ADMINISTRATIVE LAW & REGULATION

SPEECH AND PRIVACY REGULATION IN THE WORLD OF DRUGS AND HEALTHCARE*

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MR. WALLER: I'm the Chair of the Federalist Society's Food and Drug Subcommittee and I'm welcoming you to Speech and Privacy Regulation in the World of Drugs and Healthcare.

The Federalist Society for Law and Public Policy Studies is a group of conservatives and libertarians interested in the current state of the legal order. It is founded on the principle that the state exists to preserve freedom, that separation of powers is essential to our Constitution, and that it is emphatically the province of the judiciary to say what the law is and not what it should be. The Federalist Society seeks to promote both an awareness of these principles and to further their application through its activities and programs like this.

This morning, we have two important topics to cover. The first is HIPAA and Privacy and the second is the First Amendment. Our plan is to have our speaker Paula Stannard and then proceed to the First Amendment panel.

Paula graduated magna cum laude from Amherst College in 1987 and — I found this particularly interesting — she had her degree in political science and Latin. She received her J.D. from Stanford Law School, and she now serves as Counselor to the General Counsel of the U.S. Department of Health and Human Services, where she has worked on proposed bioterrorism legislation, regulatory reform initiatives, and of course the HIPAA privacy rule.

So, without further adieu, Paula Stannard.

MS. STANNARD: Thank you. The first thing I'd like to stress is that the Administration believes firmly in the need for federal protection for the privacy of healthcare information. But we recognize that that protection cannot occur at the expense of patient access to quality healthcare, and not at the expense of the commonsense practice of medicine.

Earlier this spring, we proposed some modifications to the Privacy Rule. In considering how to modify the Privacy Rule, our touchstone was the commonsense analysis of patient expectation. What would reasonable patients expect? We believe that they would expect that the confidentiality of their medical records would be protected, but in such a way that it did not interfere with them getting needed medical care or their ability to communicate with their doctors regarding their health and treatment.

What I'd like to do today is briefly outline the framework of the Privacy Rule and then focus on a couple of areas which are particularly relevant to the food and drug area — adverse event reporting and other public health reporting; research, and marketing provisions.

I will close my introduction with a caveat. We have proposed modifications affecting some of the areas that I'm going to be talking about, and my comments will talk about the modifications. But these proposed modifications are still not the final word on how the Privacy Rule is going to be modified. So, stay tuned.

The framework of the privacy rule. The Privacy Rule governs the conduct of what we call "covered entities". Those are healthcare providers who transmit health information in electronic transactions, health plans, and healthcare clearing houses. Some other organizations and entities provide support services to these covered entities, and are called "business associates". The Rule requires that a covered entity enter into a written contract with its business associates, requiring the business associate to protect the confidentiality of health information.

Now, the Privacy Rule governs the uses and disclosures of identifiable health information. It doesn't govern at all de-identified information. It also requires that individuals receive a notice of covered entity's privacy practices and how the entity uses that information.

There are broad requirements, and very specific requirements also, but there are three categories of types of uses and disclosures by purpose. The first category is use of healthcare information for treatment, payment and healthcare operations. Now, these uses and disclosures are sufficiently related to treatment that an individual seeking care would understand that his health information is going to be used for those purposes. And so, we believe it would be unfair to the providers and other covered entities to create obstacles for use of the information for these purposes. Under the proposed modifications, there is really no restriction or no requirement that a patient authorize the use of his medical records or health information for treatment, payment and healthcare operations.

The second category of purposes that healthcare information can be used or disclosed for is public health or other

public purposes. And in weighing importance of public health versus the importance of individual rights, there are certain purposes that were determined to be of sufficient importance that information can be used or disclosed without an individual's authorization. There are restrictions on how that information can be used, but this category includes such things as reporting of infectious diseases to public health authorities; adverse event reporting; research; reporting of suspected abuse; and healthcare oversight activities.

And then, there's this big third category of everything else, which requires specific patient authorization before his health information can be used or disclosed.

Now, going to specific areas of interest, adverse event reporting is, as I said, a use or disclosure that we have categorized in the public health area. As I said, the rule recognizes the importance to public health and public safety of covered entities being able to use or disclose health information in certain areas for public purposes.

Adverse event reporting falls into this category. It includes adverse event reporting of drugs, biologics and medical devices. As you know, the way an adverse event is reported is that a provider, a doctor, usually reports this information to the company that has made the drug, biologic or device. They, in turn, either voluntarily or as required by law, report that information to the FDA.

The current rule permits covered entities to report adverse events to the manufacturer, if disclosure is made to a person that's required or directed to report such information to the FDA. This includes to track products; to enable product recalls, repair or replacement; or to conduct post-marketing surveillance. We heard, however, that this may not cover the universe of the current adverse event reporting. There was also concern that the rule made voluntary reporting by a provider to an FDA-regulated company impermissible in certain circumstances, where a company was not required by law to report these events to the FDA. So, as I said, we've proposed a modification to assure that a provider can continue to disclose this information to the company.

