ADMINISTRATIVE LAW & REGULATION

SPEECH AND PRIVACY REGULATION IN THE WORLD OF DRUGS AND HEALTHCARE
AN ADDRESS BY THE HONORABLE DANIEL TROY*

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MR. TROY: Thank you very much. It is always a pleasure to get outside the beltway. You know what Justice O'Connor said about Washington, D.C.? She said it's a city that has even more lawyers than it does people.

I know you all want to hear about the First Amendment, which is not going to be the topic of my talk. It is a pleasure to speak to the Federalist Society, but it actually makes me feel a little bit old. I remember when there was no Federalist Society.

Culture counts. The Federalist Society was created in reaction to a particular culture that pervaded the law schools during the 1980s. And reflecting on the Federalist Society's effect on that culture and on the legal culture generally caused me to think about FDA's culture, as well. Even though I'm far from a sociologist, I want to share with you some reflections about FDA's culture so that you can better understand the context in which FDA's decisions, including decisions about the First Amendment, get made. One word of warning up front — when the eminent sociologist Daniel Bell was asked what he specialized in, he quipped, "I specialize in generalizations."

To talk about culture, generalizations are necessary, and I well recognize that there are exceptions to every rule. Also, I am not talking about particular individuals, although, of course, individuals can affect the culture. And as a further caveat, I have only been the chief counsel of FDA for nine months, and as one of only two political appointees at the Agency, I am confident that the Heisenberg Principle applies to any attempt on my part to measure the culture.

So, my observations are from the perspective of a new political appointee trying to absorb the culture of an agency that has been around for nearly a hundred years and is recognized internationally as the premier healthcare regulatory agency in the world. I hasten to mention and emphasize that FDA is a wonderful place to work, and I really do find it an honor to serve as FDA's chief counsel.

The first thing to understand about FDA is that there is no single culture at FDA. Rather, at the very least, each of the five product centers — centers for drugs, biologics, devices, foods and veterinary medicine — have their own distinct culture. Often, you hear suggestions like, "Why aren't the Centers for Drugs and Biologics merged because they have similar functions?" Well, such a merger was attempted, I believe around 20 years ago, and it failed because the culture and tradition of the drug center, which has always been part of the FDA, differs very much from that of the biologic center, which was part of NIH until 1972. Now, you would think that after 30 years, both centers would look and feel the same, but they really don't. They certainly have more in common than they have differences, but some of their approaches to product approval and to development are distinct.

A second observation is that cultures, even within the offices of the various centers, can vary. To generalize, compliance offices, who are the people who are, of course, assigned to bring legal action against violations, tend to have a more technical view of industry. This should not be surprising. They also, though, tend to have a better sense of, and be a bit more realistic, about the legal constraints on FDA. This is also, of course, understandable, given their law enforcement orientation.

By contrast, the product review divisions tend to have a more cooperative, collaborative approach towards industry, and this cooperative relationship served the nation quite well during the weeks and months following 9/11, when FDA and industry really joined hands to respond to a variety of public health challenges. And of course, people in the product review centers particularly recognize, and all of us recognize, that it serves us all well, it serves the nation well, when companies develop new and exciting products that advance public health.

One area where compliance and product review cultures clash is when we have to decide whether to approve a significant new product or manufacturing change when the applying company is out of compliance with our Current Good Manufacturing Practices, which we know as CGMPs. That is, the product itself could be safer and more effective than products that are already on the market. But, it may be made in a facility that is not up to legal standards. Now, this is a real dilemma. Fortunately, it is one that does not come up too often, but it does come up.

On the one hand, approving a new drug, device or vaccine with beneficial effects can, of course, improve the public health, and in some cases quite dramatically. On the other hand, if companies are making those products with processes that are not in compliance with the CGMPs, then the products themselves are technically deemed to be adulterated by the statute, even if the products can be used safely. Our statutes and regulations actually constrain our ability to approve new products, if the manufacturing facilities do not ensure the safety, purity, potency, quality and strength of a biologic, or the safety and effectiveness of the device or drug.

