NOS. 11-5332, 12-5063

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

R.J. REYNOLDS TOBACCO COMPANY, et al.,

Plaintiffs-Appellees,

v.

FOOD AND DRUG ADMINISTRATION, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

APPELLEES' OPPOSITION TO APPELLANTS' PETITION FOR REHEARING AND REHEARING EN BANC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and D.C. Circuit Rule 26.1, Plaintiffs-Appellees make the following disclosures:

RJRT is a North Carolina corporation with its corporate offices and manufacturing operations located in Winston-Salem, North Carolina and is the second-largest tobacco product manufacturer in the United States. RJRT is a wholly-owned subsidiary of R.J. Reynolds Tobacco Holdings, Inc., which in turn is a wholly-owned subsidiary of Reynolds American Inc. ("RAI"), a publicly-traded corporation. Brown & Williamson Holdings, Inc. and Invesco Ltd. hold more than 10% of the stock of RAI. British American Tobacco p.l.c. indirectly holds more than 10% of the stock of RAI through Brown & Williamson Holdings, Inc.

Lorillard is the third-largest tobacco product manufacturer in the United States, with its corporate offices and manufacturing operations in Greensboro, North Carolina. Lorillard is a wholly-owned subsidiary of Lorillard, Inc. Shares of Lorillard, Inc. are publicly traded.

Commonwealth Brands, Inc. ("Commonwealth") is a tobacco product manufacturer with its corporate offices located in Bowling Green, Warren County, Kentucky, and its manufacturing operations in North Carolina. Commonwealth is a wholly-owned subsidiary of CBHC, Inc., which is a wholly-owned subsidiary of

Imperial Tobacco Group p.l.c. Shares of Imperial Tobacco Group p.l.c. are publicly traded.

Liggett Group LLC is a Delaware limited liability company and tobacco product manufacturer with its principal place of business in Mebane, North Carolina. Liggett Group LLC is an indirect, wholly-owned subsidiary of Vector Group Ltd., which is a publicly-traded corporation. No parent corporation or publicly held company owns more than 10% of the stock of Vector Group Ltd.

SFNTC is a New Mexico corporation, with its corporate offices located in Santa Fe, New Mexico and its manufacturing operations in North Carolina, that manufactures tobacco products sold under the Natural American Spirit brand name. SFNTC is a wholly-owned subsidiary of Reynolds American Inc. ("RAI"), a publicly-traded corporation. Brown & Williamson Holdings, Inc. and Invesco Ltd. hold more than 10% of the stock of RAI. British American Tobacco p.l.c. indirectly holds more than 10% of the stock of RAI through Brown & Williamson Holdings, Inc.

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INTRODUCTION

On June 22, 2011, FDA promulgated a regulation pursuant to § 201 of the Family Smoking Prevention and Tobacco Control Act ("Act") that required nine new graphic warnings on the top half of the front and back of cigarette packages and the top fifth of advertisements, 76 Fed. Reg. 36,628 ("the Rule"). As the panel majority recognized, these unprecedented "warnings," which include images of dead bodies and diseased body parts, are, at their core, anti-smoking advocacy designed to persuade prospective purchasers not to purchase a lawful product. As such, they violate the First Amendment by "forc[ing] the manufacturer of a product to go beyond making purely factual and accurate commercial disclosures. . . [and] by making every single pack of cigarettes in the country a mini billboard for the government's anti-smoking message." Op. 11 (internal quotations omitted).

The proposed warnings will not create more informed consumers and were never intended to. Consumers are fully aware of the risks addressed by the Rule, which is why FDA's own study found that the warnings had no measurable effect on consumer knowledge of the smoking risks the warnings address. Accordingly, FDA selected the warnings *not* to increase consumer knowledge, but to make viewers "depressed," "discouraged," or "afraid," and then emblazoned each one with a hotline number admonishing consumers to "QUIT" smoking "NOW." As the panel properly concluded, "[t]hese inflammatory images and the provocatively-named hotline cannot rationally be viewed as pure attempts to convey information

to consumers. They are unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." Op. 20.

Having found that the Rule was not aimed at providing factual information to consumers—and was therefore not subject to the lower level of scrutiny set out in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985)—the panel assessed whether the Rule could be justified under the more stringent test of *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). Op. 22-30. After thoroughly reviewing the administrative record, the panel properly concluded that the Government had not come close to meeting its burden of demonstrating that the proposed warnings would directly and materially advance its announced goal of "encourag[ing] current smokers to quit and dissuad[ing] other consumers from ever buying cigarettes." Op. 23.

