

CATO INSTITUTE

POLICY FORUM

ADS FOR REDUCED-RISK TOBACCO:
PUBLIC SCOURGE OR PROTECTED SPEECH?

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Moderator:

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Cato Institute

Featuring:

Mathew Myers, President, Campaign for Tobacco-Free Kids;

Carlos T. Angulo, Associate, Zuckerman Spaeder LLP;

John Calfee, Resident Scholar, American Enterprise Institute;

And Erik S. Jaffe, Chair, Federalist Society

Subcommittee on Advertising Law and Regulation

The Cato Institute

F.A. Hayek Auditorium

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P R O C E E D I N G S

MR. LEVY: Good morning to everybody and welcome to our debate on ads for reduced-risk tobacco. I'm Bob Levy and senior fellow in Constitution studies here at the Cato Institute, and before introducing our panel, let me briefly set the stage.

The key policy question that we'll be addressing today is this: Do ads for reduced-risk tobacco products save lives in the long run?

Advocates for those ads point to research showing that smokeless tobacco, for example, is 98 percent safer than cigarettes. Therefore, the more advertising, the better, as long as the ads are truthful.

Opponents begin by disputing the data on harm reduction, but more important, they argue that the benefits are outweighed by the costs. First, people stay addicted to nicotine when they otherwise might have quit. Second, some consumers take up tobacco when they might otherwise have abstained. And third, some consumers compensate for reduced risk by increasing their consumption. The conclusion, say the opponents, health claims in tobacco ads ought to be banned.

The First Amendment issues are quite different. Here are the constitutional ground rules. In 1980, the Supreme Court

held that non-deceptive commercial speech about a lawful activity can be regulated but only if, first, the government has a substantial interest in doing so; second, the regulation directly and materially serves that interest; and third, the regulation is no more extensive than necessary.

Now, that said commercial speech restrictions are less rigorously scrutinized by the courts than are restrictions on noncommercial speech. Advertising is protected for its informational content, and accordingly, ads can be prohibited when they're false or misleading. That's not the case you might have observed with political speech.

Furthermore, the requirement that regulation of commercial speech be no more extensive than necessary to advance a substantial government interest is much less confining than the requirement in the political speech arena where a regulation must be the least restrictive means of advancing a compelling State interest. So, that's the constitutional framework.

Now, very briefly, let me bring you up to date and tell you why we're holding this forum at this time. UST manufactures smokeless tobacco products like Skol and Copenhagen. The company has asked the Federal Trade Commission for permission to make the following statement in its ad. The Surgeon General has found that smokeless tobacco "is not a not a safe substitute" for cigarettes, but "many researchers have expressed the opinion that

the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes."

Now, Senator Richard Durbin, who is a Republican from Illinois, and Henry Waxman, who is a Democrat from California, have asked the FTC to reject UST's request. They say any move to make comparative risk claims in ads without the involvement of a science-savvy agency like the Food and Drug Administration would do more harm than good. But it's the Federal Trade Commission and not the Food and Drug Administration which oversees tobacco advertising. There are several bills before Congress which would give FDA more authority over tobacco and tobacco ads, but their prospects are unknown.

Meanwhile, Star Scientific, a manufacturer of purportedly lower risk cigarettes, would also like the Federal Trade Commission to make way for health claims. And like UST, Star argues that such information in those ads would help adult consumers make better educated choices. We haven't yet heard from the Federal Trade Commission.

So, with that background, let's get on with the debate. First, we're going to consider the constitutional issues. Carlos Angulo is going to speak first, followed by Erik Jaffe. Then we're going to turn to the public policy questions with Matt Myers leading off, followed by Jack Calfee. Each speaker is going to have eight minutes, rigorously enforced, and then in the

same order, each speaker will have up to 3 minutes for rebuttal, after which we'll open the floor for questions from the audience. I'm going to introduce Carlos Angulo now and the other speakers when they present their opening remarks.

Since 1999, Carlos Angulo has been an attorney at Zuckerman Spaeder where he works on legislative and policy matters and represents the Campaign for Tobacco-Free Kids, as well as a number of other clients, before the Food and Drug Administration.

He received his undergraduate degree magna cum laude in 1986 from Haverford College, Phi Beta Kappa, and his law degree three years later from Yale.

After law school he served in the Justice Department's Civil Division and clerked on the 11th Circuit Court of Appeals for Judge Phyllis Kravitch. From 1994 to 1996, Carlos was on the staff of the Senate Judiciary Committee, advised Illinois Senator Paul Simon on a variety of constitutional issues, and then became legislative counsel to Maryland Senate Paul Sarbanes.

Among his papers are a publication on who should participate in presidential debates and a report on racial disparities in the American criminal justice system.

Please join me in welcoming Carlos Angulo.

(Applause.)

CARLOS T. ANGULO, ASSOCIATE,
ZUCKERMAN SPAEDER, LLP

MR. ANGULO: Thank you very much.

The First Amendment issues I think are interesting and complicated regarding reduced-risk products and are not quite as stark, I think, as might be initially thought, in the sense that you don't necessarily have to take the position that advertising of this nature should be absolutely banned or absolutely permitted.

The position that oftentimes is taken by advocates of regulation is that these claims need to be scrutinized by an agency before they are determined to be truthful and not misleading and before they are allowed to be disseminated in the marketplace. Now, that's not an absolute determination on how to deal with this advertising, but it is an approach that tries to balance the interests of the public in receiving truthful information with the interests of the government in assuring that this information is truthful and is also safe and that the public health is preserved by virtue of this information.

I think we've got two legal contexts, one of which is constitutional and the other of which is statutory, that we need to address.

The first is the statutory context, which is you've got the federal Food, Drug and Cosmetic Act, which has been around for several decades now and which has as one of its centerpieces a drug approval process that addresses products for which there are health claims made. A drug is defined under federal law as a product that is intended to cure, mitigate, or prevent or treat a disease or one which is intended to affect the structure or function of the body. If a product is intended for that purpose, it becomes a drug under federal law, and it has to be approved by FDA for safety and effectiveness.

Claims that a product is intended to mitigate a disease or prevent a disease or is good for you oftentimes will lead to the conclusion by FDA that it is a drug and that it is subject to regulation or approval before it can be advertised in the marketplace. If a drug is advertised in the marketplace without such approval, it is misbranded and its marketing is illegal.

So, we're dealing with commercial speech in the context of products that claim to be better for you or claim to mitigate or prevent disease, and reduced-risk products are oftentimes among those types of products. They claim that if you use this product, as opposed to traditional tobacco products, you will have less likelihood of getting cancer or getting heart disease or getting emphysema or those types of diseases. And a lot of

the reduced-risk products that we're dealing with have explicitly made those types of claims in the marketplace.

So, the question is, how does the First Amendment deal with those types of claims or with FDA's effort to ensure that these products are safe and that these claims are accurate before they allow them to be made in the marketplace?

Until the 1970's, you really had no commercial speech protections under the First Amendment. The Supreme Court had held that there was no commercial speech protected by the First Amendment. That changed in the 1970's with a couple of different cases, the Bigelow case and the Virginia Pharmacy case, which did establish that commercial speech is protected by the First Amendment, but there are some important limitations on that type of protection.

The first limitation is that if speech promotes an unlawful activity, it's not protected under the First Amendment. So, if you say, buy our illegal drugs, buy cocaine, that's obviously speech. It's commercial speech, but it's not protected under the First Amendment because it's promoting the illegal sale of illegal drugs.