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More broadly, the presumption of the whole CGMPs process or regime, if you will, is that the public health is best served when companies are in compliance with CGMPs. So, what FDA can and can't do in this context and in these circumstances often comes down to a legal question. We at OCC, at the Office of Chief Counsel, frequently have to moderate between the review and compliance divisions, and it's often quite a tough call.

But far more important than their differences, FDA-ers, in my experience — all of nine months — share many, many things in common. Perhaps the overriding shared experience is too much to do in too little time. Practically every employee feels continuously overwhelmed. Now, this may be because we take on too much; it may be because we're assigned too much; it may be because of the simple fact of having approximately 10,000 people try to regulate products that account for close to 25 percent of the American economy. Probably, it's some of each. But for whatever reasons, resources, particularly time, are always at a premium.

This feeling of being hassled and harried, which sometimes allows for too little time for introspection or reflection — not to speak of a healthy family life — is compounded by the challenges of the FDA's physical arrangements. As some of you may know, FDA is spread in about 40 locations in the D.C. area, with many of us at the Parklawn Building in Rockville, which is, to be blunt, a particularly inhospitable building that was named after an adjacent cemetery. The hallways are narrow; it's very long and inhospitable. And the physical environment does not promote a lot of informal interactions. So, FDA staffers really don't have enough opportunities to chat or interact informally with people from other parts of the Agency.

Most interoffice business, and even much intraoffice business, is done via email or in hour-long pre-arranged meetings. Less is done by phone, in my experience, than in other organizations. This can lead to delays because if the matter can't be resolved by email — and email has its virtues but it has its drawbacks — resolutions must frequently wait until a formal meeting has been set up with all of the relevant players able to attend. Scheduling these meetings takes a lot of time, and coordinating everybody's schedules and getting everybody together can push things off and make things slower than people might like. Now, the fact that these meetings do take place and that issues are resolved underscores the highly collaborative nature of the Agency. And I can't emphasize enough, FDA is a very collaborative place.

As you all know, FDA decisions often require a scientific evaluation. But that scientific evaluation, then, has to be refracted through our legal mandate. And so, there's a need to often include a lot of disciplines in the decisionmaking process. And this need is complicated by the distances that we have to travel to actually see each other. So, this need for collaboration, plus the physical challenges, sometimes slows the decisionmaking process. The collaboration does generally make for better decisions, but it is at least one of the reasons why some people think FDA is slower than it should be.

One of the things I have to emphasize is that people at FDA work amazingly hard. We are not talking about lazy bureaucrats, by and large. You might imagine I'm there a lot and the parking lot on a Sunday has tons of cars in it. I mean, I have the misfortune to carry a Blackberry, which some people call a "Crackberry" because it's so addicting. But I get emails morning, noon and night. Of course, I'm responding to emails morning, noon and night. It's one thing for me to do that. The culture of the Agency is a very hard-working place.

I think that one of the reasons for that is that FDA-ers really share a very strong sense of mission, and that is to protect the public health. You've heard that mantra. It really helps an organization when everyone has a shared sense of mission and feels good about what they do. I think FDA functions as well as it does not only because everybody has a common mission but also because the Agency does tend to attract people who are personally committed to government protection of the public health.

Now, this sense of mission is, of course, a plus, but the Agency has to be mindful that balance and perspective is needed as public health issues are addressed. As a government agency, we have to ensure that we accomplish our mission with fealty to the powers that Congress has given to us. As I occasionally remind people, our statute does not end at charging us to safeguard the public health in whatever way we think appropriate. Rather, as you all know, it runs on for hundreds of pages and has been amended — I am told; I have not counted, but I am told that it was amended 99 times, and I guess the Bioterrorism Bill, once it's signed, will make an even hundred.

The statute sets forth not just the objectives of public health protection, but also provides direction on how those public health objectives should be achieved. We must not forget that the definition of our mission, as well as of our powers, is determined by statute.