The second area of interest is in public health and public purpose is research. The research provisions of the privacy rule apply to human subjects research, like clinical research, as well as research involving just health records. A covered entity can only disclose identifiable health information to a researcher, if the researcher has obtained a individual's specific authorization, or if the researcher obtains a waiver of authorization from an institutional review board or privacy board. And if a researcher presents an authorization to a doctor or medical center, or a certificate that an IRB has waived authorization, that provider is entitled to rely on that piece of paper if that reliance is reasonable.

The current Rule establishes eight criteria that an IRB or privacy board has to consider before they can waive the requirement that there's individual authorization of access to the health records. We heard a lot from researchers that these criteria were vague, confusing, and sometimes internally contradictory. So, in the proposed modifications, we have proposed to streamline and simplify that to make it more closely aligned to the Common Rule, which is a rule that is common to about 17 federal agencies that fund medical research and so governs federal research, as well as other research conducted in America.

As I said, these proposed criteria more closely follow the common rule but apply specifically to privacy considerations. And the first criteria is that the use or disclosure of the health information involves no more than minimal risk to the individual's privacy. We've explained what that means: It means adequate planning to protect identifiers from improper use or disclosure; an adequate plan to destroy identifiers as soon as possible consistent with the needs of research; and adequate assurance that there's no reuse or disclosure of the information, except for other research, for oversight, or as required by law.

The second criteria is that the research could not practically be done without the waiver; the researcher couldn't go out and get individual authorizations. And finally, the research could not practically be conducted without access to the protected health information. In other words, this health information is necessary to the research.

We've also proposed a couple of other modifications to simplify just the administration of the privacy rule in the research area by combining the requirement for authorizations for various types of research and by combining of an authorization to disclose health information with informed consent. Then, there are certain proposed transition provisions that permit current research to continue without hindrance.

I indicated that there are two ways that a researcher can get identifiable information under the privacy rule. We're looking at another way to enable researchers to get information. The current rule doesn't apply to de-identified information, as I indicated earlier. But de-identification requires removal of 18 types of information, and many researchers indicated that they really need some types of information that was included in those 18 categories; information that doesn't directly identify the patient, but nevertheless contains certain identifiers, such a zip code or dates of admission or discharge. As I said, this information is not considered de-identified under the Privacy Rule, but it is necessary for certain research or for analysis of healthcare use or quality for state hospital associations, for example.

We've sought, through the comments received during the comment period, input on how to construct a limited data set that could be used for such purposes, what types of information would not be facially identifiable, what type of information that would be, and what purposes such a limited data set could be used for. You couldn't directly identify someone by that information but it would be useful for research purposes. We're proposing that a covered entity be required

to sign a data use agreement with a researcher or whoever receives this limited data set to control the use of that information by the researcher and prohibit reconsideration.

The final topic that I'd like to talk about briefly is marketing. In general, if someone desires to use identifiable health information for marketing purposes, it requires patient authorization.

The current rules establish three categories of types of communications and establishes different Privacy Rule with respect to how identifiable health information can be used. There are certain communications that are not considered to be marketing and do not require authorization. There's another category of communications that is considered marketing but doesn't require an authorization. But the provider has to provide notice to the individual whose health information is being disclosed and marketed, identify who's making the communication, if the covered entity is receiving payment for this communication, how can opt out, and the basis for targeting the individual. And then there's a third category that requires specific authorization.

Everyone agreed that these three categories were confusing and that no one was sure whether a communication fit into which one of those categories. We've attempted to propose common sense modification to these marketing rules using the understanding that patients don't want their health information to be used for unsolicited marketing pitches that have nothing to do with their care. But they do want to receive information about their treatment alternatives and, for example, benefits and services offered by their health plans or healthcare providers. This is certainly one of the areas in which we've received the most comment on.

Our proposed revision is to have just two categories — marketing and not marketing. Marketing will require an authorization by an individual. Communications not considered marketing would not. We excluded from the definition of marketing communications on treatment for the individual; communications about the individual's case management or care coordination; communications to recommend treatment or therapies or different providers; and communications about plan or network providers and products and services that a plan or provider has.

These modifications, if adopted, would permit prescription refill reminders, recommendations of alternative treatment — things like that. I should note that regardless of what modification is proposed, a covered entity is required to disclose in the notice of healthcare privacy practices that they give to their patients if they're going to be using the healthcare information to communicate appointment reminders or information about treatment alternatives or other health-related benefits and services. This provides an opportunity for the patient to object to such a use or to request limitations on their use.

I look forward to your questions on the privacy rule and other aspects of HIPAA. Thank you.

MR. WALLER: Do you have any practical tips for HIPAA compliance? What should people really be focusing on right now?

MS. STANNARD: I think the most important question that people should be focusing on is whether your company, entity or organization is a covered entity. That requires looking at whether they are a "health plan," as defined both in the statute and the regulations. Both the statutes and regulations provide a long list of specific health plans that are included, and then throw in any other organization that provides or pays for healthcare.