Another important limitation on the First Amendment protections for commercial speech is that the greatest amount of protection is entitled to speech that is truthful and non-misleading. Oftentimes what we're talking about really are

simply factual statements that can't be sort of disputed or require no scrutiny by an agency or by anyone else to determine whether they're truthful.

In other words, oftentimes the government has tried to say you can't advertise alcohol content because that might encourage behavior that we don't want as the government, or you're not allowed to advertise drug prices. Now, these are factual statements that policy makers have determined the public shouldn't really be exposed to, and the courts have said when you have those types of factual statements, you're basically acting paternalistically in telling people that they're not entitled to know something that is true. And those are the types of cases the Supreme Court has focused on in dealing with commercial speech. They've basically said it's not up to the government to determine what truthful information the public is entitled to and what truthful information it's not entitled to.

What we're dealing with here I think in these reduced-risk cases addresses both these issues. The first issue was unlawful activity and whether commercial speech that's promotes unlawful activity is protected under the First Amendment. Remember what I said earlier which is that the federal Food, Drug and Cosmetic Act says that if you market a drug that is unapproved by FDA, you're acting illegally. Therefore, if you advertise a drug that is unapproved by FDA,

you're promoting illegal activity and you're speech is not entitled to First Amendment protection.

The second point is dealing with the issue of truthful speech. We're not talking here, with reduced-risk products, in terms of alcohol content or prices of drugs or something factual that is unobjectionably factual and unobjectionably true. We're dealing with claims that a particular product has a particular effect on one's body or will assist an individual in avoiding certain types of diseases. And those types of claims are a little different from claims about prices of a product or about the content of a product that are straightforward and factual.

These types of claims are claims that really do require some scrutiny by an agency, in particular under our law, to determine whether they're true. When you're dealing with claims of that sort, there's no real problem with them as long as they are proven to be true and not misleading. And that's what the agency's role is in these types of situations.

In reduced-risk situations, oftentimes the claims have not been tested for accuracy. The government clearly has an interest in ensuring that the claims are truthful and not misleading because the public safety is very much at issue with respect to drugs that claim to have certain effects. And by subjecting them to review, you're simply ensuring that truthful information be disseminated in the marketplace.

Now, are there other ways of dealing with these types of claims? Can you require a disclaimer instead of an approval by FDA? You could, but the effect of that would be to totally eviscerate the current statutory regime for drug approval. I mean, if you were allowed to put a disclaimer on your product that said "not approved by FDA" and then to make all the claims, there would really be no possibility of FDA ever reviewing drugs for safety and efficacy if one could simply circumvent that review by putting something on the label that says "not approved by FDA" and that would be deemed enough.

In conclusion, I just want to point out again that no one is really saying that reduced-risk products are inherently bad or that claims for reduced-risk products should automatically be banned, but rather that these claims should be subjected to scrutiny by an agency that determines whether there is safety and efficacy for this product, and that that type of review, advancing a very substantial government interest, is not inconsistent with the First Amendment.

Thank you.

(Applause.)

MR. LEVY: Our next speaker is Eric Jaffe. Erik is a private attorney in D.C. In 1986, he received his B.A. cum laude from Dartmouth, majoring in molecular genetics and winning a number of debating awards. Four years later, he got his J.D.,

graduating first in his class at Columbia University. He was articles editor of the Law Review.

After law school, Erik clerked for Judge Douglas Ginsberg on the U.S. Court of Appeals for the D.C. Circuit. Then he spent five years at Williams and Connolly, followed by another clerkship, this time on the Supreme Court for Justice Clarence Thomas.

Erik currently serves as chairman of the Federalist Society Subcommittee on Advertising Law and Regulation. He has published articles on organ transplants, due process, the Takings Clause. His most important contribution to the literature will, no doubt, appear in the next issue of Cato's Regulation magazine in an article that he and I co-authored, recommending the wholesale repeal of most of the campaign finance regulation.

Please extend a warm welcome to Erik Jaffe.

(Applause.)

ERIK S. JAFFE, CHAIR, FEDERALIST SOCIETY
SUBCOMMITTEE ON ADVERTISING LAW AND REGULATION

MR. JAFFE: Thanks, Bob.

Well, I'll mostly focus on the First Amendment and only at the end sort of touch upon the Food and Drug Administration's

authority in this area because I, quite frankly, find it somewhat incidental and irrelevant to the First Amendment issue.

I think it is an interesting question. I don't think it's a complicated question. I think it's a remarkably simple question if we assume for a moment that the information is truthful. And I don't take Carlos to disagree with me on that. I think what we will ultimately be disputing is the mechanisms for ensuring truthfulness, not necessarily the consequences once truthfulness is established.

If you assume at the front end that it's truthful, I think the First Amendment question is a slam dunk. The government has no interest, and I don't mean a little and I don't mean some. I mean no interest whatsoever in suppressing truthful information about a lawful product. Zero. And that's true whether or not that product kills you.

If it kills you more or it kills you less, it doesn't make a difference, because as long as the government lets it be sold, the initial calculus -- is the cost outweighed by the benefit -- has been made at a political level and that calculus necessarily assumes the answer is yes. Otherwise, we ban it. So, having not banned it, the government doesn't have an interest in stopping its use by lawful uses.

It has an interest in stopping kids from using it. I'll concede that. It's not lawful to sell to kids. That's fine.

So, the question then is how do we go about deciding whether the information is truthful. The traditional First Amendment answer on deciding whether information in the marketplace is truthful is to let the marketplace handle that all by itself. The government, particularly as a prior matter, doesn't usually step in and regulate the truthfulness or non-truthfulness of claims, and that's generally the case on noncommercial speech, and there's no good reason why it should not be the case for commercial speech as well.

If I say my Mercedes Benz is safer than your Geo Metro, I don't think really think that I need to run that through NHTSA to get that checked out. I think we can give Mercedes the benefit of the doubt on that one, and if it turns out they're lying, somebody will sue them, particularly if somebody who bought a Mercedes got into an accident and died. We'll sue them and the market correct itself. That's the normal mechanism for dealing with false claims that cause consequences.

Just so with reduced-risk tobacco. If it turns out that these claims of reduced risk aren't true, somebody who switched from smoking cigarettes to chewing tobacco or to one of these new tobacco products, sucking on nicotine lozenges,

whatever it is, will turn around and sue them for having been exposed to a greater risk. And the courts will take care of that under appropriate burdens of proof.

The notion, however, that the government can impose a prior restraint on the statement of an otherwise presumptively truthful amount of speech, factual speech for that matter, seems a little odd in the First Amendment context, but I actually think it's not viable. That's really, quite frankly, the end of the First Amendment analysis as a practical matter.

To overcome, to allow you to get a prior restraint, you have to come up with some remarkable governmental interest to justify that, and I don't think it can happen in this case. The only argument is that might not be true, not that it is inherently false, and the consequence of it perhaps not being true is that somebody might die.

Well, but that's the consequence of saying that my ladder won't slip. That's the consequence of saying these are no-skid shoes that you're going to wear on your motorcycle. That's the consequence of saying driving a car is safer than driving a bike. It's the consequence of a lots of things. It's not unique to cigarettes. It's not unique to anything, quite frankly, and it's never before been held to overcome this.

So, the only answer that I see, therefore, that would get us out of this dilemma is the answer Carlos gives, which is

the exception to the First Amendment doctrine about whether or not you promote an unlawful activity. The truthful, non-misleading I've dealt with. That's true if it's false, but usually that's taken care of after the fact.

