have any document except for your brief which
12 expresses your views on that statute?

13 MS. KLEIN: Well, I mean, the first point is it's
14 not -- we don't regard the language of the Tobacco Control Act
15 as ambiguous --

16 JUDGE GARLAND: Well, you --

17 MS. KLEIN: -- since it explicitly --

18 JUDGE GARLAND: I see. Yes.

19 MS. KLEIN: -- excludes drugs, and so the issue of
20 *Chevron* deference really only comes up if there were an
21 ambiguity.

22 JUDGE GARLAND: Yes.

23 MS. KLEIN: If there were an ambiguity.

24 JUDGE GARLAND: Well, you have an argument in your
25 brief that we should give you *Chevron* deference.

1 MS. KLEIN: Well, it's if --

2 JUDGE GARLAND: You want to give that up, or --

3 MS. KLEIN: -- there were an ambiguity then we
4 should get *Chevron* deference to our brief, and as the Supreme
5 Court said in *Auer*, the question isn't --

6 JUDGE GARLAND: But *Auer* was about interpreting
7 regulation, and *Mead* sort of throws *Auer* overboard with
8 respect to statutes, doesn't it?

9 MS. KLEIN: No, the question is whether there's a
10 delegation of authority to the Agency. And here the FDA is
11 explicitly vested with responsibility to determine what
12 products it deems to be tobacco products --

13 JUDGE GARLAND: By regulation it says.

14 MS. KLEIN: By regulation, but --

15 JUDGE GARLAND: Your brief is not --

16 MS. KLEIN: -- the absence --

17 JUDGE GARLAND: -- your brief is not a regulation.

18 MS. KLEIN: No, that's correct, Your Honor. But the
19 Agency is not, has not issued a proposed rule-making --

20 JUDGE GARLAND: Yes.

21 MS. KLEIN: -- to deem --

22 JUDGE GARLAND: Right.

23 MS. KLEIN: -- electronic cigarettes generally. I
24 mean, it's not clear how else the Agency would express its
25 understanding of the Tobacco Control Act except in a brief.

1 JUDGE GARLAND: Well, we have, as you point out in
2 your brief, given *Chevron* deference to advisory letters, more
3 formal things, right? In front of us we have nothing at all
4 other than a brief. That is --

5 MS. KLEIN: Well, and --

6 JUDGE GARLAND: -- we don't have an advisory letter,
7 we don't have anything.

8 MS. KLEIN: -- the Court has the brief that
9 represents the position, you know, reviewed at high levels at
10 FDA --

11 JUDGE GARLAND: That's what the Government says
12 about every brief, and we never give you deference, so --

13 MS. KLEIN: The Supreme Court gives us deference to
14 our briefs. I mean, we're often -- the Court calls for the
15 views of the United States --

16 JUDGE GARLAND: Yes, but --

17 MS. KLEIN: -- on statutory questions --

18 JUDGE GARLAND: -- but that --

19 MS. KLEIN: -- HHS comes in, and --

20 JUDGE GARLAND: -- you would describe those as
21 *Skidmore* deference. Is there a case in which the Supreme
22 Court post-*Mead* has given *Chevron* deference to a Government's
23 brief?

24 MS. KLEIN: Post --

25 JUDGE GARLAND: However well written.

1 MS. KLEIN: However well written. I'm not aware of
2 one. But again, Your Honor --

3 JUDGE GARLAND: Okay.

4 MS. KLEIN: -- since the Agency's basic point is
5 that the Tobacco Control Act explicitly defines tobacco
6 product to exclude drugs, we don't believe the Court needs to
7 reach the *Chevron* question with respect to the Tobacco Control
8 Act.

9 JUDGE KAVANAUGH: And I suppose your position is if
10 all we had in front of us were the FDCA and the Tobacco
11 Control Act you would win easily, it's the --

12 MS. KLEIN: Yes.

13 JUDGE KAVANAUGH: -- *Brown & Williamson* that creates
14 the confusion, and so I suppose your theories interpret *Brown*
15 & *Williamson* to the extent there's ambiguity there in the
16 direction of the text?

17 MS. KLEIN: Correct. Yes. Thank you, Your Honor.

18 JUDGE GARLAND: Can you -- you see how that turns
19 into another question? I take it you don't believe you get
20 any extra credit from the language of the import statute which
21 only requires you to show that there appears to be a violation
22 of the statute?