Is it a "healthcare clearinghouse?" A clearinghouse is more rare. Basically, they obtain health information and payment information in one form and convert it to another form. They are basically serving other healthcare organizations.

And the third is, are you a covered "health provider?" That is limited at this point to providers who conduct electronic transactions for which the Secretary of HHS has adopted standard form transactions. One caveat to that. The original law permitted healthcare providers — doctors, pharmacists, hospitals — to choose whether or not to conduct electronic transactions, and thus, whether or not to be subject or not to the Privacy Rule and the other HIPAA transaction rules. However, in providing under the Administrative Simplification and Compliance Act for this extension of time to comply, Congress also told HHS, and specifically Medicare, if transactions are not submitted to them in electronic form, they have an obligation to deny payment. Of course, there are certain situations under which the Secretary is authorized to waive that requirement, but that's certainly an incentive for more providers to conduct electronic transactions.

MR. WALLER: If you're doing clinical trials for FDA approval and you're precluded from having any patient identifier information, how does HIPAA apply to you?

MS. STANNARD: I don't know exactly what identifiers FDA considers to be identifiers. But there's a very long list of what we consider under HIPAA, under the Privacy Rule, to be identifiers. There are some things that you wouldn't immediately think of as an identifier, such as a county of residence, a zip code, things like that that are important for certain types of research. If you need that type of information, then you either have to get an individual's authorization in order to obtain any identifiable medical information, or you need to go through an IRB process to get a waiver.

As I said, we are proposing and looking at a third option, which is a more limited data set that excludes facially

identifiable things — probably some things that under FDA are considered to be identifiers— that we could permit you to obtain as a researcher under a data use agreement, where you say you're not going to use it for any improper purpose.

AUDIENCE PARTICIPANT: Is there a private right of action under HIPAA?

MS. STANNARD: I think that, as with enforcement of any regulation, there'll be a broad range of approaches. We're certainly committed to providing assistance to covered entities in understanding what the Rule requires and complying with it. One of the things that we're working on right now is some material that we can provide to help entities to determine whether they're covered or not. Obviously, HHS is required to investigate any complaints that it receives, and the Privacy Rule sets up some type of procedure for complaints to the entity, if someone thinks that their privacy rights have been violated, and also a complaint process, in the case of privacy, to complain to the Office for Civil Rights at HHS.

MR. WALLER: We thank you Paula for your comments and we will now move on to our First Amendment panel.

(Whereupon, the first segment concluded.)

MR. WALLER: We're honored to have two eminent scholars in the First Amendment area here with us. The first is Richard Samp, who is the Chief Counsel to the Washington Legal Foundation. Richard is a 1974 graduate of Harvard College, and he received his law degree from the University of Michigan. He was previously a litigator at the D.C. law firm of Shaw Pittman. And Mr. Samp served as the lead counsel in the *Washington Legal Foundation v. Friedman*, the case that led to the District Court decision striking down, on First Amendment grounds, FDA restrictions on the dissemination of truthful information about off-label uses of approved products.

Second, we have David Adams. He's a partner at the Venable Law Firm in D.C. He has a B.A. from the University of Louisiana, and he's a graduate of the New York University School of Law. He teaches food and drug law at the George Washington University Law School. And he was former FDA associate chief counsel for drugs in the Office of Chief Counsel, and director of the Policy Development and Coordination staff in the Office of the Commissioner at FDA. He's published numerous articles and is an expert on FDA constitutional authority.

MR. SAMP: The whole idea of First Amendment restrictions on what FDA can do is a relatively recent concept. It's something that really wasn't discussed up until about 20 years or so ago, and that's really because up until then, the Supreme Court had consistently said that commercial speech isn't protected by the First Amendment. Only since the late 1970s has commercial speech begun to get increasing amounts of protection. As that protection has increased over the last two decades, the issue of what restraints there are on FDA has become increasingly prominent.

There are still, however, many restraints on anybody actually raising First Amendment claims against FDA. Probably the biggest constraint is the agency's extraordinary power. The fact is, as everyone knows, FDA has authority not only to regulate manufacturers, but also to approve their new products. Manufacturers generally believe that one should not directly take on FDA, if one wants to get one's new products through the pipeline. Perhaps it's not much of a coincidence, therefore, that some major First Amendment cases that have been litigated in recent years have not been brought by major pharmaceutical companies.

The Washington Legal Foundation, as Bill was mentioning, has been involved in litigation for a number of years, and we expect we probably will be again. WLF is simply an interloper in Washington that gets involved in various agency matters and tries to do what we think is in the public interest, which usually means greater dissemination of information and less government restriction on what companies can say.

The difficulty, of course, for someone like WLF is how do we get into court. We've had problems with that in the past, and I'm sure we will in the future, as well. The nice thing about First Amendment claims, however, is that it's not just the speaker who has the right to assert them. The listener does, as well. The Supreme Court has said that a listener who's feeling as though he's not receiving as much speech as he would like has the standing to go into court and sue, and to say, "I want to do some more listening". That's sufficient by itself to get into court on First Amendment grounds.