So, the question is, does this promote an unlawful activity? Assuming that you're not marketing this on Nickelodeon, I think the answer would be it's lawful to sell it to adults and it's lawful to sell the product to adults independent of what claims you make about it. That would be the basic argument I have to answer this FDA Act thing.

Given that you can sell it making no claims, the fact that you turn around and make a statement regarding its effects should have zero impact, and if the Food, Drug and Cosmetic Act says otherwise, the Food, Drug and Cosmetic Act is unconstitutional. You cannot get into this little circular dance of saying it's unlawful because you spoke, therefore you can't speak, when it would be lawful if you kept your mouth shut. The speech itself cannot convert something that is otherwise a protected activity into an unprotected activity.

And I understand that there are lots of instances where the FDA takes the contrary position. I think those instances, when they're finally challenged, will fall. The FDA will not be able to do that. And the notion that something becomes a drug merely by a function of your speech rather than by a function of

its intrinsic qualities strikes me as a First Amendment violation in and of itself.

That being said, I think even as a statutory matter, there's no question that this is not a drug. There's no claim that this will improve your health. The claim is that it is not as bad as something else. So, saying that this will not kill you as much as the competing alternative makes it a health claim, that it will improve your health, that it will affect your health -- they're not saying it gets you high. They're not saying it makes you feel dandy. They're saying it has less of a consequence than the alternative product.

If that is enough to make something into a health claim and therefore make it a drug, it seems to me that there's no reason why Mercedes aren't drugs, why any car that advertises we have an air bag or antilock brakes is not a drug because certainly those ads say you will have less traumatic impact with other vehicles if you have our antilock brakes. You will have less traumatic impact with windshield if you have our air bag. All of those things are health claims that say they will alleviate the otherwise fatal or traumatic consequence of using the competing product.

I don't think any of that stuff even remotely makes something into a drug, much like I don't think good helmets, advertising that we are DOT approved for safety, makes motor

cycle helmets into a drug as compared to the little egg shells that you see some Harley guys wearing.

So, that's just as an incidental FDA matter. I don't purport to be an FDA lawyer. I couldn't really care what the FDA Act says, quite frankly. I'm a First Amendment guy. And at the end of the day, as a First Amendment guy, the FDA Act does not supersede the Constitution. What it claims to do is very nice, but it's probably unconstitutional if it in fact has the impact of regulating something strictly as a function of its speech.

Now, as a final basic problem, in terms of why it is that we don't like government prior restraints, why the First Amendment is opposed to government prior restraints, the answer why we don't let the government suppress information before it gets out as opposed to penalize it if it turns out to be false after the fact is that we don't trust the government and we have every reason not to trust the government.

The government is notoriously inclined to suppress evidence that violates its little world view, and when evidence comes out, what the First Amendment says is that we give the public the ability to judge that evidence and let the public indirectly alter the government's world view by voting in people who share the public's world view, not the other way around by having the government control information relating to its world

view and thus suppress that information to the public when it doesn't like it.

Because we know this is a massive risk, we don't let it happen, we shouldn't let it happen here. If it turns out that these companies are lying in their health claims, they'll get it in the end. They'll get it through lawsuits, as it should be.

That's all.

(Applause.)

MR. LEVY: Our third speaker is Matthew Myers. Matt has been with the Campaign for Tobacco-Free Kids since its inception in 1996. He's now President and CEO.

Earlier he was a partner as Asbill, Junkin & Myers in D.C. responsible for tobacco-related matters before the FTC's Division of Advertising Practices, and over the last 20 years or so, Matt has participated in virtually every major national tobacco-related legislative effort, one of which, the historic 1997 agreement between the industry and the Attorneys General, led to the master settlement agreement the following year, 1998.

Matt has received numerous awards for his contributions to public health, including the prestigious Surgeon General's Medallion from Dr. C. Everett Koop. He has published widely in health and medical publications, often appears on national news programs.

He has a B.A. from Tufts, a J.D. from the University of Michigan, where he was awarded the Order of the Cross and served on the Journal of Law Reform.

In 1973, he clerked for Chief Judge of the U.S. District Court in Rhode Island.

Please join me in welcoming Matthew Myers.

(Applause.)

MATHEW MYERS, PRESIDENT,
CAMPAIGN FOR TOBACCO-FREE KIDS

MR. MYERS: Thank you. It's a pleasure to be here.

This is an unusual debate in terms of the fact that the positions being taken purport to agree on some levels, but there are some really radical positions that have been offered here. Let me try to set the public policy record straight.

No one in the public health community believes that truthful, non-deceptive, complete claims should be banned. And in fact, nothing in the law currently prohibits any tobacco company from making such claims. The tobacco industry is not governed by the Food and Drug Administration except in the narrow circumstances today. So, the debate that is currently going on is not about banning those sorts of claims.

But what it is about -- and importantly, what it's about from a public health perspective -- is ensuring that claims that are made are, in fact, truthful, non-misleading, that they provide sufficient information so that a consumer can make a truly informed choice, and that the scientific claims are verified independently. In many respects what this is about is ensuring that the marketplace is provided adequate information to work and not that tobacco companies, because they are essentially unregulated, are permitted to make claims that the consumer has no way, no conceivable way, of independently verifying or judging, determining what was left out, what critically was left out, and because unlike the comparison between the Mercedes and the Geo, you don't die instantly with tobacco. It takes years and years and years and years to do so.

Let me cite another myth. This is not a debate about whether reduced-risk products that actually reduce the harm from tobacco use are something that the public health community favors or opposes because, with very few exceptions, the public health community has been at the forefront of trying to encourage the development of reduced-risk products, but under a system whereby the public can be assured that those products in fact will reduce the risk of consumers here.

In essence, what it does amount to is that the public health community, for the same reasons that we have rules and

regulations claiming what can be said about food and drugs and other products we consume, believes that there needs to be a regulatory structure so that the information isn't totally controlled by manufacturers whose sole interest is profit-making, so that there is an independent verification of any scientific claims that are made by people whose public health interests outweigh other interests, where that agency has the right to all of the information needed to make an assessment about those claims, and where an agency has some control over what is said not for the purpose of controlling speech, but for the purpose of ensuring that the marketplace can work.

Just like we have rules governing food advertising where one can technically make a claim about cholesterol that would truly be misleading about the product's overall risk of heart, in those circumstances Congress has given the FDA authority to regulate those claims so that a public that is not in a position to have the kind of scientific knowledge, doesn't have access to the laboratory research will, in fact, not be misled so we won't return to the days of snake oil salesmen.

Now, there's a very good reason for the application of those rules and for the skepticism of trusting the tobacco corporations to make those judgments for us because we've been there before. We've done this already. Advertising for low tar products made bold claims to consumers about reduction in

exposure, about you have a choice between quitting or switching and how switching was a wiser choice. It did so with only a standardized machine test about reduced tar and nicotine that had nothing to do with the actual levels of tar and nicotine the consumers were receiving.

What was the net result? Well, consumers believed those ads and it took decades of epidemiological study before the National Cancer Institute was able to say, after 40 years of study, we now know that the products that have been marketed under those claims, in fact, don't reduce the risk of disease. So, for the tens of millions of consumers who switched, who didn't have the benefit of any independent scientific agency reviewing the claims, controlling how that product was manufactured to ensure that the product wasn't changed in a way that would mean those claims had no real meaning, the net result was, from a public health standpoint, one of the most serious lost opportunities and tragic decisions we've ever made, literally millions of people, who might have quit, switching falsely believing the ads.

Now, we see an epidemic of it today every bit as serious as the one we saw under low tar, and it's not just United States Tobacco. Let me give you several examples.

