



Direct to Consumer Information: For and Against

Dan Troy

CNE Health Luncheon
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Who should control the flow of information about medical treatments and pharmaceuticals? Should information be restricted? Should pharmaceutical companies be allowed to advertise their products to potential consumers? How much control of information should regulatory authorities have?

The issues behind Direct To Consumer information cut to the heart of the respective roles of government, physicians and patients. As patients demand an ever greater say in their treatment, this is an area with growing importance and which needs to be addressed.

To that end, CNE is honoured to host a discussion with Dr Dan Troy, Chief Counsel of the U.S. Food and Drug Administration.

Before becoming chief counsel for the FDA, **Dan Troy** was a partner at the Washington, D.C. law firm of Wiley, Rein & Fielding (specializing in constitutional and administrative law issues) and an associate scholar at the American Enterprise Institute. He has published articles in *Commentary*, *The Wall Street Journal*, *the Weekly Standard*, *the Washington Times*, *National Review*, *the American Spectator*, *Legal Times*, *National Law Journal*, *the Journal of Law and Politics*, *the Administrative Law Review*, and *Policy Review*, among others.



Mr. Troy has served on the First Amendment Advisory Committee of the Media Institute and been a member of the AAF's Legal Affairs Committee. Mr. Troy is currently the co-chair of the Committee on Constitutional Law and Separation of Powers of the ABA's Section of Administrative Law and Regulatory Policy. He has also served on that Section's Council and as its Meetings Chair. In addition, Mr. Troy was the Chair of the Federalist Society's Telecommunications and Electronic Media Practice Group.

From 1987-1989, Mr. Troy served in the Office of Legal Counsel of the U.S. Department of Justice as an attorney-advisor. From 1983-84, he clerked for D.C. Circuit Judge Robert Bork. Mr. Troy has served as a lecturer-in-law at his alma mater, Columbia Law School, where he was Book Review Editor of the *Law Review*, a Harlan Fiske Stone, and a James Kent Scholar. He graduated from Cornell University's School of Industrial and Labor Relations in 1980.

Dan Troy

I want to try and connect up two things today, direct to consumer advertising and drug prices, and my primary point is going to be that direct to consumer advertising is not just a good thing for patients and it's not just the right thing to allow from a perspective of freedom, but it is a rational, good, long term investment, and maybe not even long term, but medium term investment that will lead to lower overall healthcare costs.

But let me start out by giving complete disclosure. I confess: I like advertising. Advertising campaigns permeate our consciousness and our language and I'm not sure that that's a bad thing, but, leaving that aside, they also do much more. As Nobel prize winning economist George Stigler said almost 40 years ago, this very important quote, he said "advertising is an

immensely powerful instrument for the elimination of ignorance”. Ads help inform consumers of the range of available choices in products and services; they educate consumers about the different features of those products and services; and in doing so they can have – and we have documented that they have had, and I’m going to be talking about that data today – enormously beneficial effects on consumer awareness and behaviour.

Advertising, though, isn’t only educational and informative. It’s also a driving force in the growth and success of economies and enables companies to enter new markets, enables them to challenge entrenched market leaders for consumer loyalty and it encourages and rewards product innovation. Now you’d think that in this day and age that the importance in value of advertising would be universally accepted. Unfortunately, as I think many of you know, this is not the case, indeed there are many critics who want to lay almost every imaginable societal problem at the doorstep of advertising. So we in the United States (and you may have people here also) who see advertising as the reason too many Americans smoke, drink, get divorced, don’t go to church, spend too much money or engage in criminal activities even. I think that those critiques are fundamentally misconceived – and particularly so in the case of direct to consumer advertising of prescription medicine. What advertising does is bring very valuable information to millions of Americans, yet it is routinely targeted as the reason for high healthcare costs.

FDA has only allowed direct to consumer advertising for about six or seven years and from the moment that we’ve allowed it we have been studying it very intensively. In September 2003 we held what we call a “public hearing” where we just ask people to come in and talk to us and submit data for the record etc. We held a public hearing to get testimony and get data and information on the effects of DTC, and we’ve also done a lot of our own research on this form of ad communication. We found that direct to consumer advertising catalyses patients to visit their physicians or take other health promoting actions.

In the spring of 1999 and again in the spring of 2002 we conducted national telephone surveys of US adults to ask their views on DTC promotion of prescription drugs and the effects on interactions with their doctor. We gave special attention to those who had been to a doctor within the last three months. They were asked questions trying to measure the influence of DTC advertising on their attitudes towards prescription drugs, health related behaviour and aspects of the doctor patient relationship. The results from those two surveys, and they are buttressed by much, much, much data, many other surveys that many other entities in the United States have done – and, by the way, there’s a lot of good data from New Zealand as well – show that among respondents who had remembered seeing an ad for a prescription drug, about half in 1999 and about 40% in 2002 said that an ad for prescription drugs had caused them to seek more information, for example, about the drug or about their health. Think about that: 40-50% were driven, who’d remembered an ad – they don’t all remember ads, but most people do – were driven to take some action about the drug or about their health. About 80% of the respondents in both surveys sought additional information by asking their doctor, half talked to a pharmacist, more than a quarter of FDA survey respondents in 1999 and 18% in 2002 said an advertisement for a prescription drug had caused them to ask the doctor about a medical condition or illness that they had not talked to the doctor about before.