The difficulty, however, in getting into court with FDA is compounded by the fact that FDA, as with most government agencies, has available many procedural defenses. Chief among them is that the action being brought against the agency is either not a final agency action, or it's not ripe for review. And the best way for an agency to ensure that these defenses will be available is not to write final regulations. Rather, an agency will write lots of guidances and draft guidances, documents that try to give the industry a little bit of an idea of which way it's coming from. But it also gives the agency deniability, so that if industry tries try to challenge what you've said, you can say, well, that was just the opinion of the individual letter-writer or the musings of an agency official, but it really does not represent official agency policy.

Further complicating efforts to obtain judicial review is the fact that FDA is constantly reviewing all these various issues. On the one hand, I think it's a great thing that FDA is studying First Amendment issues and claims to be very concerned about First Amendment matters. Indeed, about two weeks ago in the *Federal Register*, FDA put out a very

lengthy notice in which it invited public comment on just what the First Amendment ought to mean to the agency, and that's a very good development. In fact, Dan Troy, FDA's Chief Counsel who likely had a good deal to do with FDA's publication of the notice was one of WLF's attorneys in our First Amendment litigation.

But the downside of FDA doing these sorts of studies is that if anybody attempts to bring FDA to court, it can argue that litigation is premature because it is studying this issue; it argues that the litigants should wait until FDA is done studying the issue before filing suit. WLF initially filed its lawsuit over the dissemination of off-label information in 1994, and it took several years to convince the court that it was not premature to take a hard look at the issue. We did win a First Amendment judgment in the district court; but then FDA, after we won, changed its policy. And whenever you have a change in policy, there's a question of whether the original decision is in any way moot?

The case went up to the court of appeals in 2000. The U.S. Court of Appeals for the District of Columbia Circuit said that a portion of our case was moot, and we've been arguing with FDA ever since about exactly what portion of the case is moot and how much leverage we have in trying to guide future FDA actions in this area.

By far the best development in this area — and it's noted in your materials — is that the Supreme Court several weeks ago, in the *Western States* decision, for the first time weighed in on the issue of FDA and the First Amendment. The mere fact that there is now a statement from the Supreme Court saying essentially that the First Amendment applies fully to FDA, just as it does to other government agencies, is a tremendous step forward.

For example, one argument that FDA has repeatedly made in defending against First Amendment claims is that because the pharmaceutical industry is a heavily regulated industry that has become used to having its First Amendment rights denied over the years, it has essentially waived those rights. A heavily regulated industry simply doesn't have as many First Amendment rights as other do. After the *Western States* decision, that is a very difficult argument to make.

Probably the most important First Amendment issue involving FDA regulation that's likely to be litigated in years to come is the issue of direct-to-consumer advertising. The issue is the subject of on-going debate in Congress. Opponents of direct-to-consumer advertising repeatedly argue that some of this advertising is misleading. The simple response to that argument is that one misleading ad does not justify blanket restrictions. If an ad is misleading, tell us how, and we take care of the problem by putting disclaimers into our advertising.

But when it comes down to it, I don't really believe that the misleading nature of some ads is the main reason that some people want to restrict advertising. The objection is not that anyone is really being misled, but that really they're getting too much truthful information. Opponents believe that too much information is not good for people because, after all, that gets people thinking that maybe they are due for some new treatment and talking to their doctors, and maybe they'll pressure their doctor into writing a prescription that the doctor may not think is absolutely necessary. Increased prescription-writing leads to increased medical costs. Many people, particularly state governors, are looking for ways to hold down their medical costs. They object to increased advertising, which is highly likely to lead to increased spending on prescription drugs. So, the real First Amendment battle coming up is over efforts to suppress advertising as a means of suppressing consumption of prescription drugs. WLF opposes any such suppression efforts and we certainly intend to be part of that battle as it continues.

I have to say in fairness to FDA, that they have loosened up considerably in the area. In 1997 the FDA significantly relaxed its rules on direct-to-consumer advertising in broadcast media; and as a result, you see quite a bit more advertising on TV than you did before. Manufacturers are allowed to advertise without having to include thousands of words of disclaimers that nobody would read anyway. There are still problems with excessive FDA restrictions on print media advertising, particularly in terms of disclosure requirements that even FDA doesn't really think are necessary. But even in that area, FDA is not enforcing its restrictions as tightly as it used to.

The result is that we are getting more print media advertising than we used to. And it's also true that we're getting a lot more drug advertising in this country than in any other country that I'm aware of. In most other countries, prescription drug manufacturers may not advertise directly to consumers. The general feeling among regulators in other countries is that consumers simply don't know enough to be able to handle the information that you can give them.

So, what direction should FDA be taking? The Federal Trade Commission has provided over the years a very good model. Advertisers are not required to go to the FTC ahead of time for permission to say truthful things about their products. Rather, advertisers can be sanctioned by the Federal Trade Commission after the fact, if they provide false or misleading speech. But the FTC never requires prior approval. Although FDA sometimes claims that it, too, does not impose prior approval requirements, the practical effect of FDA rules believes those claims — most manufacturers still go to FDA in advance to get approval for what they're going to be saying in their advertising.