A related phenomenon that I think I've alluded to earlier, to this public health orientation and this public health mission, is a tendency to take on a great deal and, arguably, on occasion, too much. This may be the nature of every administrative agency, but it is particularly true at FDA, given our sense of mission and our regulatory scope and broad charge to protect the public health. But the problem with taking on too much is that it is really hard for any organization, especially a relatively small one like FDA — in the scheme of organizations, 10,000 people is not that big an organization — to do too many things very well.

Let me give you an illustration. I think that notwithstanding some carping to the contrary, FDA does a pretty good job at approving new drugs. To be sure, we are attacked both for being too cautious and too slow, and at the same time, we're attacked for being too quick to allow untested and unproven drugs to come to the market. Although it is too facile, I think,

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that attacks from both sides means we're in the right place, we do review new drug applications in a relatively timely fashion. We have a particularly outstanding record for speed when a truly exciting and important new drug is developed with sound scientific data supporting its safety and effectiveness. Gleevec is, of course, the best example, which was approved in about four months.

Now, some in the drug industry have complained that the review process has slowed down. And, the allegation is that it's slowed down by about two months. I don't want to denigrate two months; a two-month delay in approving a blockbuster drug can mean many millions of dollars and, far worse, untreated patients. But if you compare FDA's performance with other government organizations, I think on this score we measure up pretty well.

There are, of course, by contrast, things that we just don't do anywhere nearly as well. I'll give you just one example on this score. We check maybe one- to two percent of imports. Frankly, it's scary how little we check in terms of imports. This is a resource issue; we don't have enough inspectors to do more. But this constant problem of resources and time and too much to do does lead me to believe that we need to think very carefully about our authorities and resources before we take on major new initiatives.

Now, I hasten to add, it is not always the Agency's fault that we take on as much as we do. Congress expects much from the FDA, but it often imposes additional burdens on us without necessarily giving us commensurate resources, and add to that, pressure from media or stakeholders, administration, the states, industry and others. But it's hard to do everything — especially, to do everything well. And all of us at FDA — indeed, in government generally — have to focus on what we do well and on what we want to accomplish.

FDA's focus on public health has consequences to the legal culture, as well. Before the 1980s, courts frequently engaged in what law professors today call a purposive interpretation of the statute; some others call this the New Deal era of interpreting statutes, or the Landis approach, after a great administrative law scholar who championed very broad deference to agencies. Under this view, Congress has charged expert agencies with a broad delegation — in FDA's case, to protect the public health. And under this theory of statutory interpretation, agencies were allowed to do almost anything that the statute did not clearly prohibit. This view rested, in great part, on trust in Congress and especially in expert agencies to do the right thing.

Since the 1980s, the courts have applied a more textualist approach to reading statutes. They are simply more likely to hold the Agency to the powers that Congress has delegated to it. And I think the courts have become more skeptical of the agencies' assertions of expertise in the interpretation of their enabling statutes. I hasten to add, I don't think courts have become much more skeptical of agencies' assertion of expertise when it comes to things like scientific judgments. As Rich Cooper put it, you may be able to beat FDA on the law, but you can't beat us on the science.

Why is there growing skepticism of agencies' assertions of expertise in the interpretation of enabling statutes. I think it's in part — this is a very long sociological discussion — due to the assault on authority in the 1960s, which is not just of the 1960s but is particularly captured by the 1960s. And in part, I think it's due to the rise in public choice with its attendant skepticism of legislation.

Public choice, as many of you know, views legislation as often the product of interest group pressure because of the collective action problem of the rest of us, if you will, who are not as intensely interested in particular legislative outcomes. And this view often causes courts to read statutes narrowly; for example, as contracts. There's a whole school that you should read a statute as a contract, or rather that you should read it as a charge. But there are those in the academy who champion kind of a purposivist, very broad interpretation. But that is not, shall we say, the regnant theory in the courts.