45% of FDA survey respondents in 2002 reported that when they were interested in a print DTC advertisement they read almost all or a good part of this accompanying brief summary (which, like the Holy Roman Empire, is neither brief nor a summary), but if you’ve ever seen American drug ads there’s what’s called the creative part of the ad and then there’s all the fine print that has to be, that has to accompany the drug ad, and many people say, “oh nobody reads that,” but in fact we find that people do read that if they’re interested in the drug, and we’re

working on ways to make those, that “fine print,” if you will, more consumer friendly. And this result, all the results that I’ve talked about, are corroborated by survey research released by Consumer Health Sciences last month, and those results show that patients who respond to DTC advertising by speaking with the doctor or taking other action suffer more concurrent diseases and are in worse physical and mental health than non-responders. So this is an important point because what we are finding is that DTC advertising does not really create artificial demand; by and large, it prompts action among those patients for whom action is indicated. And by the way DTC advertising is also – there’s data on this – particularly effective within the US minority population and people who are not as educated.

We in the United States have a magazine called *Prevention*. But by and large, the people who get *Prevention* magazine may or may not need DTC advertising, but the people who get *Prevention* magazine are probably people more like you and me who are in higher socio-economic classes and who are concerned much more about their health. What we have found is that advertising, and this is by the way true of food advertising as well, tends to reach those people who do not have the same time, the same resources, the same ability to reach out and search the Internet and you know, read books and read magazines and read circulars about their health, so, to further digress, I’ll just make one point, in the early 1980s when FDA finally started to allow people to talk about the health benefits of food, the federal trade commission found that the people who found out the most about the link between increased fibre consumption and lower cancer rates were single women, smokers and the poor.

So these advertising initiated consultations are characterised by really an enriched change of information and views between patients and their healthcare practitioners. This is why I really think DTC advertising, the data shows, is a good long term investment. DTC tends to encourage treatment of under diagnosed, under treated conditions, if you have a broken arm you are going to go to the doctor, you don’t need a DTC advertisement to tell you to do that, but chronic diseases such as depression, erectile dysfunction, hypertension and diabetes continue, at least in the United States, and I would imagine the same is true here in Europe, to be under diagnosed and under treated. So we actually need more – not less – messaging to the public, encouraging physician consultations to identify these costly and debilitating conditions. The more people who treat their high blood pressure and their cholesterol now, the lower are going to be the hospitalisation costs in not necessarily even the long term but even in the medium term. There is, and I think we can work on developing even more data about that, but there is data to suggest that although drug pricing goes up and spending on drugs goes up, the data is a worthwhile healthcare investment just on a straight utilitarian dollar based calculus. Now, if you only think about the short term, then maybe, maybe it is not a good investment. I suppose no investment is good if you are only thinking about the short term, except for such things as a direct transfer payment, come to think of it that might explain a lot of politics but never mind that!

The other important thing is that direct to consumer advertising, at least in the US, provides all these public benefits and they are very much public benefits, through private funds. Prescription drug advertising is obviously funded by manufacturers and by marketers, now what we at FDA do is we carefully regulate the content of DTC advertising and the ads are voluntarily submitted to the agency for review before they are disseminated. We can’t compel that, but we encourage it and people do it, in part because they want to know if we’re going to say that’s a rotten ad, it’s a lot easier to find out from the front end then to find out on the back end.

In most cases the creative content of the ad only occupies, as I’ve mentioned, part of the whole communication because the rest of the advertising space is taken up with the risk and benefit

information that often reproduces almost verbatim the FDA approved professional labelling. So it's really not an exaggeration to say that FDA uses DTC advertising to convey its own, *our* own expert view of the risks and benefits of prescription drugs. In other words, the manufacturer might control the creative, but the brief summary that we don't technically write is considered widely to be FDA real-estate because we essentially dictate what it says. I mean that the company proposes and we say: "no not that", and eventually they get to where we want them to. It's a back and forth negotiation, but FDA clearly has the upper hand in what goes on a drug label.

User fees paid by manufacturers for FDA review of pre-market approval applications further reduce the need for public expenditures to support the dissemination of reliable drug information. Now, it's clear that for DTC advertising to have all these benefits it has to be truthful, it can't be misleading and it has to be scientifically substantiated, and our own survey data has shown that healthcare practitioners and others believe DTC ads may not be giving patients an accurate picture of the risks and benefits of the treatments involved. 75% of the doctors surveyed said that they felt that the ads made it seem like the drugs would work for everyone and that patients believe the drug to be more potent than it actually is. But we also hear the other thing, we heard, and I've had doctors telling me this, and we've had patients tell us this, that the disclosures, some of the risks are so scary that they actually dissuade people from taking the drugs. So the point is a prescription drug is not a cigarette, you don't necessarily want to have this much creative and then a huge black box warning for every single drug because that will scare people off and we don't want to scare people off from asking about drugs. Remember, one very critical difference between direct to consumer advertising for prescription drugs and everything else is that the consumer does not get direct access to the product themselves, they have to go through a doctor which is a very important check on ostensible problems with direct to consumer ads.