With respect to WLF's litigation to prevent FDA from suppressing truthful off-label information, I have to say that we are disappointed that FDA has not seen fit to agree with us that we actually won our litigation. In January 2002, FDA denied the citizen petition that WLF filed, asking FDA to state that it would comply with the court order we won. Exactly where WLF is going to take the issue from here, I don't know. We may end up back in court with FDA. That remains to be seen. But there is reason to hope that FDA's respect for First Amendment rights will increase. On the one hand, FDA denied WLF's citizen petition and insisted that it has the absolute right, if it wants, to prevent manufacturers from disseminating

what are known as "enduring materials". (That is a category of written materials that includes both reprints of medical journal articles and medical texts.) These are the kind of things that FDA doesn't really think are false; but it nonetheless insists that since they have not been approved by FDA, manufacturers shouldn't be allowed to disseminate them.

But on the other hand, FDA has made it clear that they are not going to go after any manufacturer who simply disseminates enduring materials. It's only if manufacturers go beyond such dissemination that FDA is likely to crack down hard on a manufacturer for promoting off-label use of their products.

One final issue needs to be addressed. One tactic FDA has used to avoid First Amendment constraints is to claim that it's actions aren't really speech prohibitions at all. All we are doing, FDA insists, is using your speech as evidence that you really do have an intent to distribute your product for an unapproved new use. Because such distribution is a violation of the law, FDA insists that it's really your conduct we're going after, not your speech. I don't believe that any court would actually uphold that argument. FDA made that argument in the *Western States* case in the Supreme Court. The Court didn't address it; the fact that the Justices didn't address it despite the fact that it was raised suggests that the Court didn't think very much of the argument.

FDA's argument makes little sense. In effect, FDA is admitting that it has no objection to the drugs you are selling or how they are labeled. But the moment you engage in speech (by disseminating enduring materials that discuss off-label uses of your approved products), FDA will suddenly deem your otherwise unobjectionable sales activity to be a violation of the law. That's just a roundabout way of banning speech. We will continue to work with FDA to try to convince the agency that it cannot avoid First Amendment restraints by pretending that it is not regulating speech at all.

In conclusion, we've come a long way in the last decade in terms of increasing FDA respect for First Amendment rights. There has been considerable improvement in the area. Moreover, there are very good people at FDA and HHS right now who are aware of the problems and are working to curb First Amendment violations. There's obviously a lot of battling against the forces of darkness in this area that is still to come, but I'm hopeful that things will be improving in the future. Thank you.

MR. ADAMS: Good morning. It's a pleasure to be here with you folks. Bill was talking about the positions that I had at FDA. I left FDA about eight or nine years ago, going into private practice, and I represent generally drug companies, medical device companies, and companies that develop and market therapeutic products. And I was thinking before I left the agency, I used to quip that the Bill of Rights started at number two.

As Richard has alluded, over the years FDA has taken a fairly restricted view of the applicability of the First Amendment or of the restrictions in the First Amendment on FDA's regulation of advertising, promotion, and commercial speech. It has even argued that there perhaps should be a general exception for this special kind of industry that FDA regulates, pervasively regulates, in the arena of healthcare because these are healthcare products.

As Richard also has stated, the courts haven't really warmed up to that theory on the part of the agency. And so really what people have been talking about in the courts is an analysis of FDA's regulation of advertising under the commercial speech doctrine.

Before I get too much further into this, I ought to start giving my disclaimer, which is going to be a little different from the usual disclaimer because one's views, a lawyer's views, an advocate's personal views, are not always the same as the views of the clients that one represents. I was certainly well aware of this when I used to read Richard's briefs, and I knew deep down in his heart of hearts he couldn't possibly believe all of the things he said about FDA and about the dire things that were going to happen if the courts really applied the First Amendment. So, my disclaimer is that the views expressed here today are not necessarily the views of my clients; they're not necessarily my views. In fact, they're the views of Richard Samp, and this is what Richard really believes.

I think the Supreme Court case that Richard spoke about, the *Western States* case, is profoundly important, and I want to tell you why I think it's important. I'll start by giving a little bit of background on how FDA regulates promotion, advertising, commercial speech.

The agency has traditionally placed significant restraints not just on misleading or untruthful information but on information that may well be truthful and non-misleading. It wasn't really FDA who started this; it was Congress, when Congress wrote the Food, Drug and Cosmetic Act, which is in large measure one big prior restraint on truthful and non-misleading speech, especially when one looks at approval requirements in the Act, where FDA approves labeling word for word for products and approves them for specific uses. This concept is built into the Act.

There are also provisions in the Act about how products have to be labeled. The courts and the FDA have the view that the Food, Drug and Cosmetic Act really requires products to be labeled for all of their intended uses, all of the uses suggested by the manufacturer in any way. So, if you suggest a use, then it's supposed to be in your labeling under the Act, and if it goes into your labeling, then it's probably going to have to be approved, if your product is a drug. What that means is, there's a big restraint on your ability to talk about certain possible uses of your product because under the law, they become intended uses and you have to get them approved. So, you can't say that until you get approved. That's a prior restraint.