23 MS. KLEIN: We do not make that argument. Unless
24 there are further --

25 JUDGE GARLAND: Okay.

1 MS. KLEIN: -- questions.

2 JUDGE GARLAND: We'll hear from Sottera.

3 ORAL ARGUMENT OF GREGORY G. GARRE, ESQ.

4 ON BEHALF OF THE APPELLEES

5 MR. GARRE: Thank you, Judge Garland, and may it --

6 JUDGE GARLAND: Could you just clear up --

7 MR. GARRE: -- please the Court.

8 JUDGE GARLAND: -- one piece of confusion. For some
9 reason on my docket sheet it says Mr. Bonzoff is -- I find it
10 hard to believe he's on your side on this matter.

11 MR. GARRE: We noticed that on the way in, and I
12 don't want to speak for him, but I doubt very much he is on
13 our side in this case.

14 JUDGE GARLAND: Was he --

15 MR. GARRE: I think it may be an error in the
16 caption itself.

17 JUDGE GARLAND: Okay. Thank you.

18 MR. GARRE: Your Honors --

19 JUDGE WILLIAMS: There's a similar area in the
20 docket sheets.

21 MR. GARRE: Yes, Your Honor. Your Honors, I think
22 what was perhaps most remarkable about the FDA's position in
23 this case is that in the wake of the passage of the landmark
24 Tobacco Act it has the unquestioned authority to regulate
25 electronic cigarettes in all the ways that Congress thought

1 appropriate to regulate cigarettes themselves, and yet FDA is
2 here today claiming authority to regulate electronic
3 cigarettes in effect ban them as a drug under the Food, Drug,
4 and Cosmetic Act. In that sense --

5 JUDGE GARLAND: Are there differences between what
6 they could do? I assume there's some reason why they want to
7 do it under the Food, Drug, and Cosmetic Act rather than under
8 the Tobacco Control Act. I assume there's -- for example, you
9 don't have to go through an advanced approval before you can
10 market something under the Tobacco Control Act, while you
11 would under the Food and Drug Act, is that right?

12 MR. GARRE: I think that's probably right, Your
13 Honor. I think that they feel that they want to take more
14 aggressive action under the Food, Drug, and Cosmetic Act,
15 including perhaps a ban then the Tobacco Act would allow them
16 to do. But I think, I mean, we know based on Congress' recent
17 action what Congress thought was appropriate in terms of the
18 Agency's authority with respect to all tobacco products,
19 including cigarettes, and so for the FDA to come here and say
20 that it needs this authority under the Food, Drug, and
21 Cosmetic Act, I mean, we respectfully think that that position
22 is just wrong. I think FDA in many sense is asking this Court
23 for permission to go back to the future and regulate
24 electronic cigarettes as drugs in the way that FDA sought to
25 regulate all tobacco products as drugs in 1996. And we know

1 from the Supreme Court that FDA's prior assertion of drug
2 device jurisdiction over tobacco products failed, and
3 particularly in light of the passage of the Tobacco Act we
4 think that this Court should reject its interpretation here.

5 JUDGE KAVANAUGH: What about the idea that there's
6 ambiguity in *Brown & Williamson*? A lot of debate about what
7 they meant about tobacco products broadly, or just cigarettes
8 and smokeless more narrowly, and if we're going to face that
9 ambiguity why not interpret it in the direction of the
10 statutory tax, which as you know speaks very broadly and would
11 give FDA broad jurisdiction to regulate e-cigarettes as drugs.

12 MR. GARRE: Right.

13 JUDGE KAVANAUGH: Can you respond to that?

14 MR. GARRE: I guess I would make two points in
15 response to that. First, at the outset, the FDA, of course,
16 gets no deference on interpreting Supreme Court decisions.
17 Second, as Your Honors point --

18 JUDGE KAVANAUGH: No, I was talking more about why
19 don't we --

20 MR. GARRE: Yes.

21 JUDGE KAVANAUGH: -- interpret if there's ambiguity
22 in *Brown & Williamson* why don't we have the tie breaker be the
23 statutory text, the original broad text to the FDCA?

24 MR. GARRE: Well, I think really the tie breaker
25 ought to be, Your Honor, what Congress thought when it was

1 enacting the Tobacco Control Act of 2009. In that respect
2 what's really more important than this Court's own
3 interpretation of *Brown & Williamson* is what Congress must
4 have thought when it passed the Tobacco Act of 2009. And
5 actually, *Brown & Williamson* the Supreme Court said something
6 quite relevant on that, which we think ought to guide the
7 Court's interpretation of the Tobacco Act. In *Brown &*
8 *Williamson* the Court said, this is on page 157 of its
9 decision, "When Congress created a distinct regulatory scheme
10 addressing the subject of tobacco and health it understood
11 that the FDA is without jurisdiction to regulate tobacco
12 products and ratify that position." Well, in the *Brown &*
13 *Williamson* case the Court was talking about various
14 idiosyncratic statutes dealing with cigarettes, smokeless
15 tobacco and the like. Here we have Congress' definitive act
16 on the subject of FDA's jurisdiction to regulate tobacco
17 products defined in the broadest sense.