Now we share the concern, we want to make sure that the ads are non-misleading and truthful and adequately balanced because we are the only ones that have authority in the US to regulate the content of DTC advertising for prescription drugs. So we have rules that try to ensure that DTC advertising is truthful, non-misleading and supported by sound science. We actually issue hundreds of advisory opinions each year on the content of proposed ads and we also police ads after the fact and send warnings to companies who cross the line, in extreme cases we might take enforcement action against companies that have engaged in impermissible marketing practices. But an argument for strong enforcement is not tantamount to an argument against any DTC advertising but there are still some, even in the US, who continue to advocate a ban, although I have to say even Sydney Wolf, who is our biggest critic of new drugs and of the drug industry, even he conceded that given at least the legal posture in the United States with the first amendment that the DTC advertising genie is out of the bottle, or the toothpaste is out of the tube or whichever metaphor you want to choose. I think it is fair to say that DTC advertising, at least in the US, is here to stay and we think that that's a good thing.

It's also worth mentioning that David Kessler, who was the FDA commissioner under George Bush and then under Bill Clinton, who is the one who tried to regulate tobacco, he was an opponent of DTC ads, he was most recently the head of Yale's medical school and he was a big opponent of DTC ads, in fact it wasn't until one week after he left that DTC ads were finally allowed. So he was clearly the one holding up this thing that FDA wanted to try for a long time. He recently publicly did a *mea culpa* and said I was wrong, I was wrong; he said that DTC ads actually do have a net public health benefit. Now, critics of DTC advertising claim that ads increase healthcare costs, encourage drug over-consumption, strain doctor-patient relationships, mislead consumers and undermine the quality of patient care. Those are the primary critiques, and I'm sure you hear those over here. But, at least in FDA's view, these

concerns are just not corroborated by all the data that we've seen and again, that I think has been gathered in New Zealand as well.

Again, persuading patients to seek appropriate medical attention including drug therapy may, in the short term, raise healthcare costs. But you have to weigh those short term costs against the benefits of improved public health and improved long term prospects. This is especially so where out-patient drug treatments substitute for more expensive therapies in hospitalisations. So that is again the major message that I hope you will take away today, that whatever you may feel philosophically about the issue, from a utilitarian point of view this is a good investment.

The data also confirmed that advertising is not really correlated to price. The fact is, there's little or no relationship between the cost of a product and the money spent on advertising, this is a common misnomer, and economists can do a better job of explaining it than I can, but over-the-counter drugs, for example, are heavily advertised but they remain inexpensive, and some of the prescription drugs that are virtually never advertised to consumers – like Gleeevec, a new leukaemia drug by Novartis – are much more expensive than widely advertised drugs. So again, people have trouble assimilating this fact, but DTC ads do not drive up price, indeed, you only advertise if there is competition, and competition tends to reduce price.

There is also this misnomer, or this belief that drug companies are spending all of their money on promotion and then very little on R & D. The way you get to that number is you have to add up all promotional costs plus administrative, which means all overheads and then those two numbers together do exceed R & D, although not by that much, but of course overheads are a large component of any business. If you take a look at promotional spending by drug companies, a tiny amount of it goes on direct to consumer ads in the US. It's about 1% of overall drug care costs. It is increasing at a rapid rate and so it's getting a lot of attention for that reason, but 80% of promotional budgets are spent on communicating to doctors, communicating to physicians. Another huge percentage of so called promotional budgets are samples which many doctors use to make sure the people who might not otherwise be able to afford drugs in the US, because, I'll talk about the prescription drug benefit in a minute, but we right now do not have a prescription drug benefit. One of the things the doctors do with samples is they help manage the costs to patients of high price prescription drugs.

We've also found that DTC advertising doesn't lead to inappropriate healthcare costs for unnecessary doctor visits, according to 1999 and 2002 FDA survey results, the most frequently reported reasons for visiting a doctor are: the presence of a previous condition, the need for a check up, or that the respondent hadn't been feeling well. Less than 7% of respondents report that they visit their doctor only because of something they read or saw or because of an advertisement for a prescription drug, so again that gets to the point of DTC advertising so far as we've seen is not really creating artificial demand.