Here is a perfectly good one, and you can't read the print. It's for a product called Omni Cigarettes. In the print

down here, what Omni Cigarettes says is that it's the first premium cigarette created to significantly reduce -- and it lists four carcinogens, which it then says are the major causes of lung cancer in smokers. Now, there was no law that former Liggett & Myers and now Vector thought that would prohibit it from making those claims, and there is no prior approval process despite what you've heard up to this point now.

Now, what is the problem with this? Well, the reality is there are 69 known carcinogens in smoking tobacco products today. Nobody, not Vector, not Liggett & Myers, not anyone knows what the health impact of removing those four carcinogens are. But a consumer has no way to know that, no way to know that whatsoever. There are currently no rules that required Vector Tobacco from doing any biological testing. They have no idea what the consumer is actually going to receive in this product.

There's something else that this ad wasn't required to say. In order to reduce those carcinogens, they added a metal, magnesium. Do we know what the health effect of smoking magnesium is? The answer is no.

Now, U.S. Tobacco's request, seemingly simple request, to the FTC falls into the exact same category, unproven claims. UST takes the position, contrary to all of the governmental scientific conclusions, that its products cause no harm whatsoever. It wants to be able to run ads, allegedly designed

to discourage people from using tobacco products in any of its ads for any of its products, including ads like these, which are clearly not ads designed to encourage committed adult smokers to actually reduce the risk of disease. Instead, they're clearly designed to expand the marketplace.

In short, what we see in this debate is not a debate about whether reduced-risk products ought to be encouraged or whether the public health community opposes claims about products that purportedly reduce risk, but simply that the standard governmental rules to ensure the veracity of the claims, to ensure that they're independently verified, to ensure that other changes in the product that would increase the risk have been assessed so that the consumer is given the full range of information, just as we do for food and drugs so that they can make that kind of informed choice.

If U.S. Tobacco wants to make a claim today, there's no governmental authority that prevents them from doing so. Erik is absolutely right. If U.S. Tobacco is sure that its claim is true, it ought to make it and then take the consequences in the courts, or risk, contrary to Erik's conclusion, that the FDA will find that to be a health claim and make UST produce the kind of scientific evidence in this kind of scientific forum that all other manufacturers have to make in this country today.

(Applause.)

MR. LEVY: Our final speaker, John "Jack" Calfee, earned his Ph.D. in economics at Berkeley. From 1980 to 1986, he served at the Federal Trade Commission, worked on consumer protection policy, including the regulation of cigarette ads. Later he taught at Maryland University and at Boston University and spent a year at the Brookings Institution. Jack is a frequent author of op eds, as well as scholarly articles.

He joined the American Enterprise Institute in January of 1995. As resident scholar at AEI, he conducts research on advertising, tort liability and regulation. His 1997 book, *Fear of Persuasion*, analyzes issues in advertising, particularly the effects of cigarette ads. His articles include *the Ghost of Cigarette Advertising Past*, which was reprinted in *Cato's Regulation* magazine, and *the Historical Significance of Joe Camel*, published in the *Journal of Public Policy and Marketing*. His latest book on rethinking tobacco is going to be published just as soon as he gets around to finishing it.

Please extend a warm welcome to Jack Calfee.

(Applause.)

JOHN E. CALFEE, RESIDENT SCHOLAR,
AMERICAN ENTERPRISE INSTITUTE

DR. CALFEE: Thank you, Bob. It is a pleasure to be here, an interesting format.

So, I'll tell you why I think we need ads for safer tobacco use, and it's a relatively simple story I think.

First of all, safer tobacco ads, I guess you would say, would bridge the gap in information about safer ways to use tobacco to obtain nicotine. Essentially the market has some severe gaps in what people know about the effects of these products. Essentially what consumers know is very different from what researchers know, and advertising would tend to bridge this gap and bring consumers closer to what the research community has found out about smokeless tobacco, reduced carcinogen tobaccos, smokeless cigarettes, and of course, filtered cigarettes.

Advertising would tend to overcome what I think is probably the biggest information gap right now which is about the health effects of nicotine. I strongly suspect -- and I think I've seen a few surveys on this -- that smokers know very little about the dangers of nicotine versus smoke itself, and that's a severe information gap. And advertising as a way to overcome these gaps is superior to any other mechanism, as far as I can tell, that has ever been devised. Advertising is faster. It's

better targeted. It's more efficient. It's easily the best way to get this kind of information to consumers.

A second reason why we need this kind of advertising is to improve what I guess you would call the information environment more generally, not just specifically information about the products that are being sold. Competitive advertising would tend to focus on the dangers of smoking because that's where these products have their competitive advantage. That would make smokers even more aware than they are now that there are problems with the smoke that they are ingesting.

We see this kind of advertising, that is, advertising that focuses on the down side of a product in order to steal market share, in lots of other markets, insurance, even among stock brokers. Shortly after the revelations about Merrill Lynch and some other firms that appeared to have some seriously compromised incentives, underlying the statements of their stock analysts, other stock brokerage firms that did not have those conflicts of interest ran full-page ads pointing out that they don't have that kind of conflict of interest.

This kind of advertising used to take place in the cigarette market. It happened especially in the 1950's. It was always in response to new information about the risks of smoking. And it has been essentially regulation that tends to dampen and almost completely exclude this kind of advertising. Basically we

need more of this kind of advertising, the fear advertising, the advertising that calls attention to the dangers of smoking, and that happens naturally in competitive markets unless it's inhibited by regulation.

Another reason why we need this advertising is because of what you might think of as a second order or downstream effects of advertising. If you can make a claim that your product is safer, you have a greater incentive to develop a safer product. This is pretty straightforward. It's pretty obvious. We see this in lots of other markets. We see it in pharmaceuticals where the FDA regulates advertising.

But I would emphasize here that this is not just a matter of better technology. It's really a matter of better marketing generally because what's at stake here is not literally the kinds of substances that a person ingests as a result of using these products, but such things as the ease of use, the kind of ventilation process that takes place, whether you breathe deeply or not breathe deeply, taste, convenience, all those kinds of things are very important characteristics. And good marketing, supported by good advertising, would tend to produce products that are superior in these other attributes, in addition to technology, which would greatly facilitate and ease the process of moving smokers towards less dangerous products or even towards products that have no smoke whatsoever.

Well, those are the things that this kind of advertising could do, that it would do if it were permitted in these markets. The natural question is, if advertising doesn't do these things, if it doesn't call attention to the dangers of smoking, if it doesn't tell people about the relative dangers of nicotine versus tobacco, if it doesn't do all the other things that marketing would normally do if it were allowed to do so, is there a replacement? Is there someone else who will do this thing? And I think the answer is, no, there is not.

A prime example is the information on nicotine and health. If you look at the medical literature, we've learned a lot in the last 10 or 15 or 20 years, and essentially what we've learned is that whereas nicotine was once thought to be the prime culprit in smoking, the main source of danger, we now know that nicotine is fairly close to being harmless. Certainly its harms are nothing compared to the harms that arise from cigarette smoke itself. That information has not been disseminated to the public even though it's very well known to the public health community, it's very well known to the Federal Government, the NIH, and other agencies.

The information about the relative health effects of smokeless tobacco versus cigarettes of the radically redesigned cigarettes, including the cigarettes that do burn tobacco but they don't produce smoke that's ingested, again has not been

disseminated by the government. It's not been disseminated by nonprofit organizations. So, I think it's safe to assume at this point that the only people who ever disseminate that information in an effective manner would be people who are doing advertising.