You see it in the area of promotion or dissemination of information on off-label uses of approved drugs. This was the primary concern dealt with in Richard's case, the *WLF* case. You had approved drugs, approved devices, biological products, but FDA was saying that companies — not that it was a total restriction on dissemination of information on off-label uses, on approved uses, but there was a rather significant limitation — FDA had certain exceptions, certain safe harbors, under which you could provide information. Generally, the rule was that you just couldn't do it because, as soon as you did it, that would be your intended use, and you'd have to put it in labeling. So, you'd have to have your product approved before you promoted a use for it.

The second area in which FDA has gotten into the business of restraints on truthful, non-misleading speech, is in creating exceptions to the statutory approval requirement — generally the statutory approval requirement for drugs. One exception was for health claims, for foods. We started quite some time back.

Remember Kellogg's All-Bran cereal? Suddenly, All-Bran cereal, quoting the NIH — certain kinds of bran can prevent cancer, prevent a disease. Well, the drug definition says any articles intended to prevent a disease is a drug. Did FDA want to say that All-Bran cereal was a drug? No, they really didn't want to say that, especially when the NIH said it was a good idea to give that information. So, they developed a policy allowing certain kinds of health claims for foods that otherwise would have been drug claims. It's an exception to the rule. If you do it a certain way and we okay it, we will accept you.

Congress ultimately put this approach into the statute. You have to go to FDA with a certain kind of evidence and the FDA has to approve it. But the basis for the approval really restricts the way you can talk about this issue and talk about your evidence. So, the way the exception works is to limit your freedom of speech. And you can't really just have that general limitation of speech. You ought to be able to say things with appropriate disclaimers; that's the *Pearson* case.

Another area is what we saw in the *Western States* case for restrictions on compounding. Compounded drugs are new drugs theoretically requiring approval. That was FDA's position. It wasn't always totally clear, but the Supreme Court really seemed basically comfortable with the FDA's position that all of these drugs compounded by pharmacists start out being new drugs requiring approval. That's rather stunning. That means they're all illegal. It's an interesting discussion about that, that I'd like to get into, but I need to focus on the issue at hand.

FDA created an exception. Obviously, they had to. They can't stop pharmacists from compounding drugs. But, there's no way a pharmacist can run out and get approval for every drug compound. But the exception incorporated a number of elements, one of which was restrictions on advertising, promoting specific drugs — "we compound this drug, that drug, the other drug." The Supreme Court said, no, you can't condition the exception based on this limitation on speech, if there are other ways to achieve your noble ends in this situation.

Another situation involved things that were at issue in Richard's case. FDA had created certain exceptions. FDA called them exceptions — safe harbors from what FDA said was a general rule against promotion of off-label uses. If you were involved in real educational programs, supporting real educational programs and disseminating certain kinds of articles peer reviewed in certain kinds of circumstances, that was an exception. Richard challenged those policies, saying, you can't really have these limitations. FDA doesn't really have authority here.

The court agreed with Richard, but only up to a certain point. The court really didn't go all the way there. The court agreed that FDA's restrictions were not narrowly enough prescribed in terms of what the government's interest is. We have this notion under commercial speech, under the commercial speech test, that if the government has an appropriate goal and is directly advancing the goal, it still should restrict speech no more than is necessary. We've called it in the past the least restrictive means test, and the Supreme Court has flipped around, and sometimes it doesn't sound so restrictive. Now it sounds very restrictive.

The district court in the *Washington Legal Foundation* case didn't throw out all of FDA's restrictions on speech in that arena. The court said, no, FDA has been too narrow here. We think companies ought to be able to participate in continuing education programs and suggest speakers. We think companies always ought to be able to give out peer-reviewed articles, always ought to be able to give out published textbooks, things of that sort. But the court didn't go all the way and say other truthful, non-misleading speech is also constitutionally protected.

So, the third area where FDA regulates truthful, non-misleading speech is the area of pre-approval promotion. This is an area that has not gotten a great deal of attention, and that's surprised me quite a bit because my own view is that this is the most vulnerable arena of FDA regulation under the First Amendment. Companies are restricted in FDA's view, in saying things about products before they're approved. Before they're actually marketed, FDA will say you are violating the law if you start talking about your product before we approve it. That's interesting.

If you're not marketing, the statute really says you can't do this, that and the other — basically, introduce into commerce or hold for sale a product unless you do certain things, get it approved. If you're not doing that, if you're not yet selling your product, how is it a violation? The FDA says, well, you're commercializing an investigational exemption. You're somehow commercializing your product. And the statutory basis for that sort of regulation is, in my view, very questionable. And if you look at the theory behind that sort of regulation, the theory that you're commercializing an IND or commercializing a product before it gets approved, well, that doesn't really square with the only valid interests that the courts have accepted

in terms of FDA's regulation of commercial speech. FDA has talked about the commercial speech doctrine not really applying because these are healthcare products in a pervasively regulated industry.