Now you might say how does that square with your point that it's being used for a lot of under diagnosed conditions, and that it's getting people to get treated for osteoporosis and for depression and for high cholesterol and for high blood pressure, and I think the answer is, and it's a common sense answer: people tend to respond to ads that they think might involve them, so I'm not likely to necessarily run to a doctor to talk about osteoporosis because I'm not really at risk for it. I might be more likely if I were not running as often and I was as heavy as I was a few years ago, to say when I saw an ad for high blood pressure or for high cholesterol: "You know maybe I should go talk to my doctor about that!" That's what we are really seeing happen, it's driving people to go to the doctor. In most cases the doctor is using that to have a conversation and not simply saying: "Here's a prescription!" Well no doctor worth his or her

salt should be doing that. I can tell you, my brother-in-law, my father-in-law, both of whom are doctors, they don't exactly hand over prescriptions like candy, they use the interactions as a basis for asking their patients: "Well, you've come to me because you say you're having problems in the bedroom, but maybe it's because you're forty pounds over weight, so maybe you don't need Viagra. Maybe you need to go on a diet." They use the question as a basis for a conversation.

So, we found that basically maybe half of survey respondents were given a prescription for the drug they asked about and at least 30% were given a prescription for a different drug, and more respondents in 2002 reported that they received a recommendation to change their behaviour or lifestyle even compared with respondents in 1991, so 41% of people said that they received a recommendation to change their behaviour and lifestyle. That's a good thing because you want to talk about something that reduces healthcare costs. If you drive somebody into the doctor's office and instead of getting a prescription, which obviously costs the system some money, they are told by their doctor to exercise and lose weight. If they do so that is the thing that is really going to drive down healthcare costs, I mean the biggest single driver of increased healthcare costs in the US right now is obesity, I don't know whether Europe has the same problem, I must say walking around I don't observe it to the same extent, but obesity is a huge problem in the United States and I think we've only really recently woken up to it. However, the head of the Department of Health and Human Services, Secretary Tommy Thompson, for whom I work, has made this his major crusade. Because the best thing that he can do to save Medicare and Medicaid (our healthcare providers) money is by getting people to lose weight because that will have a direct impact on reducing healthcare costs. Not perhaps immediately in the short term, but in the very-close-to-medium and long term

So the notion that patients override the medical judgement of healthcare practitioners to gain access to advertised prescription drugs that they don't need lacks empirical support. I'm not saying it never happens, you can never say never, but more than half of FDA survey respondents who are practitioners said that they felt some pressure to prescribe a specific drug, but at the same time most of them reported that their relationship with their doctor was excellent or good and didn't change for the worse regardless of whether they enquired about a prescription drug or came to the office visit expecting to get a prescription. Now there are no doubts some patients demand that their doctor gave them the advertised drug. But lets face it eliminating DTC advertising won't cure human arrogance and bad manners, and, by and large, most doctors are willing to say if somebody's asking for an inappropriate or wrong drug: "No. I'm not going to give you that."

Now there are some doctors who are always going to object to DTC advertising just like there are many doctors who object to consumers having information but most of them don't. According to our surveys doctors continue to respond positively to patient enquires about prescription drugs. I mean I think you see this particularly – it's sort of a generational thing. Younger doctors in particular almost expect that their patients are going to be more partners in their own healthcare and going to be more involved in their healthcare and are going to be engaged and ask questions. In a world with the Internet, which in addition to being used for pornography, is most often used for healthcare. There is good information out there and a lot of people in the higher socio-economic levels tend to use the Internet for that purpose. Only about 4% of respondents reported that their doctor was angry or upset if they asked about DTC ads.

At the bottom it seems that opponents of DTC advertising seem to be objecting more broadly to changes to the whole healthcare paradigm. Healthcare practitioners used to occupy a different, a particular role in the delivery of healthcare and the decisions were sacrosanct. And

patients and payers didn't second guess their clinical judgements. But of course, the advent of the consumer information revolution and managed care have changed all that. Some doctors, I think, believe that DTC advertising threatens their status even more. But overall again we've not seen that dramatic opposition from doctors; some doctors' organisations even support it. When we survey the doctors, they may not like, or they may want improvements in DTC ads – but they are not opposing them, at least in the US.

Now critics of the DTC ads focus on the evolving pharmaceutical marketplace when, in fact, the whole healthcare system is in transition. Of course it's not DTC advertising, which has only been around in the United States for seven years, that caused that transitional process, but is really a response to it. And so, at least in the US we question whether the objections to DTC are really more voices from the ivory tower, remote from the real world of informed and increasingly empowered patients.

So it seems to me that unequivocal opposition to DTC – which is, I think, something we see in Europe – is representative of really a public sector orientation on questions of healthcare. It seems to very simplistically equate an increase in drug expenditures with increasing overall healthcare costs, but that again ignores the public health benefits the drugs can produce. Patients, I think, might actually be willing to pay more towards the cost of effective drugs so I was going to talk more about drug pricing, but I think I will stop there because I do want to have the opportunity to engage, hear from you and also ask questions, answer questions that you might have about it.