18 JUDGE KAVANAUGH: Well, then it's a little question
19 begging, because then they say it doesn't move the line, they
20 have the provision that says this does not mean an article
21 that's a drug, and so that just gets us back to what did *Brown*
22 *& Williamson* mean?

23 MR. GARRE: Well, with respect, I don't think it
24 does, I think what it shows is that Congress ratified the line
25 that FDA itself advanced before the Supreme Court in *Brown &*

1 *Williamson*, and that everyone believed at the time of *Brown &*
2 *Williamson* and after the time of *Brown & Williamson*. If you
3 look at FDA's brief in that case, and with respect I think my
4 friend on the other side is not being fully fair to the FDA's
5 representations in that case. FDA told the Supreme Court,
6 "Until FDA issued the regulations at issue here," this is back
7 in *Brown & Williamson*, "the only instances in which it found
8 that tobacco products were intended to affect the structure or
9 function of the body involved cases in which there were
10 express market claims of therapeutic value."

11 JUDGE GARLAND: But doesn't that --

12 JUDGE KAVANAUGH: That was actually wrong. Yes.

13 JUDGE GARLAND: Well --

14 JUDGE KAVANAUGH: Sorry.

15 JUDGE GARLAND: Good point. I mean, it was wrong,
16 but --

17 JUDGE KAVANAUGH: So, it's factually --

18 JUDGE GARLAND: -- leaving aside the Government's
19 point is that at least in those days tobacco products meant a
20 product with tobacco in it. I think that there weren't any e-
21 cigarettes, at least people didn't know about e-cigarettes at
22 the time other than Favor.

23 JUDGE WILLIAMS: I don't think that is the
24 Government's position. The Government's position is the
25 tobacco products as used in *Brown & Williamson* is not products

1 with tobacco in them, but only cigarettes and smokeless
2 tobacco.

3 MR. GARRE: That's right. And I think --

4 JUDGE GARLAND: Well, if that's the -- still, your
5 point was, I take it, that by using tobacco products they
6 meant anything that was derived from tobacco, and that's not
7 under either of Judge Williams' interpretation of the
8 Government, or my interpretation of the Government, neither of
9 which are entitled to *Chevron* deference.

10 MR. GARRE: I think the Government today is
11 maintaining that the FDA at the time of *Brown & Williamson*
12 meant only cigarettes and smokeless --

13 JUDGE GARLAND: Yes.

14 MR. GARRE: -- tobacco.

15 JUDGE GARLAND: Yes.

16 MR. GARRE: In fact, if you look at the briefs in
17 *Brown & Williamson* I think it suggests that the FDA had the
18 literal interpretation of tobacco products. I mean, as Judge
19 Kavanaugh -

20 JUDGE GARLAND: Well, I don't know what literal
21 means. I guess I would say if I think back to that time
22 tobacco products seems like a product with tobacco, unless --
23 I mean, obviously, if there were a lot of e-cigarettes around
24 at the time then you wouldn't think that because there was
25 something else. But --

1 MR. GARRE: But, Your Honor, we don't have to
2 speculate on this question because the Government,
3 fortunately, answered it in its briefs in *Brown & Williamson*.
4 It noted in its reply brief that if the Supreme Court rejected
5 its interpretation of drug and device under the Food Cosmetic
6 Act then it would have no jurisdiction to regulate nicotine
7 inhalers that were sold for smoking pleasure. Well, that
8 argument obviously did not move the Supreme Court, but yet the
9 FDA is here today saying that it needs jurisdiction under the
10 Food, Drug, and Cosmetic Act to regulate something that is
11 precisely like the nicotine inhaler that the Solicitor General
12 referred to in its reply brief. And the same argument goes
13 for cigars, and that's really the larger question --

14 JUDGE KAVANAUGH: That footnote is a little murkier
15 than what you just described. I mean, it's phrased in kind of
16 triple negative, but --

17 MR. GARRE: Well, I mean, I think --

18 JUDGE KAVANAUGH: -- you know --

19 MR. GARRE: -- it's clear that from that footnote
20 that FDA didn't have the crabbed view of tobacco products that
21 it's advancing in its briefs here, that it's only cigarettes
22 and smokeless tobacco, that it understood when it took tobacco
23 products in the question presented when it referred to tobacco
24 products all throughout its briefs that the issue before the
25 Supreme Court was the one that all anticipated, which was the

1 FDA's authority to regulate tobacco products. Its position
2 today would apply equally to cigars, because cigars are not a
3 cigarette, they're not a smokeless tobacco, they are a tobacco
4 product. If this Court agrees with the FDA that it has
5 jurisdiction to regulate electronic cigarettes as a drug or
6 device then surely it has jurisdiction to regulate cigars as a
7 drug or device.