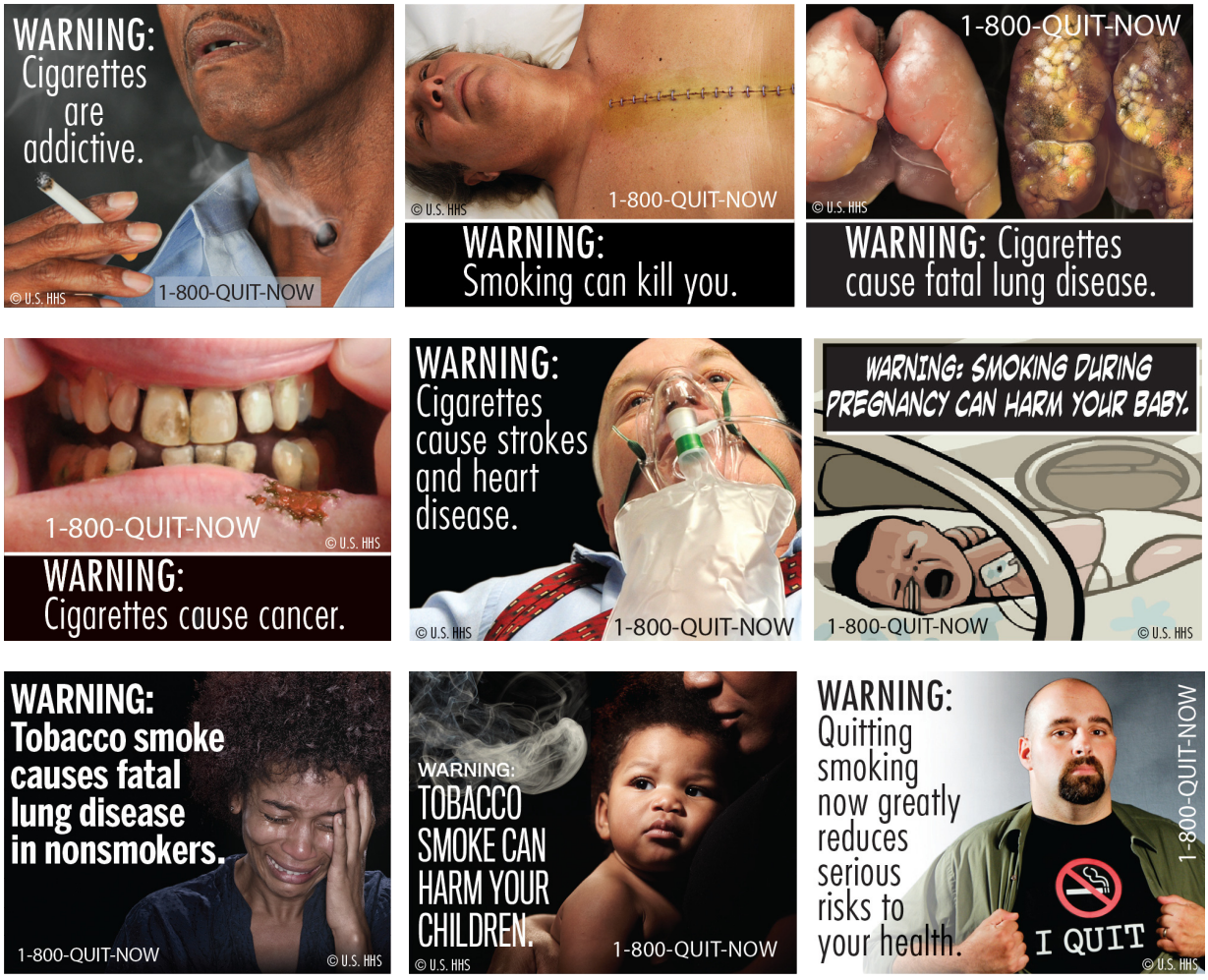
In seeking rehearing, the Government claims that the panel refused to recognize its interest in "ensuring that consumers and potential consumers understand the health risks of smoking." Pet. 1. That is simply not so. Indeed, the panel expressly acknowledged that "the government can certainly require that consumers be fully informed about the dangers of hazardous products." Op. 11. Instead, the panel simply recognized that, given the record *in this case*, the Rule does not—and was not intended to—further that interest. That decision is clearly correct, as numerous studies, including FDA's own massive study of the very

warnings at issue, show that the warnings (a) address health risks of which consumers are already aware, (b) do not increase consumer knowledge of health risks, and (c) were therefore selected simply to advocate the Government's view that even fully-informed consumers should make a personal choice to not smoke.