However, I would urge you in closing, I'd urge you to take a look at the data that has been submitted to FDA on the question of DTC advertising and in particular we recently did issue this call of data and Pfizer's comments, you can get these things, probably could ask Pfizer, but they may be on our website, but there are ways to get them. Pfizer's comments submitted to us on direct to consumer advertising provide a very good summary of all of the data out there. I've read many of the individual surveys, that's a document that some might call it a meta-analysis, but it's not technically a meta-analysis. Basically, it surveys all the surveys and it summarizes all the surveys. There's also some very, very good material that the New Zealand equivalent of the FDA put out that is on the web. They have a very comprehensive discussion of what the arguments are that are for and against, and I would urge you to take a look at that, because it may be less radioactive if something comes not from the United States but comes from New Zealand, so it's really worth taking a look at that material.

So with that I'm happy to take your questions, I do think that advertising is a powerful tool and closing, as I said, to quote George Stigler "it is an enormously powerful tool for elimination of ignorance" – and that can particularly be true with respect to prescription drugs as well. Thank you very much.

Q&A

Question 1

Thank you Dr Troy, for those excellent remarks. I wanted you to speculate a little bit on the European situation. I realise I might draw you into making some radioactive remarks, so maybe you can case them as coming from New Zealand or something. But we have, arising from the advertising directive in Europe, a ban on the advertising of prescription medicines. It is a curious thing because everyone's interested in better information to patients and so on, but it's a fact that you can advertise that this margarine lowers cholesterol and you can advertise that this wine lowers cholesterol but a drug approved by the agency to lower cholesterol and an

ad developed along the lines of the label of that agency cannot be aired, and information can't be provided, and it has all the effects in Europe that you described for the United States. But it also has another effect in that it is anti-innovative. You made these remarks in regards to advertising in general, but one of the ways that the industry is limited and constrained is by the fact that governments, in addition to controlling prices and reimbursement and so on, also control information and ban information on ads, and the newcomer to the market has that much more difficulty in bringing a new product. It also accounts for market access delays.

Now I know you know this situation both in the US and here and I was just wondering if you have any thoughts on how things might evolve in Europe and how we might slowly get to the point where we're allowed to provide better information to patients as medicine companies.

Dan Troy

I think you, and all of you here, are much more familiar with the situation in Europe than I am and I think you've done a very nice job of highlighting the irrationality of the ban on direct to consumer advertising. The idea that information can really be bottled up in this world at this point with the Internet is just, it's silly, it's not doable, I mean I suppose if you have a population that doesn't have access to the Internet and doesn't speak English, maybe you can control their access to information, but if people can just get on the net and get the information that they want, then what you end up doing by banning DTC advertising, I've tried to suggest this before, you basically restrict the information to those people who are the most sophisticated, if you will, because they are the ones who are able to get the information.

I think one of the reasons why FDA is pro-DTC advertising as it is, is because in the United States, FDA is not CMS. CMS is our provider of, our national health insurer if you will, although you all know we don't have nationwide health insurance, we have it for our elderly Medicare and for the poor Medicaid. But insurers in the US, they take the same position that I think many take here in Europe, which is: *We don't like it because it drives up costs*. That's why I think the primary way to win this debate is not to engage in the philosophy of it. That is to state that it is going to save insurers money. What you should be doing is, the rational insurance company should be paying, should be doing everything they can. This is a point that Dr Bob Temple, who's our sort of chief medical officer, goes on about: they should be paying people, they should be "incentivising" them to go and talk to their doctor about lipid lowering drugs. This is the single most important thing that people can do, all of you in this room: I'm not a doctor but I'm telling you what a doctor said. Go check your lipids, go check your cholesterol, and if your lipids are too high take a statin drug. One of the things that was raised early is the NIH, our National Institute of Health, has just come out with data which suggests that, I think we're just starting to wrestle with this, that your LDL cholesterol, your cholesterol level should be not below 100, but should be below 70, it's very hard to get your cholesterol below 70, that number, I forget whether it's the HDL or LDL number, shows you that I'm not a doctor. It's very hard to get that number below 70 without statin drugs, unless you've got God-given genes you are not going to be below 70. So we in the United States, the doctors in the United States are going to have to figure out what are the implications of this, I mean does this really mean that a population that was previously thought to be healthy should all be on statins. that debate is just starting, the NIH just came out with that data last week but if you're engaging again, if you're, just like insurers won't insure or they have higher costs for people who smoke or they have higher costs for people who are overweight. The rational insurance company should be saying, we are going to "incentivise" you to check your blood pressure, check your lipids.

That argument is one that I think needs to be pressed in this arena here, and the other argument that needs to be pressed to consumers is: Why should you be denied information, because you

can't be trusted with it, because you might go to the doctor, and why is it that? You know, as you put it, advertising tells you all sorts of other things but it can't tell you about, frankly, these things that are much more important, it's much more to know whether you should go to the doctor because you might have depression or you might have osteoporosis than to go and get a new cell phone or to go buy the latest and fastest computer, it's really the world turned upside down that we are denying consumers information where a) it's so important to them, but b) they don't get to make the choice anyway, they still have to talk to their doctor about it and at the end of the day if the doctor is not going to write a prescription, they are not going to get this drug, so you have this enormous safeguard and this enormous check and yet this is one category of advertising that is banned. It's upside down. I don't know whether that's helped you in the European context.