FDA also earlier on talked about its general interest in preventing misleading information and discussions about products, before they get approved, as being inherently misleading. The agency hasn't gotten very far with that theory. But the courts have agreed — even Richard Samp's favorite judge, in his case — that FDA has a valid interest in preserving the integrity of the drug approval process and having incentives for people to do good studies, get their drugs evaluated and approved and get this good information and labeling. That's a valid interest, and hardly anybody can disagree with that.

But in the area of pre-approval promotion, how is that interest furthered? It's not a disincentive; it's not going to prevent people from getting their products approved. In fact, it occurs in a situation where the company is trying its darnedest to get a product approved. It is hoping for an approval in the near future. So, the basis for that sort of regulation is not clear under the statute, and it's kind of hard to square with the only valid interest FDA has asserted that the courts are willing to accept in terms of regulating commercial speech.

Again, let me emphasize what this primary governmental interest is that the courts are accepting and that become the basis for evaluating FDA's authority. Is the government's interest in preserving the integrity of the drug approval process, in having a real incentive for people to go through this process? If they can go out and promote their products without going through the process, why would they spend millions of dollars to do really good studies and go through and jump through all the hoops and get their drugs labeled and have FDA totally control their labeling? There wouldn't be very much reason to do that. Most people seem to agree. That was the reason that Congress, when it was putting some of these provisions into the Act under FDMA did so.

So, when you look at that basis for the government's regulation of commercial speech and you look at what the Supreme Court was starting to say not just in the *Western States* case but a few years ago in a case called the *Liquor Mart* case, you start worrying about FDA's position, if you're an FDA person. I started writing an article on this issue after the *Liquor Mart* decision because what the Court was saying there was — the Court had come up with a very restrictive standard in terms of assessing whether there is more regulation than is necessary in terms of regulation of speech.

The Court had come up with a very strict interpretation and application of this least restrictive means test. The Court said, really, you have to look at whether there are any alternatives, any legislative alternatives — not just does FDA have a regulatory alternative to restricting speech, but could the whole system fundamentally achieve this government interest. And by some program or some means, some legislative enactment that wouldn't restrict speech as much as this one does. The court said that the burden is on the government to show that there isn't some mechanism, some form of legislation, that could advance the government's interest, that would restrict speech less.

The court didn't say that the alternative had to be a necessarily politically realistic alternative, so what does that mean? The government essentially has to prove a negative, that there is nothing Congress could do that would achieve our governmental interest, other than restricting speech — not just that there's nothing Congress can do practically, but if one theorize a Congressional enactment, that might well be an alternative because the court hasn't suggested that your First Amendment rights depend on whether the alternative is a political reality; only that there's a legislative alternative. That's going to have to be fleshed out, but that could be an extraordinarily difficult burden for the government.

So, what does all this mean at this point? It means, first, that FDA is going to have to look to changing its regulatory paradigm. It ought to be doing that now; I'm sure it is. And the regulatory paradigm is going to have to be focused on the government's interest in protecting people from misleading speech. This concept of being misleading is pretty broad, the courts agree that it's pretty broad. FDA will probably end up focusing on ensuring that the information that people provide is balanced and includes not just the positive but the negative. Also, that it's substantiated and that the lack of substantiation or that the problems are really discussed and emphasized.

Now, FDA hasn't done too much of this in terms of preventing information on off-label uses and this sort of information because it really hasn't had to. But now, they're really going to have to look at that. The fact of the matter is that the courts have been pretty kind to affirmative disclosure requirements. The conservatives on the Supreme Court have always talked about more information being better. In the *Pearson* case, the court talked about the fact that there ought to be disclaimers. I believe FDA has a lot of room to operate in terms of regulating this kind of speech by requiring more information, by requiring balanced information. I think creative lawyers at FDA, if they really sit down and noodle this, are going to find ways of restricting speech and regulating promotion that you don't necessarily see out there now. I think this is possible, and I think it will happen.

The second thing — what we have now, I think, is probably the most significant policy development, or change in policy, since the 1962 amendments, where the approval requirements were engraved a little more firmly into stone, the breadth of products. The scope of products that have to go through the approval process for drugs I'm talking about was broadened considerably, and the standards were tightened extraordinarily by bringing in a requirement of proof of effectiveness, based on adequate and well-controlled clinical investigation. This is rather significant.

But what we have now, in the face of the Supreme Court decision and FDA's reaction to it, I think, presents the potential for another significant change in how the agency regulates the industry; not just drugs, not just in the arena of

therapeutic products, but also in terms of food and dietary supplements. But I think, more significantly, in the arena of therapeutic products. And I think the industry really needs to focus on this and participate very aggressively in this policymaking and policy development process. I think there is a potential for extraordinary change in the way FDA does a large part of its job.

The third thing is that I think the General Counsel's Office at FDA has a responsibility now to go out and educate the regulatory centers within FDA — this is the Center for Drugs, Center for Foods, Center for Medical Devices and Centers for Biological Veterinary Medicine — about what's happened. Something significant has happened. Essentially, the law has changed in a really significant way. And you say, well, constitutional law never changes.