But some in FDA do still regard the statute as vesting in FDA vast, almost unlimited, authority to protect the public health. Over the years, FDA has from time to time declared a broad category of products or activities subject to its jurisdiction, but asserted that, for now, it's only choosing to regulate a subset of those products or activities. Now, this strategy, to a certain extent, is a corollary of the tendency to try to solve many problems and eschew acknowledgement of limits. There are certainly advantages to this strategy; in particular, it does preserve future flexibility. But it can do so at the sacrifice of credibility.

Also, I think the two frequent declarations that a particular activity is only tolerated subject to FDA's enforcement discretion can lead to charges of our being arbitrary. What is more, such a position may mean picking unnecessary fights. Drawing a line and defending it on occasion can put the Agency in a better position than asserting unlimited authority, which we may be unwilling or unable to defend if it's challenged. Speaking personally, I'd rather stake out the high ground from which I can shoot down on my attackers than to have to spread my forces out so widely that I have to defend every twig and bush.

While I'm on the subject of culture, and I guess implicitly lawsuits, talking about the legal culture, I do want to address a perception about the FDA culture that I hear occasionally. That is that FDA is retaliatory. I hear far too often that people don't sue the Agency or appeal decisions to higher-ups because they're afraid of retaliation against themselves personally or against their companies or on unrelated matters. I want to address this directly because I have not seen retaliation.

In fact, I have to say that, if anything, I have often see FDA consider pulling its punches in one context because of

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a dispute in another, to avoid the perception of piling on. But in any case, retaliation is simply unacceptable. Although we are all human, we all have our likes and dislikes, our emotions and our feelings, we do have an obligation to be professional. But when I ask for specifics on these charges, I rarely get them. I'm not saying that it never happens. But I would say that, personally, I would recommend that anyone demonstrated to be engaging in retaliatory behavior be promptly and severely disciplined, but I think there's more, shall we say, smoke here than fire.

As you may know, I work hard to avoid the agency being sued. Why? Because I don't want to lose control of my legal agenda and my legal resources. I'd rather be offensive and pick the lawsuits I can file, rather than be playing defense. It's not that I'm afraid of being sued, I just think that it doesn't always help us achieve our goals. In order to avoid that, I try to keep an open door to letters, papers and meetings, if necessary or appropriate, to try to reduce lawsuits. And I'm happy that on occasion, we've been able to do that.

But I want to emphasize that if you believe that FDA is acting in a manner that's inconsistent with its legal rights and obligation, I hope you will let me know, and I promise that I will read your letter. I have already read dozens and dozens, and if necessary and appropriate, I may meet with you in an attempt to solve your problem. I may be able to solve your problem without a meeting. I may not be able to solve your problem. But in the event we can't address your grievance, I will recognize that regulatees or others have rights under our law to sue us if they disagree with an outcome. And in that case, we should try hard to disagree without being disagreeable.

It's easy to lose sight of this, no doubt. Sometimes, outrageous behavior on the part of a litigation opponent can warrant a strong response. But generally speaking, our obligation is to try to approach disputes as dispassionately as possible, and at least from what I've seen in the people in my office, I think they do that.

Now, I know that going over somebody's head can be a difficult decision, but I have to tell you, I think a lot depends on how you do it. I don't have trouble if someone tells me that they intend to go over my head, if they say, look, thank you for hearing us out; I respect your decision but I really think this is sufficiently important to me and to my company that I'll tell you what I'm doing. But I feel a need to take this to Dr. Crawford, take it to the sixth floor, etc.

I'll confess, I get annoyed if I hear about somebody going over my head from somebody else, especially if I've gone out of my way to be as courteous as possible to somebody and give them much time and attention. So, I encourage appellants to use common courtesy and keep the person whose judgment they are appealing in the loop. That doesn't mean you should hesitate, if you think the law or facts are on your side, to elevate things in a respectful way to higher-ups in the Agency.