8 JUDGE GARLAND: Were there any statutes about cigars
9 at the time?

10 MR. GARRE: Your Honor, I don't know the precise, I
11 don't know the exact answer to that question. What I'm
12 confident telling the Court is that there was nowhere near the
13 sort of parallel regulatory scheme that the Supreme Court
14 pointed to with respect to cigarettes at the time of *Brown &*
15 *Williamson* for cigars. And the argument that the Supreme
16 Court referred to in its decision was pertaining to cigarettes
17 and smokeless tobacco, so --

18 JUDGE GARLAND: Well, the finding of Congress that
19 tobacco is an important industry to the United States I
20 presume that applies to -- cigars are made from tobacco, so I
21 would assume that that would apply to cigars, as well.

22 MR. GARRE: Absolutely. But I do think, and going
23 back to what Congress intended in 2009, if you look at the
24 findings that Congress issued in that statute, and its
25 purpose, they talk about the need to give FDA jurisdiction to

1 regulate tobacco products, and they talk about the fact that
2 FDA had lacked this jurisdiction before the Tobacco Act. And
3 so, this gets back to this question of what did Congress think
4 it was doing, and what line did Congress ratify when it passed
5 the Tobacco Act? And I think that the only, with respect,
6 sensible conclusion is that Congress believed that it was
7 acting in response to a decision that said that the FDA lacked
8 jurisdiction over tobacco products, and Congress was giving
9 the FDA the authority that it thought appropriate to regulate
10 all tobacco products, whether it was the cigarette, a cigar,
11 smokeless tobacco, electronic cigarette, or anything in the
12 terms of the definition that is derived from tobacco, or
13 nicotine, which is derived from tobacco.

14 JUDGE GARLAND: What happens with their example of
15 street drugs? Would that --

16 MR. GARRE: And I think --

17 JUDGE GARLAND: -- unregulatable because needless to
18 say the dealers are not advertising them as therapeutic?

19 MR. GARRE: Our view looking back over history and
20 looking at the statutes that the only sensible line
21 interpreting the structure or function definition of drug is
22 that it's limited by claims of therapeutic purpose. Now of
23 course, this Court doesn't need to reach that broader question
24 in this case.

25 JUDGE GARLAND: So, what does that do with street

1 drugs?

2 MR. GARRE: Well, I think our position is that FDA
3 would lack jurisdiction to regulate street drugs unless they
4 were marketed for therapeutic claims, and we think that there
5 is evidence in the record that FDA has taken that position
6 before. We frankly think that the FDA has taken somewhat
7 inconsistent positions on that. This Court doesn't reach that
8 question, I think it can limit its decision to tobacco
9 product, and particularly in light of the significance of
10 Congress' action in 2009, I think it makes it a much easier
11 case for this Court under looking at tobacco products, and the
12 broader question of authority to regulate other products as a
13 drug or device when marketed without therapeutic claims. We
14 do think that that is the sensible line, we think it's
15 supported by the text of the statute.

16 JUDGE GARLAND: So, your view, for example, though
17 still with respect to nicotine where there are no claims at
18 all, I know nicotine water and they just leave off any claim,
19 that would not be subject to regulation?

20 MR. GARRE: That's right, unless they were marketed
21 for therapeutic claims, and most of these nicotine products
22 are in fact marketed for therapeutic claims. If you look at
23 in the record --

24 JUDGE GARLAND: But if one company markets it with a
25 therapeutic claim your position is if another company doesn't

1 the other company is free to sell it, though, right?

2 MR. GARRE: I think that's generally right, Your
3 Honor.

4 JUDGE GARLAND: And so, therefore, it would be
5 unregulatable, the other company, and as long as there's at
6 least one company that's doing wide spread advertising of
7 nicotine water for therapeutics, and then any other one can
8 come in and just not advertise.

9 MR. GARRE: I think that's right, Your Honor. I
10 mean, and I'm not sure that it would be as much of a problem
11 as you might be suggesting. I think there's a reason why
12 people market nicotine gum for smoking cessation, because many
13 people want to stop smoking. There may be a smaller category
14 of people, or a category of people who would wish to, you
15 know, derive the pleasures that they would otherwise get from
16 cigarettes from a smokeless product, but yet there's a reason
17 why people are out there marketing their products as smoking
18 cessation products.