The Rule would thus be a wholly unjustified intrusion on the protected speech of companies marketing a lawful product. The petition should be denied.

BACKGROUND

The Rule requires the placement of nine new graphic warnings on the top half of the front and back of cigarette packages and the top fifth of advertisements:



These warnings do not address any information deficit about the health risks of smoking. Rather, consumers are already aware of the health risks addressed by the warnings. *See* Doc. No. 1354221 ("Apps. Br.") at 10-12. Gallup polls taken every year for the last decade show that 96% to 99% of Americans know that smoking causes lung cancer, and similar polling shows comparable results for each risk addressed by the warnings. JA249-51, 266. Although the Government claimed that the public is unaware of specific details regarding some risks, "none of the proposed warnings purport to address the information gaps identified by the government," Op. 17 n.8, and the studies it cited actually confirmed that consumers know the health risks that the warnings *do* address, Apps. Br. 11-12.

Because telling people what they already know does not change behavior, numerous studies show that graphic warnings have no demonstrable effect on smoking rates. Op. 25-27 (reviewing studies); Apps. Br. 12-14. As far back as 1994, the Surgeon General rejected the assumption that "young people had a deficit of information that could be addressed by presenting them with health messages in a manner that caught their attention," and concluded that "smoking-prevention programs based on the information deficit approach [are] not effective." JA303. Numerous other studies have reached similar conclusions. *E.g.*, Deloitte, *Tobacco Packaging Regulation: An International Assessment of the Intended and Unintended Consequences* at 4 (2011) ("data from 27 countries over a period of 14

years" "consistently demonstrate that . . . [graphic warnings] ha[ve] not had a statistically significant direct impact upon licit tobacco consumption"), *available at* http://tinyurl.com/8vbll4l; *see also* JA256-59; Apps. Br. 13. This is precisely why, as the panel noted, FDA estimated that the impact of the new warnings on smoking rates would be "in general not statistically distinguishable from zero." Op. 27 (quoting 76 Fed. Reg. at 36,776).

Although there is no actual evidence that graphic warnings reduce smoking, there is a body of literature—relied upon by the Government, the Rule, and other countries that use graphic warnings—that speculates that large graphic warnings might lower rates by more "effectively communicat[ing] the negative health consequences of smoking." 76 Fed. Reg. at 36,639. Critically, although the Government repeats the "chosen buzzwords" that graphic warnings more "effectively convey" the risks of smoking, Op. 29; Pet. 2, this literature does *not* conclude that graphic warnings will be more "effective" because they convey factual and uncontroversial information about the risks of smoking. Rather, it merely asserts that graphic warnings may be more "effective" in disseminating anti-smoking *advocacy*. Indeed, in discussing "effective" cigarette warnings, the Government's chief authority, the IOM Report, "states unequivocally that 'the primary objective of tobacco regulation *is not to promote informed choice but rather to discourage consumption of tobacco*.'" Op. 23 n. 12 (quoting IOM Report

at 291) (emphasis added). This literature thus advises that any "'[n]eutral' images that fail to elicit an emotional reaction should be avoided at all costs." David Hammond, *Tobacco Labeling and Packaging Toolkit, A Guide to FCTC, Article 11* at 64 (2009), *available at* http://tinyurl.com/68ghuc6. In short, as exhaustively chronicled before the panel, Apps. Br. 14-16, 41-53, the Government's "voluminous literature," Pet. 3, does *not* find that emotionally-charged warnings are better than textual warnings at providing new information about smoking risks.