Question 2, from journalist

I quite agree with you, just like to strengthen your point, coming from a semi-socialist country myself, my experience has been, well first of all that if you want to go to the doctor you better get to know one because the system didn't provide one and when it came to prescriptions you'd better read before hand. The information I think is the most interesting thing, I'm allergic to penicillin myself, which is lethal as you probably know, at least two doctors in my life have tried to kill me probably because they didn't have the proper information. I'm also allergic to other things that go in the same family as penicillin, there is a great antidote for that, but I have to marry a lady whose mother is a doctor just to get a prescription for it which I think would be regarded as strange. As a matter of fact, I trust myself a lot more than I trust doctors.

Dan Troy

I married into a medical family as well, lots of benefits.

Question

Hello, Tim Evans from CNE. Dan as I think you know, CNE over the months and years to come wants to do more campaigning, more reports, and gain more media coverage on this issue. Because for us, as a group of free marketers, we believe there's a basic human right to live in a society where you have freedom of information, freedom of speech, freedom of commercial speech and there's a kind of weird, I mean being a European it's a kind of weird situation because on the one hand we like to think of ourselves as being more cultured than Americans, on the other hand here we are in the middle of denying free speech in one of the most important areas that we can think of as human beings. Given your knowledge of Europe, and given your understanding of these issues and the data available from the US side, what would your advice be to CNE as it does more in this area, as we try to campaign for what we believe is this basic human right and we have a major report coming out on this subject in late October, what would your advice to us be?

Dan Troy

I didn't make the First Amendment argument because I found, and Charles was there in Copenhagen when I tried, when I make First Amendment arguments in Europe they don't go over very well, but I did write a piece on the original understanding under the US Constitution of the First Amendment and I showed that it clearly applied to commercial speech. The whole idea that there's commercial and non-commercial speech is sort of a modern, almost Marxian concept, by which I mean the bifurcation of rights between economic rights and civil or human rights is really a nineteenth century concept, and at least our framers and the people who they learned from, the Whig politicians and Scottish Enlightenment philosophers, didn't think about things in that bifurcated way. I think it was Madison who said justly that every man can be said

to have a property right in his own opinion. First Amendment rights and free speech rights were seen as a form of your personal property.

This whole notion of commercial speech is something that I think was first articulated by the United States Supreme Court in the 1940s, at a time when Socialist notions were I'd say at their apex in the United States. It's a made-up concept, and if you go back and you take a look, as I did, at colonial newspapers, ads were news. I mean, most of the newspapers started because of advertising and if you think about a world where people were not as besotted with information as we are, I mean finding out that there was a new product available, you know that shipment from England had come in with new material, that was much more important than knowing about what was going on in the court of Brussels or whatever it was from the colonial perspective, with all due respect to the court of Brussels.

Indeed when I remember at one oral argument recently someone said in a commercial speech case, he said aren't people much more interested in mortgage rates for example than they are in the war in Bosnia? Now maybe they should be more interested in the war in Bosnia but people tend to be really interested in their own mortgage rates.

The other point I will make on the First Amendment is that there are two cases really that led in the United States context to overturning this notion that commercial speech had no constitutional protection at all. One of them was an abortion case, people don't know this but what happened was five or six years after the United States Supreme Court recognised a right to abortion, Virginia banned a New York doctor, I think they tried to sanction a New York doctor for advertising the availability of abortions services in Virginia. The Supreme Court said you can't do that, if you've got a right to an abortion you've got a right to find out about the availability of an abortion.

And then the next year Justice Blackman, who as many of you know was appointed by president Nixon but ended up as quite a liberal member of the bench, he wrote a case that is the case that formally said commercial speech gets constitutional protection and it was a drug case. It is called the Virginia Board of Pharmacy case and what had happened was, I think it was Virginia again was banning advertising of the prices of drugs. What it does is it drives up the price of drugs and so Blackman wrote this opinion that, getting to answer your question, is worth looking at because he wrote about just how important it is to people to be able to find out about the costs of drugs, and how if you allow competition in drug pricing guess what, drug prices will go down, not up. And so, I mean I recognise the American experience carries baggage coming here, but I guess the only thing I can advise for the European context is there's now this great pilot project going on for the world going on in the US and New Zealand about direct to consumer advertising and there's lots of data being generated on it. Get the data and we need to hammer the data over and over and over and over again – it's not leading to bad outcomes, it's leading to good outcomes.