Even if you look at non-controversial topics, nothing to do with smoking and health, for example, the relationship between cholesterol and heart disease, once again most of the information that's being disseminated these days is not coming from the public health community, and it's not coming from NIH or other federal authorities. It's coming from advertising for products that reduce cholesterol and therefore prevent heart disease.

Then a final point or question that arises, when one thinks about this, is why have we been in this situation? Why are we in a situation in which anti-smoking groups are not telling people more about the essential information about the relative risks of different products? And I think the reasons are pretty straightforward.

One, their assumption has been that marketing causes smoking, and therefore, the main solution to smoking is simply to eliminate marketing.

The public health community has gambled heavily on cessation rather than harm reduction. It's a gamble that so far has not paid off and probably will not pay off.

And then, as Matt explained at great length, there is this instinctive insistence upon comprehensive regulation and comprehensive controls, the effect of which inevitably is to freeze technology in place and to freeze information in place and to forestall the improvements that would otherwise arrive.

Thank you.

(Applause.)

MR. LEVY: We're next going to give each speaker up to three minutes for rebuttal, and to save a little bit of time, I'd like to ask the speakers to remain in their seats and use the table mikes. We'll hear first from Carlos Angulo.

MR. ANGULO: Just a few brief points. I think Erik's overall view of how to deal with these type of products is to let the marketplace decide what's truthful and what's not truthful. That really would argue for virtually no regulation whatsoever of any commercial speech, and that's clearly not what the Supreme Court has determined is the way to handle commercial speech.

If anything, commercial speech has less protection than most types of speech under our constitutional system and under the Supreme Court's interpretation of that system. And that would be true even if the speech is unimpeachably true. Even under those circumstances, the courts will ask what is the government's interest in regulating it, is there narrow tailoring, et cetera. So, that analysis applies even if the

speech is absolutely and unimpeachably true. It certainly applies in a situation where you don't really know whether speech is truthful or not, as in the context of what we're talking about here.

The second point is that the whole prior restraint theory is one that really doesn't apply in commercial speech cases, and the Supreme Court has suggested that and other courts have held that. A prior restraint is basically an effort by the government to restrict speech before it's even been made. In general, that type of prior restraint is frowned on by the courts.

However, in commercial speech cases, the courts have said the prior restraint doctrine really doesn't apply because there's no chilling effect on the speaker. If someone restricts your speech before you make it, generally you're going to be dissuaded from making that speech in the future. But the profit motive for commercial speech, the desire of companies to make the speech in order to advertise their product, is great enough that there will be no chilling effect by prior restraint. So, that whole analysis really doesn't apply in the commercial speech case.

The third point I think I'm making is to talk about speech as truthful neglects the fact that courts have also looked as to whether the speech is misleading. As Matt was pointing

out, the fact that something is truthful doesn't necessarily mean that it's not misleading because you can say something that's true and leave out a lot of other stuff that makes the message as a whole misleading, and the courts have looked at whether speech is not only truthful, but also whether it's misleading. I think it's sort of simplistic to say that truthfulness is a black and white matter that really courts and regulators don't need to be involved in.

The final point I want to make is just the question of whether drugs are different. The first point to make is that a car is not a drug, even under the definition in the statute, because a car makes no claims as to treatment or mitigation or prevention of a disease. An accident is not a disease. So, when you're talking about drugs, you're dealing with diseases and not bad things that will happen to you generally.

The other point with respect to drugs and the points that Erik made are that it is not the speech that is illegal in the context of whether a drug can be marketed based on certain claims. The claims reflect the intent of the manufacturer as to how it will be marketed. You can use speech as evidence of intent without running afoul of the First Amendment.

If someone says, I'm going to kill someone, you can use that speech against them. It's not saying that there's anything wrong with the speech necessarily. It's just saying that it's

evidence of your intent to do something illegal. And, here again, the speech is evidence of marketing a product as a drug. And if you intend to market the product as a drug, you are subject to FDA approval. And that is the illegality; it is the intent to market the drug and not the speech itself.

And I will finish with that.

MR. LEVY: All right. Erik Jaffe, three minutes for rebuttal please.

MR. JAFFE: The only real issue that like I said, I think we're disagreeing on is the procedural mechanism for dealing with falsity or misleadingness. I don't think it makes much of a difference there for the constitutional analysis, and it strikes me that why is it that we have such a grave concern about falsity in commercial speech, yet we vigorously protect supposed falsity, even outright misleadingness, in political and other forms of speech.

I actually think that in terms of the consequences of falsity, the consequences of false commercial speech are trivial -- trivial -- compared to the consequences of false political speech. In false political speech, you elect someone who is a philanderer or a crook or a corporate toady. I'll be evenhanded on the political sides. And you have a disastrous government for four years.

You buy a product and start using a product, and after a few years it comes out that that product has effects 40 years out, you can stop. At the end of the day, even if you drop dead -- even if you drop dead -- from having used that product -- quite frankly, lots of people die from bad political decisions. We go to war. We have economic crises. We build dams. We build bridges. We have lousy roads. We don't impose certain restrictions. We impose other restrictions. People die from bad choices, and the fact that those choices are commercial doesn't make a whit of difference.

The First Amendment says those risks, the risks of making poor choices on incomplete information, are worth taking in a paradigm where we get as much information out as quickly as we can, rather than let the government suppress the information until it is satisfied that it has reached a certain critical mass that it's now balanced and not misleading. That is not the government's task.

As for whether or not the government can do that on food and drugs, like I said, it's my opinion, as yet unconfirmed, that that won't survive constitutional scrutiny. As to whether the Supreme Court differs from me, I note that I think there's only been one case in the last 15 years where they've actually upheld a restriction on commercial speech. They are consistently getting more and more rigorous. I strongly doubt whether the

commercial speech doctrine will survive another 10 years, but we'll see.

But at the end of the day, it's doubtful that they would ever strike down truthful advertising, a restriction on truthful advertising, unless it was truthful advertising for an illegal product. So, it may be true that marijuana makes you feel good, but no one is going to let that ad run because you can't sell it. But the moment you can sell it, it seems to me you can speak the truth about it, and I would be shocked if the Supreme Court said otherwise.

That's really all I have to say in rebuttal. At the end of the day, this just comes down to who do you trust. I don't trust companies, but I trust the government even less, and there are plenty of people to answer the companies. There is no one to answer the government when it tells you you make not speak.

MR. LEVY: Thank you, Erik. And now we'll hear from Matt Myers.

MR. MYERS: Let me be quick.

First of all, the government isn't telling them it cannot speak. So, that's a misnomer about what this debate is about. This debate is, in large part, the difference between theory and facts. There are real public health implications here. We've heard lots of glib statements about advertising for

safer products. The only difference is we don't know if those products are safer, and consumers don't have the opportunity to find out until literally tens of thousands, if not millions, of them are dead.

Now, Erik may disagree that the government has a role in actually protecting consumers and that it can control what is said about a product or, more importantly, that it can force a manufacturer to disclose information that only it has about the actual ingredients, components of the product that increase the risk, that it can control how that product is manufactured and the claims that are made so that the people who have to make the decision are actually provided with complete information, not incomplete information. So, in a very real way, despite all the debating rhetoric -- and that's what this comes down to -- this comes down to a debate about how do you provide consumers with information so that when they choose a product based on safety concerns, they are provided the full range of information that they need.

Now, this is a debate that Bob says is, in part, prompted by U.S. Tobacco's filing with the FTC. They're a perfect example of a company that discloses what they want the consumer to know and what they don't want the consumer to know. They came out with a great deal of hoopla about lower nitrosamine, safer product, only to find that when a State

independently tested their products, there were a host of very dangerous components in that product that they didn't tell the consumer about.