Nor do the Government's studies even conclude that graphic warnings have reduced smoking rates. Rather, the studies conclude that survey respondents either (a) find graphic warnings more noticeable than textual warnings, *i.e.*, that shocking and attention grabbing warnings are more shocking and attention grabbing; and/or (b) tell researchers in a highly contrived setting that graphic warnings made them *think* about quitting. Op. 25; Apps. Br. 47-53. As one illustrative example, the Government cited a study it claimed had found "that the Canadian [graphic] warnings were more visible and more informative than the warnings appearing on cigarette packages in the United States," but the reference was to nothing more than a summary of a researcher's subjective impressions after conducting a 1.5 hour focus-group discussion on the possible effectiveness of graphic warnings with 65 young adults from Detroit, who were paid $50 to participate. Apps. Br. 49. As the panel majority noted, even Dr. Hammond, one of the primary academics relied

on by the Government, conceded that these studies provide no basis for "attribut[ing] . . . declines in smoking to the new health warnings." Op. 27.

The Rule implements the recommendations of the foregoing literature by forcing Appellees to engage in emotionally-charged anti-smoking advocacy. As the panel and FDA both acknowledged, these warnings "ha[ve] a different purpose" than "disclosure requirements for other products"; they are not intended to inform consumers of how to use a product properly, but to "encourage cessation and discourage initiation." 75 Fed. Reg. at 69,540; Op. 24. In the words of Secretary Sebelius and Commissioner Hamburg, they will "rebrand[] our cigarette packs"; convey that "smoking is gross"; "dispel[] the notion that somehow [tobacco use] is cool"; and thereby "encourage smokers to quit." Apps. Br. 3-4; Op. 11.

Two analyses of the Rule conducted by FDA itself confirm that the warnings do not create more informed consumers and are instead intended to attach "negative affect" to cigarettes as a form of anti-smoking advocacy. *First*, FDA conducted a Regulatory Impact Analysis ("RIA") that analyzed the expected benefits of the Rule by comparing the impact of similar warnings introduced in Canada in 2000. 76 Fed. Reg. at 36,709. Although FDA "d[id] not account for potential confounding variables," *id.* at 36,720, and thus produced "an overly optimistic prediction" of the impact of graphic warnings on smoking rates, Op. 27, it nevertheless concluded that the Rule "would reduce U.S. smoking rates by a

mere 0.088%, a number FDA concedes is 'in general not statistically distinguishable from zero,'" *id.* (quoting 76 Fed. Reg. at 36,721, 36,776).

Second, FDA also commissioned a massive consumer study ("FDA Study") that "included approximately 18,000 participants [and] was the largest study of consumer responses to graphic cigarette health warnings ever conducted." Apps. Br. 6. It compared the responses of a control group—which was shown the new text in the format of the current warnings (on the side of the package)—to a separate group that was shown the proposed graphic warnings to assess whether the graphic warnings (1) increased viewers' intention to refrain from smoking; (2) increased viewers' knowledge of the health risks of smoking; and (3) were "salient," *i.e.,* caused viewers to feel "depressed," "discouraged," or "afraid," or to describe the warnings as "informative," "meaningful," or "difficult to look at." Op. 6-7; 76 Fed. Reg. at 36,638. The FDA Study demonstrated that the new warnings had no statistically significant effect on viewers' knowledge of smoking risks or even their intentions to quit smoking. Apps. Br. 6-8; JA304-07. Not surprisingly, however, the shocking graphic warnings were rated by viewers as substantially more "salient," *i.e.*, shocking and attention-grabbing. *Id.*

Given these results, it is clear that FDA did not select its graphics based on their demonstrated effectiveness in informing consumers of health risks. Rather, it selected them based on their "salience," explaining that research "suggests that

warnings that generate an immediate emotional response from viewers can result in viewers attaching a negative affect to smoking (*i.e.*, feel bad about smoking), thus undermining the appeal and attractiveness of smoking." 76 Fed. Reg. at 36,639. Attaching this "negative affect to smoking" could, FDA speculated, "motivate positive behavior change." *Id.* at 36,652. Indeed, FDA relied on "salience" despite evidence that "recall of associated warning message statements may be *reduced* in the short term by moderately or highly graphic pictorial warnings versus text-only controls ." *Id.* at 36,639 (emphasis added).[1]

ARGUMENT

It is axiomatic that the Government may not force private parties to speak against their will. Although *Zauderer* recognized an exception to this rule for "purely factual and uncontroversial" commercial disclosures aimed at preventing consumer deception, 471 U.S. at 651, that exception does not extend to compelled advocacy. As the Supreme Court held in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011), the state may not regulate speech in order to "seek to remove a popular but disfavored product from the marketplace. That the State finds [nonmisleading] expression too persuasive does not permit it to quiet the speech or