19 JUDGE GARLAND: I'm sure there's an easy answer to
20 this, what about injectable nicotine? Is there some separate
21 statute about drugs that are injected, or would the same be
22 true that they couldn't regulate an injection of nicotine?

23 MR. GARRE: I think if it's marketed for --

24 JUDGE GARLAND: No, it's not marketed for --

25 MR. GARRE: If it's not marketed for --

1 JUDGE GARLAND: -- if there's no claim attached to
2 it.

3 MR. GARRE: -- a therapeutic claim that's the line
4 that we think is drawn.

5 JUDGE GARLAND: FDA could not regulate it?

6 MR. GARRE: Not as a drug, it could regulate it
7 under the Tobacco Act because it would be a tobacco product,
8 it's derived from tobacco. So, I mean, this case is much
9 easier, I think, than *Brown & Williamson* was. In *Brown &*
10 *Williamson* the Supreme Court was faced with the alternatives
11 of, you know, say it's a drug, cigarettes are a drug, so FDA
12 can regulate it, or say it's not and my gosh, FDA doesn't have
13 that authority. This Court if it holds that FDA lacks
14 jurisdiction to regulate to electronic cigarettes as a drug,
15 Congress gave it all the authority it thought appropriate in
16 the Tobacco Act.

17 There was some question earlier about whether or not Njoy
18 markets its claims as a therapeutic product, and I think
19 factually that question is really answered by the appendix to
20 the Government's own reply brief where they attach Njoy's
21 marketing materials. And on page three of those materials
22 Njoy's materials say Njoy products are not a smoking cessation
23 product and have not been tested as such. But perhaps more
24 significantly for this Court's purposes the District Court's
25 preliminary injunction specifically gives FDA an opportunity

1 to go back and argue that these products are marketed as a
2 smoking cessation product, and to the extent that FDA can show
3 that, and I understood my friend here to say that they're not
4 even going to try to show that, but to the extent that they
5 could show that, then they would have authority, and the
6 District Court's injunction would not apply.

7 JUDGE WILLIAMS: I should know the answer to this
8 question, but if I knew it I've forgotten. Does *Brown &*
9 *Williamson* in the opinion talk about the nicotine products
10 which the FDA was regulating, and which were marketed with
11 claims of therapeutic effect?

12 MR. GARRE: It does not, Your Honor.

13 JUDGE WILLIAMS: It never talks about that?

14 MR. GARRE: It never talks about that. It does use
15 the broad phrase tobacco products --

16 JUDGE WILLIAMS: Yes.

17 MR. GARRE: -- repeatedly throughout its decision.

18 JUDGE WILLIAMS: Right. Right.

19 MR. GARRE: And I think -- and obviously, as I noted
20 earlier, the nicotine inhaler was something that was brought
21 up in the briefing. If this Court has no further questions.

22 JUDGE GARLAND: Thank you.

23 MR. GARRE: Thank you, Your Honors.

24 JUDGE GARLAND: Does the Government have any time
25 left? All right. We'll give you a couple of minutes. That's

1 all right. I actually have a question. So, why does the FDA
2 want to regulate under the Food and Drug Act rather than, and
3 Cosmetic Act rather than the Tobacco Control Act?

4 ORAL ARGUMENT OF ALISA B. KLEIN, ESQ.

5 ON BEHALF OF THE APPELLANTS

6 MS. KLEIN: Well, as the Tobacco Control Act, if you
7 look at the statute, it's got two basic purposes, reduce the
8 harm caused by tobacco smoking, the tobacco problem, you know,
9 if it's the Family Smoking Prevention and Tobacco Control Act.
10 And that is by reducing new users, and helping existing users
11 to quit. They helping existing users to quit part, Congress
12 understood nicotine products, isolated nicotine products to be
13 part of that solution. These are the provisions that say fast
14 track applications for new nicotine -- new smoking cessation
15 products, or nicotine, consider applications for extended use
16 nicotine replacement therapies. See, this is why it matters,
17 on the Plaintiff's theory if you can just sell electronic
18 cigarettes without having to show safety or ethicacy and just
19 say, you know, get your nicotine hit from these, you destroy
20 the incentive for a manufacturer to do the clinical studies
21 and go through the work to say use my electronic cigarettes as
22 nicotine maintenance therapy. It just, it wouldn't make
23 economic sense, you'd be undercut in the market. Whether or
24 not -- it's the nicotine water point, if someone is saying buy
25 my electronic cigarettes because you can use them for nicotine

1 maintenance instead of smoking and that's better for you, then
2 it's clearly a drug, and it requires a serious investment of
3 resources to get FDA approval for that, which people won't do,
4 manufacturers won't do if Njoy or other distributors,
5 manufacturers can just sell the same thing, and as long as
6 they say not a nicotine smoking product, or don't explicitly
7 say anything about smoking cessation they can just sell them.