What this is about, very frankly, is how does the government step in to ensure that that marketplace of ideas is, in fact, complete so that consumers can make choices, so that when we hold consumers responsible for them, they aren't basing it on the fact that a company has chosen not to tell them something that was very important for them to know but which wasn't in the company's economic interest.

So, when Erik says he doesn't trust corporations or government, but he trusts government even less, the reality is here for tobacco we have solid evidence that when it's only the manufacturers who have the information, consumers die and never have the opportunity to make a truly free and independent and informed choice.

MR. LEVY: Thank you, Matt.

For our final rebuttal, Jack Calfee.

DR. CALFEE: So, the crux gets down to the nature of regulation. I would suggest that whatever there is you don't like about the content of advertising claims for cigarettes in the last 50 years or so, almost every objection that anyone can make can be attributed to the way those claims were regulated

rather than the way those claims would have emerged and sometimes did emerge from competitive markets.

The measurement of tar and nicotine was not invented by the industry. It was adopted by the Federal Trade Commission. We had competing measurement standards until the FTC specified there would be only one measurement system. That system, with minor changes, has remained fixed for roughly 40 years now. The system itself has been used for more than 50 years. That gives an idea, I think, of how dynamic regulation of information is likely to be, if it's regulated strictly by the government. If the FDA were to regulate this, we can assume the regulation would be more stringent and it would go more slowly.

Right now, we are faced with the bizarre situation that public health people are claiming that smoke is inherently dangerous, that there's nothing you can do to make smoke appreciably less dangerous, or it's very difficult to make it appreciably less dangerous. But on the other hand, if a product emits no smoke whatsoever, there's no reason to assume that that product is probably safer. I think that kind of mind thing gives you an idea of how regulation is likely to work.

When I looked at the Institute of Medicine report that came out recently on how we could encourage harm reduction in this market, if you read through the descriptions of the kind of regulation they have in mind, it's perfectly obvious that the

regulation that people are advocating would theoretically permit truthful claims, but in fact it would simply freeze the information we have right now because the regulatory standards are simply too high.

The specific example was a specific proposal that if a new product wants to enter in the market, it has to do biological testing to show that it is less dangerous than any existing product. The problem is there are many things other than biological testing that would determine whether or not a new product is superior, whether it's safer. It might taste better. It might be easier to use, et cetera. The way this mechanism would work would be new products, better products would be forestalled if there's one product out there that does well in biological testing no matter how badly it does in other respects. I think that's an example of how regulation is being misconceived right now and why distrust of competitive forces is forestalling the improvements that this market would otherwise generate.

MR. LEVY: Thanks very much to all of our speakers.

We've reserved time for questions from the audience. We have a microphone. Please wait until the microphone is brought to you, and then identify yourself please by name and affiliation. Please keep your questions short, no speeches, so that we can accommodate as many questions as possible. Do we have any questions from the audience? Yes.

QUESTION: Hi. My question is for Mr. Myers. I agree with you that the problem is that it's difficult to determine how safe something is without a long-term study that could take 40 or 50 years. Now, if there was a product developed that turned out to be more safe, after all this testing was done, would you advocate withholding the information that it might possibly be safe and thus killing the people who might have switched to it before the study is finished?

MR. MYERS: Obviously not. The reality is the public health community has encouraged the manufacture of products that would actually reduce risk. What we have said, however, is that we don't trust the tobacco industry to be the sole arbiter of that fact and to be the sole determiner of what tests need to be done.

The public health community doesn't advocate waiting 40 or 50 years. It has encouraged the development of alternate standards that could be used to measure whether a particular product would actually, based on the best science, reduce the risk of disease caused by tobacco products. Under those circumstances, it has always been the public healthy community's recommendation that, in addition to both activity designed to discourage people from using tobacco and help them quit, that for those people who continue to smoke, there ought to be reduced-risk products. Oddly enough, it's been the manufacture

of those products that has prevented the putting in place the kind of health and safety regulations, separate from the speech issues, that would provide the government with the ability to accomplish those goals. Thus, consumers are left in a real snake oil market. Trust a tobacco company that a product is actually safer without any proof.

MR. LEVY: Matt, could we take the UST specific example and ask whether or not you would ban this statement? They've asked the FTC for permission to say that smokeless tobacco is not a safe substitute for cigarettes, but many researchers have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes. Is that a permissible claim in an ad or not?

MR. MYERS: I think it's a more complex question than that. Sadly UST is the one smokeless tobacco company that has failed to acknowledge what all the scientific evidence shows and that is that its products cause serious disease.

Second, the point of comparison the UST uses in its petition are to a Swedish product that is totally unrelated to its own product, and when its own product was tested in the United States, it was found to have far higher levels of nitrosamine and other problems that increased the risk.

What the UST petition shows, however, is that we need the kind of broader government regulation so that broad claims

can be made. Smokeless tobacco products are not safer. There's no evidence that smokeless tobacco products are safer if they're used as an adjunct to somebody who continues to smoke. And we know that in large part that's what happens.

Smokeless tobacco products aren't safer if what they do is not discourage adults from quitting but encourage children to start, and the data shows that a child who uses smokeless tobacco products is three times as likely to go on to smoke cigarettes. Even an adult who uses smokeless tobacco products, there's virtually no evidence that they use it to either significantly reduce their smoking or to quit smoking. So, under those circumstances, a simple-sounding question requires a broader analysis to determine whether, in fact a statement, when made to the public, provides truthful information.

MR. LEVY: Do you have a comment?

DR. CALFEE: That's quite a regulatory standard, Matt, as I understand it, that if you demonstrate your product is safer in the sense that it causes less harm, that that would not satisfy you and presumably it would not satisfy the FDA. You would have to prove that the dynamics of the marketplace are such that after your product enters the market, goes through all the marketing competition and so on, the net result is that the people who might have used something else are not being harmed as

a result of moving to this product as opposed to quitting or something like that.

It would be a little bit like if you were to advertise that antilock brakes are safer, but you would not be permitted to make that claim until you have proved that can rule out the possibility that people will compensate for that by driving more dangerously, knowing that the brakes are safer. I suggest that is an impossibly high standard. You would never be able to meet it until such time as the FDA would decide for policy reasons that they thought the product was a useful one to have marketed.

MR. MYERS: Actually, Jack, we have a couple things. As you know, FDA makes these kinds of determinations for products all the time.

DR. CALFEE: That's good news or bad news?

MR. MYERS: Well, you and I would differ on that, obviously.

First, there's a critically important question, and that is the evaluation of the relative safety of smokeless tobacco products depends on the product itself. The Federal Trade Commission simply doesn't have the capability or frankly the information because UST hasn't provided them with all of the information.

Second, it does make a difference in how that product is going to be marketed as to whether or not the government

should give its stamp of approval for the claim. That's what UST is asking. If UST believes that's scientifically truthful and that it can verify that and defend it in court, as Erik suggested, there is nothing to prevent them from making that claim today. What they want is to do just what you said the government shouldn't do, as it did with the tar and nicotine testing, and that is put a government stamp of approval so that the consumer believes the government has made an independent verification. If UST wants to make the claim today, go trust the marketplace, go trust the courts, and we'll see what happens.

MR. LEVY: Should the government put a stamp of approval on needle exchange programs or should it restrain from doing so on the grounds that, after all, if you make it safer to consume heroin, people will consume more of it?