[1] Although the court in *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012) addressed a similar issue, the foregoing record was not before the Sixth Circuit, which considered only a facial challenge to the general requirements of the Tobacco Control Act and expressly did not address the specific manner in which the Rule implemented the Act. *Id* at 569 n.17.

to burden its messengers." *Id.* at 2671. Accordingly, a speech regulation that does not serve to inform consumers and instead compels a message that consumers should not buy a lawful product cannot withstand First Amendment scrutiny.

Here, the panel majority held that: (1) the graphic warnings were not subject to *Zauderer* because, in both purpose and effect, they do not create more informed consumers, and (2) assuming that the Government has a legitimate interest in restricting speech to shape consumers' personal choices, the Rule does not "directly advance" that interest "to a material degree." Both conclusions were clearly correct and neither warrants *en banc* review.

1. There is no real dispute that the American public is overwhelmingly aware of the risks addressed by the warnings. As the panel noted, not a single study in the Government's "voluminous literature" identifies an information deficit that is addressed by the required warnings. Op. 17 n.8.[2] That is no doubt why FDA's own massive study showed that the warnings had no statistically meaningful impact on viewers' knowledge of the risks addressed. *See supra* at 8-9.

[2] This failure is particularly striking because the FDA Study asked all participants, after viewing graphic warnings or a control, if they believed a regular smoker is likely to suffer each of the smoking-related illnesses addressed by the warning. FDA Study, App. A at 1. Raw data from the study thus constitute the most recent, expansive, and direct evidence available regarding consumer knowledge of smoking risks. If these data revealed any relevant information deficit, FDA would surely have cited them. Yet FDA has not only failed to cite these data; it has failed even to disclose them. Apps. Br. 46-47.

The warnings, therefore, were not selected based on their ability to increase consumer knowledge. Instead, they were intentionally crafted to attach "negative affect" to cigarettes and convey a message to consumers that smoking is not a legitimate or acceptable personal choice. Thus, as Appellees explained before the panel: (a) the warnings use artificial digital enhancements, actors, and cartoon drawings, to dramatize the effects of smoking-related illness; (b) the graphics are affirmatively misleading (*e.g.*, suggesting that an autopsy is a likely result of smoking) and/or convey no information at all about the risks of smoking (*e.g.*, an image of a man wearing a t-shirt with the international no smoking sign and the words "I QUIT"); (c) the graphics were intentionally selected for their ability to shock, even at the expense of consumer recall of smoking risks; (d) the warnings explicitly urge consumers to "QUIT-NOW"; and (e) the sheer size and placement of the graphic warnings go far beyond anything necessary to provide consumers with purely factual and uncontroversial information. Op. 20-21; Apps. Br. 23-30. Accordingly, it is clear that, in both purpose and effect, the graphics do not provide consumers with additional factual information to enable reasoned decision-making.

The panel was therefore correct to conclude that *Zauderer* did not apply, Op. 19-20—a point that the Government appears not to contest—and, for the same reason, that the Rule could not be justified under *Central Hudson* based on a non-existent ability to increase consumer knowledge of the risks of smoking, Op. 23-24.

2. The panel also correctly concluded that the Government cannot satisfy its burden under *Central Hudson* based on an interest in reducing smoking rates. It was rightly skeptical that the Government's desire to discourage purchases of a lawful product can ever justify a speech regulation under *Central Hudson.* Op. 24, n.13. After all, the Supreme Court in *Sorrell* recently held that the government could not regulate speech to "seek to remove a popular but disfavored product from the marketplace." 131 S. Ct. at 2671. But even putting this aside, the panel correctly concluded that the Government did not come close to carrying its burden of proving "that the graphic warnings will 'directly' advance its interest in reducing smoking rates 'to a material degree.'" Op. 27.

In this regard, the panel extensively reviewed the record evidence, including the "only two studies that directly evaluate the impact of graphic warnings on actual smoking rates"—the RIA and the FDA Study—and correctly found that neither demonstrated that the Rule would reduce smoking rates to a "material degree." *Id.* The panel further explained that, whereas graphic warnings have been used in dozens of countries, numerous studies find no demonstrable impact on smoking rates. Op. 25-26; Apps. Br. 13-14.