8 JUDGE KAVANAUGH: So, your answer is we want to ban
9 e-cigarettes if they're not safe, that's the --

10 MS. KLEIN: Well --

11 JUDGE KAVANAUGH: -- short answer to Judge Garland?

12 MS. KLEIN: -- the answer -- I should read what FDA
13 just said to the President of the Electronic Cigarette
14 Association. FDA invites electronic cigarette firms to work
15 in cooperation with the Agency toward the goal of assuring
16 that electronic cigarettes sold in the United States are
17 lawfully marketed. And what that means is --

18 JUDGE KAVANAUGH: That means safe, right?

19 MS. KLEIN: -- safe and effective for --

20 JUDGE KAVANAUGH: So, another way to phrase it, we
21 want to ensure that they're safe or else they'll be banned?

22 MS. KLEIN: Well, we want to encourage nicotine, the
23 development of nicotine maintenance products, products that
24 are not as bad, not bad for you in the way cigarettes are,
25 that would be a safe long-term alternative to cigarettes, so

1 come, work with us. And so, yes, I guess if they're unsafe,
2 if that can't be shown, or if it can't be done technologically
3 then they would not --

4 JUDGE KAVANAUGH: Then they'll be banned --

5 MS. KLEIN: -- be approved, but --

6 JUDGE KAVANAUGH: -- and you can do that under the
7 FDCA, but you couldn't do that under the Tobacco Control --

8 MS. KLEIN: Yes.

9 JUDGE KAVANAUGH: -- Act, right?

10 JUDGE GARLAND: Is the gum, for example, that has
11 been approved?

12 MS. KLEIN: Yes, nicotine gum --

13 JUDGE GARLAND: And that is -- that I assume
14 therefore means it's been shown to be both safe and effective?

15 MS. KLEIN: Exactly. That's safe and effective.

16 JUDGE GARLAND: Now, what about this nicotine water,
17 is that --

18 MS. KLEIN: No, nicotine water was just --

19 JUDGE GARLAND: That was stopped.

20 MS. KLEIN: -- sold, it wasn't --

21 JUDGE GARLAND: I see.

22 MS. KLEIN: They didn't go through the process of
23 approval. But there are other FDA approved nicotine products,
24 lozenges, and the nicotine patch, Pfizer sells a prescription
25 inhaler. So, you know, Pfizer spent all that money to invest

1 in --

2 JUDGE GARLAND: I see.

3 MS. KLEIN: -- to say, you know, inhale this and use
4 it instead of cigarettes, that's important for the public
5 health, we want companies to be developing those products.
6 So, that's why -- it's not just that FDA thinks it matters,
7 it's reflected in the Tobacco Control Act itself in those
8 provisions that direct FDA to consider a fast track
9 applications for new nicotine replacement therapies, and then
10 also specifically what's missing now from the market are
11 products that could be used in the long term, like nicotine
12 maintenance, like methadone maintenance, rather than just for
13 12 weeks, which is all we have right now.

14 JUDGE GARLAND: So, presumably you couldn't ban this
15 unless you could show it wasn't safe, at least in comparison
16 to the Pfizer inhaler?

17 MS. KLEIN: I mean, if a company comes in and says
18 here's my evidence, it's safe, an electronic cigarette is safe
19 and effective for nicotine maintenance, so that instead of
20 using a cigarette you're using my product, that meets the
21 showing, that's why the impression that these will necessarily
22 be banned is wrong, it just depends on the technology, what
23 the, you know, what the evidence will show about how these
24 devices are for delivering nicotine. There's no inherent
25 reason that a device that delivers nicotine like all the FDA

1 approved devices, you know, can't be shown to be safe and
2 effective.

3 JUDGE GARLAND: All right. Could you --

4 JUDGE WILLIAMS: But --

5 JUDGE GARLAND: I'm sorry. Go ahead.

6 JUDGE WILLIAMS: To my recollection I haven't gone
7 back to it. Is the Tobacco Act itself sets up a special
8 program for tobacco products that I won't say have therapeutic
9 effect, but that help one control ones use, right? So, isn't
10 there -- I mean, in order to be in that category,
11 manufacturers of e-cigarettes have incentives to go through
12 the hoops that the FDA may create for them? No? Why not?