If one is in the intellectual arena, as obviously CNE is, you have to in the long run have faith in the rationality of people and the rationality of arguments, I mean if we think that rational argument doesn't make a difference then what are we doing? I think that there's a lot of data to mine and many, many arguments can be generated I think on almost every one of the small points that I made that it doesn't drive up costs, it does lead to good healthcare outcomes, it particularly causes people to find out about under-diagnosed conditions, all these points can be strung together as I did in the talk. But you really can focus on each one of them and again go back to the data. It's not that "old" data, because again, the phenomena started in 1997 and FDA did this major survey in 1999 and then again in 2003. But there's just a lot of data out there on this because people are interested and they are studying it.

FDA is not necessarily known for its, lets just say, free-market thinking, but what's interesting is that almost to the last person, I will really say to the last person, I have not encountered a person yet at FDA who opposes direct to consumer advertising. If FDA career staffers who are not necessarily strong on believing in the First Amendment can accept that DTC advertising is a good thing for the public health, this should give you some hope. Because if they could be persuaded of it, if David Kessler could change his mind then maybe Europe isn't a lost cause on this issue.

Stephen Pollard

Is there someone who'd like to challenge this view of DTC, there must be people since we do actually live on a continent, which doesn't agree with any of that.

Question 4

I'm a lawyer in the Commission. Just a question to understand. You said this advertising, one of the side effects that you thought was beneficial, is that doctor visits take place more often because people go and visit their doctor and talk to them. Now in the country that I know best which is Germany where I come from originally, just now a healthcare reform has been introduced with one of the measures very simple, a ten euro fee, everybody has to pay cash when visiting the doctor to drive down doctor visits, why is there maybe a difference between America's wish to increase doctor visits while the Germans try to drive down doctor visits? I'm not an expert in the field but I could imagine you have not enough doctor visits because many people don't have insurance or the doctor visits are very expensive even if you have insurance, out of pocket expenses, while in Germany, until now, every doctor's visit was paid for because everybody is insured and so people shopped around: if the doctor didn't prescribe what they liked they go to the next doctor. That has stopped with the benefit in the first few months of a few billion less of expenses. Now if the effect, as you say, based on a lot of data of direct advertising, is to increase doctors visits is that something we should wish nevertheless?

Dan Troy

Well you're right, if it's a free good probably not. I mean I have to say I did have one healthcare plan when I was at my law firm where all I had to do was a \$15 co-pay and I could go to the doctor, that's all, \$15 which is pretty much nothing, and I would sit there saying you know I'm not using this benefit, I've got to think of which doctor to go to, there was no barrier at all to my going to the doctors and so somewhere between your system where it was until recently a free good and our system where there are people who can't afford to go to the doctor who should, somewhere in between there, there should be, there's the right healthcare outcome. We are trying to do everything we can to address the problem of the uninsured, but you're right, if it's going to be a free good, i.e. going to the doctor, then you need to think about whether or not you want to increase doctors visits although again the key point is that by and large the people who went to the doctor in the US should have been to the doctor sooner, so maybe you need something like what you've done which is impose enough of a cost on the doctors visit that there'll be some, not so it won't be unaffordable, but there'll be some incentive to not just go at the drop of a hat. I think that that's a very fair and reasonable point, but if there is a free lunch, and we all know there is no free lunch, but if a lunch appears to be free people will take advantage of it.

So that is why you cannot, I mean you – making, I think a very important point – you can't disconnect DTC advertising from other phenomena that are going on in your healthcare system. But in a world where we care about cost containment and we care about people having good healthcare outcomes, good public health, DTC advertising is a help, not a hindrance. It's

a benefit, not a burden. And it should, based on what we are seeing in the US and in New Zealand. I don't know what New Zealand's healthcare system is like, but if they have full insurance then it may be even more apposite or relevant to study their situation and their system and what the implications have been there than to look at the US health system, there's of course more data on the US experience with DTC advertising but I was very impressed with the materials that the New Zealanders have out there.

Stephen Pollard

Can I ask you to change tack slightly? You talked about the fact that you can't separate out DTC from other phenomena that are going on in healthcare systems, one of which is price controls and regulation and so on, and I wondered if you could comment on a phenomenon that's common to both North America and Europe, the whole phenomenon of parallel trade and re-importation. I mean, where we are now moving fast to a position where we have competition based not on efficiencies but based on who can have the most stringent form of price control, and I just wondered if you could share some of your experiences with re-importation from Canada, perhaps.

Dan Troy

Well, I don't call it re-importation from Canada, I call it smuggling, why? First of all, in the United States context, it is illegal to – for other than the manufacturer – to import drugs into the US. Second because re-importation suggests that the drugs made in the United States get sent to Canada and come right back but with a price control policy attached to them. That is just not the case with the majority of drugs that are so called the subject of re-importation. So in the United States, it's illegal, but more important it's very problematic from a public health perspective because we at FDA can't assure the safety of those drugs. Now I'm not saying that going into a Canadian pharmacy is dangerous: it is not. But buying drugs from a website that has a little Canadian flag on it is not necessarily an assurance that it is indeed coming through the Canadian system because the Canadians don't really regulate that and stand behind it, and FDA doesn't really regulate and stand behind it. We've had numerous examples, we've done a lot of drug buys from these websites, and we've found that their products are problematic.