While I'm on the subject, I just want to suggest a few more dos and don'ts for dealing with people at FDA. I have to say, I don't think this advice is specific to FDA's culture, in part because these are sort of personal. Some of these suggestions may seem obvious, but you'd be surprised by how some people in regulated industry have behaved.

First, if you're having a confidential conversation with an agency official, don't issue a press release, not only reporting on the conversation but distorting what was said.

Second, you may be invited to a meeting with an official who had a meeting with a competitor. Sometimes I'll do this. Someone will come in and I'll say, "Well, I really want to hear from the other side." If you get that call to come in and meet with us because I already met with your competitor and you didn't even know about the original meeting, don't call and demand that you immediately be given the material that the competitor shared with the Agency. It's particularly not a good idea to file a FOIA request for the material without first telling the person who invited you that you're doing so. I think that would be common sense.

Third, a lot of this is just conscious common sense — put yourself in the shoes of Agency officials. It's probably not realistic to demand long, written decisions overnight.

Fourth, there are ways to say that you may be forced to take a matter to litigation without threatening to do so. But enough about that. My bottom line is, you shouldn't hesitate to elevate things if you think that truth, justice and the American way is on your side, but you should use common sense and common courtesy in doing so.

I'm going to make one final observation about FDA's culture. I'm not alone in this, but obviously, some of us have been trying to raise the Agency's consciousness about the implications of the developing commercial speech case law for the Agency's regulatory scheme. I want to conclude my remarks by discussing this issue in the context of the Agency's mission orientation and distinct culture.

We do realize that the legal paradigm is shifting, and that we cannot afford to put our collective heads in the sand. If the *Washington Legal Foundation* and [Pearson] lines of decisions aren't a wake-up call in that regard, *Western State* certainly was. As you all know, that case marked the first time that the Supreme Court struck down part of the Food, Drug and Cosmetic Act on First Amendment grounds. What is more, the Court said, in passing — and I really do think this was in passing — "Even if the government did argue that it had an interest in preventing misleading advertisement, this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that a drug had not undergone FDA testing and that its risks were unknown."

To be blunt, I'm really not sure that the Court meant this literally or meant it for all it says. Certainly, one could envision a world where certain drugs were marketed under FDA's imprimatur, while others were marketed without FDA's

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approval, so long as they were clearly marked as such. And some would argue that that's really the regime we have in the dietary supplement context. But that's not the system we have, and it's not the system we've had for a very long time.

I want to emphasize that this is a hypothesis, but I surmise that currently, consumers and healthcare providers alike expect that FDA, or at least some governmental entity who they may or may not be able to name, has assured that at least certain products that they're consuming and prescribing are safe and effective. Accordingly, one could contend this as a hypothesis, as a kind of Burkian argument — this is the Federalist Society; you have to mention Burke — that we could not simply shift over to a two-track, disclaimer-based system. Another way that you could put it is that there may well be, hypothetically, a market failure with respect to information about drugs, at the very least, that makes a pure disclaimer-based type of regime unworkable, at least at this point. Again, I emphasize that this is a hypothesis, but these are the kinds of questions that we hope will be addressed in response to the Agency's First Amendment notice.

We know that there are some who believe the FDA shouldn't have to worry about the First Amendment, and others take a completely opposite view. Somewhere between the Wild West and the complete command and control model lies a balanced, thoughtful, nuanced approach that respects the First Amendment, which serves the public health and FDA's mission, and which comports with FDA culture.

With your help — and I do mean that — and with the help of conferences like this one — and I'm sorry I missed the discussion this morning — I am confident that FDA will be able to develop such an approach. But, I'm not saying the task will be easy. As conservatives — again, this is the Federalist Society — we know that change is hard, and it's at its best when it's done gradually. It will not happen overnight, but I personally am optimistic. After all, look at how much the Federalist Society has accomplished.

* Mr. Troy's remarks were part of a conference sponsored by the Federalist Society's Administrative Law and Regulation Practice Group. It was held on May 31, 2002 in Philadelphia, Pennsylvania.

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