13 JUDGE GARLAND: I think that's a reference to the
14 modified.

15 JUDGE WILLIAMS: Yes.

16 MS. KLEIN: No. No. I believe you're --

17 JUDGE GARLAND: That's only with --

18 MS. KLEIN: -- talking about the specific products
19 for reducing dependence on cigarettes. This is the, the
20 provision is codified at 387R and that are discussed by the
21 public health groups. These are the provisions that say FDA
22 should consider a fast track application for new nicotine
23 products that can be used as nicotine replacement therapy,
24 instead of a cigarette use this product. I don't know if
25 we're talking about the same provisions, but that is what I

1 was discussing.

2 JUDGE GARLAND: And that's under the FDCA?

3 MS. KLEIN: Yes. Well, I'm sorry, these provisions
4 are part of the Tobacco Control Act --

5 JUDGE GARLAND: Yes, but it says there --

6 MS. KLEIN: -- directing --

7 JUDGE WILLIAMS: Yes.

8 MS. KLEIN: Yes. Yes.

9 JUDGE KAVANAUGH: Yes.

10 MS. KLEIN: FDA --

11 JUDGE GARLAND: For regulation under the FDCA.

12 MS. KLEIN: Exactly.

13 JUDGE GARLAND: Can I ask a fact question? Were
14 there statutes regulating in some way, or labeling, or
15 whatever, of cigars at the time of (indiscernible)?

16 MS. KLEIN: There were statutory schemes addressing
17 cigars. I believe this Court's case *Swisher* maybe, has
18 discussed the cigar issue.

19 JUDGE GARLAND: How do you spell it?

20 MS. KLEIN: S-W-I-S-H-E-R. My only concern is that
21 that may have been the Eleventh Circuit version of the same
22 case, but this Court has a decision that talks about the, it's
23 mostly about taxation, but it talks about the cigar scheme.

24 JUDGE KAVANAUGH: What about in *Brown & Williamson*
25 the point Mr. Garre made in the reply brief that the

1 Government referred to the nicotine inhaler, basically said
2 Respondents concede that under their theory nicotine inhalers
3 would escape FDA review, in other words be unregulatable. You
4 all --

5 MS. KLEIN: I agree that --

6 JUDGE KAVANAUGH: -- put that before the Supreme
7 Court as this is what's going to happen if you go with
8 Respondents, and the Supreme Court went with the Respondents.

9 MS. KLEIN: I mean, Respondents were making a broad
10 argument that the Supreme Court explicitly didn't address,
11 which was that everything depends on manufacturer claims, and
12 as long as there are no claims then, you know, that intended
13 use is a term of art that depends on claims, and I find that
14 footnote somewhat opaque, and so --

15 JUDGE KAVANAUGH: Yes.

16 MS. KLEIN: -- as I read it it was addressing that
17 argument, and --

18 JUDGE GARLAND: The argument that the Court said
19 they were going to go ahead with --

20 MS. KLEIN: The Supreme Court didn't reach --

21 JUDGE GARLAND: -- arguendo, that we don't need to
22 reach it. Yes.

23 MS. KLEIN: Exactly, they didn't reach any of the
24 broader arguments. They relied on the cigarette specific and
25 smokeless tobacco specific legislation.

1 JUDGE WILLIAMS: At the risk of (indiscernible), in
2 Section 3, purpose, subsection 4, it talks about the purpose
3 of overseeing and ensuring that there is oversight of the
4 tobacco industry's efforts to develop, introduce, and promote
5 less harmful tobacco products. Are you saying that that
6 purpose of the Act is then shunted over into an amendment of
7 the Food, Drug, and Cosmetic Act?

8 MS. KLEIN: No. And now I'll talk about the
9 modified risk tobacco product provisions. Modified risk
10 tobacco products are a subset of tobacco products. So --

11 JUDGE WILLIAMS: Right.

12 MS. KLEIN: -- we're already now, we're out of the
13 drug universe. The classic example is the light cigarette.

14 JUDGE WILLIAMS: Yes.

15 MS. KLEIN: And the catalyst for that modified risk
16 tobacco product provision was the light cigarette fraud
17 that --

18 JUDGE WILLIAMS: Right.

19 MS. KLEIN: -- it's discussed --

20 JUDGE WILLIAMS: Right.

21 MS. KLEIN: -- both in this Court's RICO opinion,
22 and in lots of other places. And so, basically, these were
23 just two different cigarettes, you know, they both were real
24 cigarettes, they had tobacco in them, they met the definition
25 of cigarette, and the --

1 JUDGE WILLIAMS: Yes, but this is broadly worded,
2 this is less harmful tobacco product --

3 MS. KLEIN: Yes, but --

4 JUDGE WILLIAMS: -- right?

5 MS. KLEIN: -- tobacco products. And again --

6 JUDGE WILLIAMS: I understand. But just taking the
7 words as they're written for a moment, and taking the view
8 that these products are regulatable under this act, doesn't
9 the FDA have authority under this act to draw distinctions
10 between genuinely less harmful and not genuinely less harmful
11 tobacco products, and therefore to create, I would think, an
12 incentive system, which you said you were worried about, the
13 FDA, your client was worried about?