You heard me say this yesterday, but what's going on in the United States is a very dishonest debate about price controls. Again, the only thing that a Canadian drug has – that's if it is, indeed, a Canadian drug (which, you know, FDA's primary problem is a safety problem), we can't be assured that it is a Canadian drug – but the only difference, again between it and a US drug is that it's got a price control policy attached to it, and so this is really a backdoor way of importing price controls, but nobody's willing to talk about that in the United States in that way, but that's really what is going on. Now you can have an honest debate about that but the problem with price controls is they tend to maybe work in the short term, but in the long term they are going to radically diminish innovation, destroy the incentives for innovation. You know we need more incentives for innovation, not fewer because the pipelines are not as full with, you know as they once were, and the therapies that are now being worked on are much more challenging. So we need to think as a world community about incentives for innovation and it's hard to imagine that price controls are the answer for that.

The other thing one can imagine: One could imagine a world, give the more radical vision first. You could imagine a world where some drugs were unlicensed, where I could buy a drug that was blessed by the FDA or by the European equivalent or I could buy a drug that was blessed by the Underwriters Laboratories or a Good Housekeeping seal of approval or some other third party certifier or I could buy a drug that you know, said "buyer beware", you know, it's up to you. That's not the system that we've opted for and I think that's a system that many different societies including the United States tried and there's a reason why the FDA's closing in on its

100th birthday. Too many people get sick and die when the trade in drugs is entirely unregulated and I say that as someone who, you know, has a fairly libertarian bent, so I think we as a society, a world community have decided you can't truly have a completely unregulated trade in drugs, there's too much market failure because consumers are not able to evaluate drugs the same way that they're able to evaluate cell phones and computers, although I don't know, I can't evaluate cell phones and computers very well.

So, the other thing you could imagine is you could imagine a world where there is, a sort of a most favoured nations approach or as long as one of the developed countries in the world had certified a product, it approved a product, that everybody else would accept that certification, you only needed to punch the ticket of say, you know, let's say Belgium. There are two problems with that, one is how can you be assured that the product that has been approved by Belgium is the same product that you are getting in the US, but that's more of a distribution issue, but the second is the fear that there would be a race to the bottom, right, because if all the countries are competing to be the ones where a company will come to get their drug approved then, sort of, to rationally if they're making money out of this which they probably would in one way or another, they would set their policy not at the FDA gold standard, not at the highest place, but actually at the lowest place where they would get, where the drug could be approved, and then everybody else would be bound by that. But you can have an honest debate about that, I mean maybe there's a way of making that kind of a system work, but that's also not the way the debate is being held in the US.

I know I'm running over time, so I'll just close out by saying that we in the US are struggling with the issue of drug pricing perhaps from a different perspective than you all are, but right now the US is, at least the way it looks to the US, and I recognise there's some controversy about this, it seems to us that we are subsidising the rest of the world when it comes to R & D and it seems to us also that there may be ways where we can work together to foster drug innovation. I'll just give one example. Now we don't have a lot of solutions to this, some of you are aware of Mark McClellan's speech in Cancun where he basically raised this issue and talked about some kind of a better system. Too many European countries do not have policies that promote generic drugs and I don't mean promote through advertising, or that basically require a transition to generic drugs, once generic drugs come on the market, and generic drug prices are much higher say in a place like Italy than in the US. That doesn't make any sense, I recognise that for the US to come and say everybody else should spend more on drugs is not a very popular or tenable position. But there may be ways that European countries can adjust some of their spending that would do a better job at helping to foster R & D and innovation because people seem to think, I'll close on this point, in the US as well as worldwide, they seem to think that drugs are somehow a public good, or a free good and that they're primarily being developed by government. There is this perception, the National Institute of Health is the one that's really driving drug innovation and drug investment and it's just not the case. I am very afraid that the long term prospects for drug innovation are not very good and that we are at risk of killing the goose that laid the golden egg. The idea that people are characterising the pharmaceutical industries, the worldwide pharmaceutical industry in the same category as the tobacco industry is very troubling. This is an industry that whatever profits they've made they have more than repaid the public in terms of net benefits on public health. We are talking about an industry that has generated miracles, modern miracles over the past twenty five years or so. When my father-in-law started practicing medicine, as he said to treat a heart attack you put somebody in bed and you sat by them and you held their hand, you tried to keep them calm and that's pretty much it, then finally we had nitro-glycerine tablets.

Nowadays things that can be done for people with heart attacks are remarkable, I'm not saying government has played no role in that, NIH obviously does a lot when it comes to basic

sciences, I know that there's been support from European governments as well, but by and large those modern miracles have been the product of the pharmaceutical industry that the FDA regulates. It needs to be regulated but we need to do what we can as a world community to try and foster innovation, and with that I'll close.

– end –

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