MR. MYERS: I have no expertise on needle exchange programs. The types of standards that we're talking about here for tobacco products are the types of standards that the FDA applies routinely to other products that are consumed by Americans today and they take place in an environment within industry that has a proven track record of simply not telling the whole truth to the American public. The American public shouldn't be left defenseless and shouldn't have to turn to product liability defense attorneys as its sole mechanism for finding out what the industry knows and has withheld from them.

MR. LEVY: Erik.

MR. JAFFE: Just to be clear about this, it's not like the Federal Government has a spotless record of telling people the truth. It's the Federal Government that suppressed information about low tar/high nicotine cigarettes, so the earlier example about low tar/low nic causing compensation and equal harm is an ironic example of the real answer being suppressed, which is people spoke to a constant level of nicotine and should be given low tar/high nicotine cigarettes, which was squashed by the government.

So, the notion that, yes, tobacco companies have every incentive on the planet to lie to you, absolutely, with the one check being that if you catch them, you're going to sue them until their heads spin. That's fine. That's the way every product is. In fact, that's a bigger check than the check that you have against politicians who have a much greater impact on your life and a much more devastating impact on the country because you can't sue politicians for lying to you at the end of the day.

So, the question is, do we trust tobacco? No. But there is no consumer on the planet that doesn't now know that. If they didn't know it in the 1950's because they thought American business was pure, well, great. Let the folks in the 1950's talk about that, but today we all have a healthy

skepticism and what we don't have is a healthy skepticism of the government. So, what the government has suppressed from the public, which is that nicotine is not anywhere near as harmful, which is the answer that smokeless tobacco, while killing you and while having carcinogens, is still less harmful than smoking, which is all anybody really wants to say at the end of the day, that is just incontestable, yet we won't let it out because we haven't satisfied some ridiculously high burden of proof.

MR. MYERS: Let's be perfectly clear here. Facts do matter.

MR. JAFFE: Yes, they do.

MR. MYERS: Wait just one second. The Federal Government is not the sole possessor of that information. If UST wants to put out its information, it's free to try to do so, and the same thing was an argument with regard to the relative risk of low tar/high nicotine cigarettes. The Federal Government didn't suppress that information.

MR. JAFFE: It suppressed the product.

MR. MYERS: If a tobacco company had information that that was true --

MR. JAFFE: It suppressed the product.

MR. MYERS: It did not suppress the product. If the tobacco company wanted to produce the product, it could have produced it.

MR. JAFFE: They couldn't have sold it. They could have put it in a warehouse.

MR. MYERS: No, that's absolutely not true.

MR. JAFFE: It is true.

MR. MYERS: That's simply a factually inaccurate statement, just like --

MR. JAFFE: You're wrong.

MR. MYERS: Just like the statement that Jack said that the only reason the tobacco companies didn't compete on safety was the federal government. In fact, the tobacco companies own documents show they didn't compete on safety because they agreed not to compete on safety. There was nothing in the federal government that would have prevented them from doing so.

MR. LEVY: That story does not hold up --

MR. CALFEE: There's one point I think maybe we can all agree on. The real issue is who's going to regulate these claims. Right now the FTC regulates them, and I too like Matt am curious as to why UST is going through petitioning the FTC rather than simply making the claim, but I suspect the motivation has to do with the issue of who's going to regulate the claim. Will it be the FTC or will it be the FDA? I think we need to bear in mind there are lots of risky products that are regulated by the FTC and these are products that involve a great deal of technical information. Hospital advertising is regulated by the FTC.

Doctor advertising, laser surgery is regulated. All that advertising is regulated by the FTC. The idea that if it's risky, the FTC can't handle the advertising I think is totally inaccurate.

MR. LEVY: Let's see if there are any other questions from the audience. In order to conserve time, we may have to dispense with the answers.

(Laughter.)

MR. LEVY: The second row.

QUESTION: I have a question for Mr. Angulo. You had mentioned during your presentation on if something is a drug, it would be a chilling effect on the marketplace if you could make a claim and then just say "not verified by the FDA." When you go to health food products, there are tons of herbal supplements, things that purport to help you lose weight, be more mentally alert, ward off cancer, all of these claims, and they all have this claim "not evaluated by the FDA." Are these products not under the same regulation you're talking about? Why is it any different from a tobacco company saying here's a product, it's inherently harmful, but we think it might be safer, this claim not evaluated by the FDA?

MR. ANGULO: There are sort of several answers to that. The first is that dietary supplements are under a separate statutory scheme.

The second is if a dietary supplement, though, does make a health claim, it is regulated as a drug. It can say certain things, but it can't say, you know, helpful in treating X disease or Y disease or helping curing or preventing these diseases. So, to that degree, any statement that a dietary supplement makes, it would be regulated as a drug and I think for the very reason that we don't want these products to be making claims about diseases without someone scrutinizing those independently.

The idea that the public can assess whether a statement of that sort is not misleading is sort of odd in the sense that they're the ones who are going to be misled by it. Maybe after decades of evidence that something is bad for you, you determine that, yes, it was misleading, but at what cost do you reach that conclusion? The whole point of having someone scrutinize it independently prior to those statements being disseminated in the marketplace is a critical feature I think of the current regime and is one that makes a lot of sense under the circumstances, and is certainly not inconsistent with the First Amendment.

MR. LEVY: In the back row of the front section.

MR. VERHI: Richard Verhi, U.S. Smokeless Tobacco Company.

Matt has misstated our position on a number of items, and I agree with Matt that facts are important. For those people

who want the facts, our request to the FTC is available on the front desk, and I urge you to read it.

But I do have one question for Matt. Assuming that the manufacturers, either voluntarily or otherwise precluded from making these comparisons, as you know, a number of your colleagues in the public health community do agree that smokeless tobacco is significantly reduced-risk. Do you think the public health community has an obligation to disseminate the information?

MR. MYERS: I think the public health community currently does its very best to provide those who come to it for information in its literature, the most accurate scientific information about all tobacco products that it has in its possession. So, the answer to you is we do our very best to tell the truth about what we know.

DR. CALFEE: What does that mean, Matt? You lost me there. His question is whether or not you are disseminating information. For example, does your organization make it easy for children to understand that if they're thinking about smoking, that they'd be a lot safer if they used a smokeless product?

MR. MYERS: What it does mean is that we provide, both on our web site and in separate information, the most accurate scientific information based on what the CDC, the National Cancer

Institute, the Surgeon General, and the other recognized organizations have said about the relative safety of different tobacco products. And we do that for smokeless tobacco. We do it for cigarettes, and we take people straight to the best governmental information that's available, including for these products.

MR. LEVY: All the way in the back.

MR. SWANSON: James Swanson from the Cato Institute. I have a question for Carlos.

To get back to the Constitution, you said that the Supreme Court disfavors commercial speech, but you also said that "our constitutional system" disfavors commercial speech. Given that the First Amendment says "freedom of speech," period, and doesn't make any qualification, I wonder what you meant when you said that separately from the Supreme Court, our constitutional system disfavors free speech?

MR. ANGULO: I think I just meant that the Supreme Court has held that commercial speech is disfavored. I don't think I meant to draw any earthshaking conclusion between our system and the Constitution.

MR. LEVY: Would you agree with the Supreme Court in that respect, that commercial speech should be subjected to a different standard than, say, political speech?