14 MS. KLEIN: The review provisions for modified risk
15 tobacco products are not like the drug review provision.
16 There's no safety --

17 JUDGE WILLIAMS: No, but they're what --

18 MS. KLEIN: -- in efficacy.

19 JUDGE WILLIAMS: -- Congress thought was suitable in
20 the comparison between tobacco products.

21 MS. KLEIN: Yes, but again -- so, if you say my
22 Marlboro regular, my Marlboro light is safer than my Marlboro
23 regular, you know, it doesn't have as much tar in it --

24 JUDGE WILLIAMS: But you weren't saying that the
25 substantive provisions implementing this purpose for are

1 confined to classical cigarettes, are you?

2 MS. KLEIN: No, but they are confined to tobacco
3 products.

4 JUDGE GARLAND: Can I ask, I thought that this
5 distinction was the one set out in 387K where there is defined
6 in subsection B1 a modified risk tobacco product which is for
7 use to reduce harm, or the risk of tobacco related disease as
8 compared to C, which are tobacco dependent, and those are
9 certainly covered by the Tobacco Control Act.

10 MS. KLEIN: Yes.

11 JUDGE GARLAND: So, in other words, to lower, for
12 example, the risk of cancer.

13 MS. KLEIN: Yes.

14 JUDGE GARLAND: As compared to tobacco dependent
15 products, which are defined in C as a product for the
16 treatment of tobacco dependence, including smoking cessation,
17 which is not a modified risk tobacco product if it has been
18 approved as a drug or device, and is subject to the
19 requirements of sub-chapter five, which are the Food, Drug,
20 and Cosmetic Act, right?

21 MS. KLEIN: Correct.

22 JUDGE GARLAND: So, in other words, if it has to do
23 with lessening the risk of cancer, or emphysema, or something
24 like that, then it's covered by the Tobacco Control Act, and
25 if its purpose is to reduce tobacco dependence then it's

1 covered by the Food, Drug, and Cosmetic Act, is that --

2 MS. KLEIN: No.

3 JUDGE GARLAND: No. All right.

4 MS. KLEIN: Because the first part --

5 JUDGE GARLAND: Then you need to clear it --

6 MS. KLEIN: -- is only if it's a tobacco product.

7 JUDGE GARLAND: Yes, I understand that.

8 MS. KLEIN: Okay. All right.

9 JUDGE GARLAND: But with respect to tobacco --
10 whatever --

11 MS. KLEIN: With respect to a tobacco -- right.

12 JUDGE GARLAND: -- the definition. I know you're
13 resisting Judge Williams' question on that.

14 MS. KLEIN: Yes.

15 JUDGE GARLAND: I got that point. But assuming it's
16 a tobacco, even if it is a tobacco product --

17 MS. KLEIN: Yes.

18 JUDGE GARLAND: -- that's the distinction the
19 statute is drawing?

20 MS. KLEIN: Yes. So, if smokeless tobacco is sold,
21 and this is actually happening, is sold as use this in order
22 to wean yourself of cigarettes, so smokeless tobacco, so
23 without question it's a tobacco product, then it's being used
24 to treat dependence --

25 JUDGE GARLAND: As a drug.

1 MS. KLEIN: -- and it's a drug.

2 JUDGE GARLAND: I see.

3 MS. KLEIN: Even smokeless tobacco. Yes.

4 JUDGE GARLAND: Okay.

5 MS. KLEIN: Unless the Court has --

6 JUDGE GARLAND: Okay.

7 MS. KLEIN: Thank you.

8 JUDGE GARLAND: No further questions? The case is
9 submitted. Thank you very much both sides.

10 (Recess.)

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DIGITALLY SIGNED CERTIFICATE

I certify that the foregoing is a correct transcription of the electronic sound recording of the proceedings in the above-entitled matter.

A handwritten signature in black ink that reads "Paula Underwood". The signature is written in a cursive style with a large initial 'P' and 'U'.

Paula Underwood

September 26, 2010

DEPOSITION SERVICES, INC.