Moreover, the indirect evidence relied on by the Government simply asks and answers the wrong question. As the panel explained, that evidence consists of studies finding that (a) shocking graphic warnings do not create more informed

consumers, but merely are more noticeable than textual warnings, and (b) survey participants will tell researchers, in a highly contrived setting, that graphic warnings make them "think" about quitting. Op. 25. This "questionable social science," *id.*, however, merely shows that (a) attention-grabbing warnings grab attention, and (b) smokers will tell researchers they intend to quit, which is a notoriously bad predictor of actual smoking decisions due to the social stigma attached to admitting that one intends to continue smoking indefinitely, Apps. Br. 47-53. Such studies do not even "purport to show that the implementation of large graphic warnings has *actually* led to a reduction in smoking rates." Op. 26. They therefore cannot possibly overcome the *direct* evidence that graphic warnings have had *no* statistically significant impact on smoking rates. *Id.* at 28. In short, after carefully reviewing the administrative record, the panel correctly held that "[a]lthough FDA maintains that the data 'are suggestive' that large graphic warnings 'may' reduce smoking consumption, it cannot satisfy its First Amendment burden with 'mere speculation and conjecture.'" *Id.*

3. The Government's arguments for *en banc* review lack merit.

a. The Government primarily complains that the panel majority refused to recognize its legitimate interest in informing consumers about the risks of smoking. This, however, is false: the panel majority expressly acknowledged that "the government can certainly require that consumers be fully informed about the

dangers of hazardous products." Op. 11. The panel, rather, merely held that based on a close "review of the . . . administrative record," the Rule at issue *in this case* had neither the purpose nor effect of furthering that interest. Op. 17-21, 23, 29-30. That is, because "none of the proposed warnings [even] purport to address" subjects on which there is an "information gap," and because the Government has no interest in shocking people simply to shock them, the only remaining interest potentially justifying the Rule *in this case* was actually reducing smoking. Op. 17, 23-24. And on that measure, the Rule plainly failed First Amendment scrutiny.

b. The Government also offers a single paragraph of argument that the warnings will directly and materially impact smoking rates. But as already noted, the Government's "questionable social science" provides no basis for this conclusion. Op. 25. As the panel majority explained, Op. 26-27, FDA *itself* concedes that any decrease in smoking rates in Canada cannot be attributed to the warnings and instead estimates that the effect of the warnings would be "not statistically distinguishable from zero." 76 Fed. Reg. at 36,776. Similarly, the Government cannot rely on studies finding that shocking graphics are more "effective" because they are rated as more memorable, or cause survey participants in a highly contrived environment to tell researchers that they will *think* about quitting smoking. *See supra* at 12-13. Nor can FDA " define 'effectiveness' however it sees fit"—*i.e.*, to mean simply grabbing consumers' attention without

actually changing behavior—as that "would not only render *Central Hudson*'s 'substantial interest' requirement a complete nullity, but it would also eviscerate the requirement that any restriction 'directly advance' that interest." Op. 29.

c. Finally, the Government does not even seek to defend the Rule as written. Rather, it explicitly states that it does not seek review of the panel's unanimous ruling that one of the myriad reasons why the Rule is unconstitutional is because, although not required by the Act, it includes the "QUIT-NOW" hotline in each of the new warnings. Pet. 13-15, 7-8 n.2. On the basis of this admission alone—that the panel correctly invalidated the Rule as written—*en banc* review should be denied. If the Government thinks that a different rule would be constitutional—*i.e.*, one that excludes the "QUIT-NOW" hotline (and may or may not include other changes to the particular graphics in the warnings)—then FDA should pass that rule. Indeed, FDA has waived any severability argument, as it consistently maintained before the panel that, "[i]f some aspect of the statute or regulations were declared invalid, it would be FDA's responsibility in the first instance to determine the contours of any new regulations." Doc. No. 1364510 at 11. Particularly given that position before the panel, new arguments about the partial viability of the Rule should not be addressed through *en banc* review.

CONCLUSION

For the foregoing reasons, the petition for rehearing should be denied.

Respectfully Submitted,

Dated: October 29, 2012

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CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of October, 2012, I caused the foregoing brief to be filed with the Court and served through the Court's CM/ECF system.

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