MR. ANGULO: I think there are some very significant differences. I think the distinction that has been suggested, if not drawn, by the Supreme Court regarding prior restraint doctrine, for example, makes a lot of sense. If you are subjected to a prior restraint, in a lot of different contexts you are clearly going to be chilled from making the statement that has been restrained. If you are a company that stands to make millions of dollars off of a product based on its advertising and someone says, well, first you have to go through certain hoops before you can make those claims, I don't think there will be any chilling effect or very little chilling effect on those companies given what's at stake. So, I think there are certainly significant distinctions to be drawn between commercial speech and other types of speech.

MR. LEVY: Is it commercial or political if you advertise a political book, or if you advertise an event for a political purpose for which there's some admission or a political fund raiser? If you broadcast information about a political fund raiser, is that commercial speech in the sense that there's going to be some economic transactions taking place or is it political speech in the sense that its purpose is to advance the electoral prospects of one candidate?

MR. ANGULO: I'd probably have to think about that. I don't know. It has elements of both.

MR. MYERS: Fortunately, Bob, that's not the subject of today's debate.

MR. LEVY: Well, no, the separation between commercial speech and political speech and the different standards that are applied to both are certainly a part of today's --

MR. MYERS: I mean, the notion, the sort of continued drawing of the parallel between commercial and political speech I think is a little tricky in the sense that the political system that has been very wisely drawn up by the Founding Fathers creates a lot of checks and balances within the system that would prevent any individual's maybe deceptive speech to cause too much damage perhaps. Certainly there are not quite that many checks between an advertiser and a consumer necessarily.

MR. LEVY: Erik.

MR. JAFFE: The two distinctions between commercial and political speech are curious, particularly in this context in that they don't hold up. Health claims about tobacco products have been chilled. They've been radically chilled because no one is willing to take the risk that the government will decide it's improper speech and ban their product entirely. So, the owner is willing to take the risk that the speech will suddenly convert them into a drug, which is what Carlos suggests it might do, and get their product flat out banned rather than really the speech banned.

And also it doesn't chill the speech. It suppresses it flat out if you never grant approval. The glory about a prior restraint of this sort is it's not merely pass it through and it gets a pro forma stamp of, okay, we've seen it. It never gets a stamp of okay. It doesn't get a stamp of okay until the studies, as many as we want and for as long as we want, get done, and that obviously suppresses the speech that is being previously restrained.

As for whether there are secondary checks on the truthfulness, I think the check is in the room. Mr. Myers has every incentive on the planet to tell people that these companies are full of it, as do lots of other public health advocates, and they do at every opportunity. And that's a good thing. I'm not saying that's a bad thing. I think you should get up and I think you should say these guys have their science coming out of their ears, and this is all nonsense, and the government frequently runs its own studies to do that as well.

So, the check is there, and in some ways it's far more effective because a lot of money is at stake and competing products will check each other. So, smokeless tobacco will tell you that cigarettes are terrible, and there's the check right on its own side. And the guys who make Nicorette will tell you it all sucks. Use Nicorette instead. There are plenty of checks in the marketplace.

MR. ANGULO: I just want to add that the FDA's approval regime, as far as I know, has not been challenged under the First Amendment, and has certainly not been rejected under the First Amendment.

MR. JAFFE: That's true. Not yet.

MR. MYERS: There's another important correction too and that is if a cigarette maker makes a health claim and FDA steps in and says you can't make that claim, it doesn't ban the product. It bans the claim. Now, there are some kinds of products that are not traditional tobacco products, for which a different conclusion may be reached. But, for example, Omni Cigarettes, the ad I showed you during the debate. If the FDA were to decide that was a health claim and was forbidden as a health claim, the net result would not be a prohibition on the sale of the product, but a prohibition on the claim.

MR. JAFFE: The same thing with nicotine water?

MR. MYERS: Nicotine water is not a traditional tobacco product, as you know, Jack.

MR. JAFFE: Okay, but in that case it's because they banned it --

MR. MYERS: A totally different debate because nicotine is not approved as a food additive. Therefore, to the extent that water is regulated, under those laws it wouldn't be there and because there is no tobacco in it. It is not a traditional

tobacco product. And nicotine is a regulated drug in all other forms in all other circumstances. So, the same is true as if they try to put nicotine in your chocolate bar, that it would be regulated by the FDA. It has nothing to do with the debate we're having today.

MR. JAFFE: Okay, but if UST goes ahead with their claims, as you suggested they should, and if in response to that you were to petition the FDA to assert jurisdiction, and if your petition were granted, are you suggesting that all that would happen is that UST would be asked to end their claims? The FDA would not attempt to regulate the product --

MR. MYERS: If they made the claims surrounding one of their traditional smokeless tobacco products, that's all that would happen, and you know that as well as I.

MR. JAFFE: Oh, no. Actually it was a serious question because I thought the FDA at that point would say that this is a misbranded drug and you need to take it off the market and file a new drug approval.

MR. MYERS: No. They would say that that claim turns it into a drug, and you can't that claim. But just as UST is currently marketing its products without those claims, they'd be allowed to do so.

MR. JAFFE: So, in the case of cigarettes, when the FDA sought regulation a few years ago, if all claims had ceased, then

they would have abandoned their attempt to regulate the product? That was not my understanding.

MR. MYERS: The assertion of regulatory authority at that time was not based purely on claims, but that's different than the current circumstances. There they made a conclusion with which the Supreme Court ultimately disagreed, which is that given what we then knew about the intent of the industry with regard to nicotine, that it fell within the category of drug and medical device. The Supreme Court said that's not what Congress had intended, and so it's a quite different situation than you have today.

MR. LEVY: For those of you who didn't follow quite all of that, the Supreme Court did say in *Lorillard v. Reilly* in June 2001 that the FDA could not regulate tobacco products as a drug.

We have time for one more question.

MR. KAZMAN: My name is Sam Kazman. I work with Competitive Enterprise Institute. I have a question for both Matt and/or Carlos.

If you take the UST proposed claim that Bob Levy read, which you find unacceptable, is there any government disclaimer whatsoever which, if it accompanied that claim, would render the ad acceptable to you? And don't you, under the Supreme Court's decision this past May in *Western Medical* actually have an

obligation to test out disclaimers in order to find whether they're effective or not before you reject that possibility?

MR. MYERS: I assume you're not asking me that question as a private citizen. And the answer I would give to you is it's not a decision that I as a private citizen have adequate information to make precisely because you would, as you correctly said, want to test out disclaimers in a format to find out how consumers were interpreting the information in order to arrive at a conclusion that was both truthful and promoted the public health.

MR. ANGULO: Yes, I agree. I think the idea of disclaimers has certainly been bandied about in a number of different cases as a way of dealing with commercial speech, including the case you mentioned. At least one court, the D.C. Circuit, in one case suggested that while disclaimers might be an appropriate means of dealing with this issue, in the dietary supplement context, for example, the drug context was different, and it sort of exempted the drug context from that analysis. Nonetheless, the idea of disclaimers is certainly one that should be considered, but obviously any disclaimer that is included instead of some other kind of regulation needs to be subjected to a great deal of review in order to determine whether it would be effective as a means of protecting the public health.

MR. LEVY: I'm sorry. We are out of time. I want to make one very quick correction. I gave you the wrong name of a case. It was not Lorillard v. Reilly. It was FDA v. Brown and Williamson Tobacco Company in which it was determined that the FDA would not have jurisdiction over tobacco as a drug.

We hope that you will be able to join us for further discussion and a buffet lunch upstairs in our winter garden. Before we adjourn, please let's thank Matt Myers, Carlos Angulo, Erik Jaffe, Jack Calfee for a lively and informative debate.

(Applause.)

(Whereupon, the Cato Institute Policy Forum was concluded.)