In the case of the First Amendment, there isn't much text there to tell you specifically what the First Amendment means; it basically says Congress shall make no law abridging freedom of speech. The First Amendment really means what the Supreme Court says it means, and that's it. And the Supreme Court over the years is constantly changing what it says the First Amendment says. So, this very fundamental component of the law is constantly changing.

The Supreme Court for a while said there wasn't even any protection for commercial speech. And then they came up with this elaborate analysis of commercial speech that you go through, and they had been changing the rules for working in that elaborate analysis. Currently, after the *Liquor Mart* and *Western States* cases, the rules have changed significantly. FDA's General Counsel's office really needs to communicate this to the agency's regulatory components because people in industry are going to start exercising the rights that the Court has pretty strongly suggested that they have here, and realize that the *Western States* case was looking at FDA's regulation under the Food, Drug and Cosmetic Act. The Court examined the government's substantial interest in the integrity of the drug approval process and said it isn't enough. Five members of the court said that.

Companies shouldn't be left in the position of going out and doing these things and telling the Centers — having to literally challenge the way the Centers have done business for years and years, based on understanding that there's a bright-line test, that you can't do pre-approval promotions and you can't promote off-label uses. The General Counsel's office needs to quickly educate the Centers that this sort of thing is going to happen. It's not happening because these companies are bad players or don't respect you anymore; it's because the law has clearly changed.

I think the initiative that we saw published in the *Federal Register* to examine these First Amendment issues as part of that process — but I think things are going to start changing before FDA finishes that process, and I really call on the General Counsel's office to start going out and talking to the Centers about what I believe is going to happen.

AUDIENCE PARTICIPANT: I don't know whether either of you speakers have had the opportunity to read the Washington Post editorial[1] by former employers of yours, Mike Taylor and Bill Schultz. I don't know whether the audience is familiar with that editorial and what it says, but I was wondering whether if you have had a chance to take a look at it and whether either of you would like to comment on it. One of their examples was, could you say that the product will make people better, when the product itself may not but one is likely to get better just by the passage time, by letting the disease run its course. I think that the specific criticism made was that the process of opening the docket to discuss the issues was an inappropriate step.

MR. SAMP: I certainly disagree. I think it's appropriate that we are discussing these kinds of issues. As I said before, I think the real agenda of many people, such as Mr. Taylor, isn't so much that they are afraid about misleading speech getting out there, but that they really would just as soon have less speech, allow the experts to control what gets done in the area, and then maybe you wouldn't have quite as much medicine being consumed. And so, they object not only to increased First Amendment rights but even any discussion of the area because they're afraid of what might result from that.

MR. ADAMS: I don't agree with Richard. But I also don't agree with everything that was said in the editorial either. I do think that what they said reflected legitimate concerns on their part and on the part of people who have been involved in regulation in the healthcare arena over the years. There is potential harm from talking about off-label uses, talking about products in a pre-approval situation where a product's claims may not be substantiated. They pointed out one instance involving flecainide and encainide, where there was a significant off-label use and it turned out to raise some significant risks, and there was a concern that if this had been allowed to have been promoted by the companies, it would have been far worse. In fact, that's true. The discussions and promotion of off-label uses will amplify off-label use, it will amplify the effects of off-label use, and sometimes those effects can be bad. Sometimes, they'll be based on not enough information, not properly evaluated information, and it can amplify bad effects.

But you also have to acknowledge in the same breath that it amplifies a lot of good effects. An awful lot of information that comes out before FDA approves it is good, valuable information that may well save lives. To the extent that companies talk about that, the more that information gets out, you also have an amplification of positive effects, and you have to consider both those things in developing a policy.

I also think that the article really shows up why the fundamental problem is legally here for FDA. If you really look at what they were concerned about, one was the possibility of someone saying something truthful, if you drink colored water,

you might have a 50-percent chance of recovery, and in fact you'd have a 50-percent chance of recovery anyway. That would be misleading, and also the possibility that these off-label uses might be bad and that you would amplify the bad effects.

But really, the problem is if you look at the legal basis for what FDA is doing or trying to do here, the government interest that FDA says it's trying to protect is not really based on misleading information. In fact, FDA has authority to police misleading information, and FDA has authority not to allow people make statements about colored water being 50-percent effective. That's misleading on its face, I believe, and FDA could in fact require people to provide balanced information when they start talking about uses of products.

In terms of the off-label use being amplified, the government itself endorses off-label use. The government thinks that is a good thing. And the government is really asserting just an interest in court of keeping an incentive for products to go through the drug approval process. The problem is, if that's the only interest you can identify, there are really these alternative mechanisms out there by which Congress could encourage to go through the drug approval process without restraining speech.

The concern, you know, is really more on immediate effects in the public health for misleading information and harms to the public. But those immediate effects, from an amplification of off-label use and from misleading information don't get directly tied in to what the government asserts its interest is here. That's what the conundrum is.

I think what the General Counsel's office is doing there is something that they have to do. They have to go through an evaluation and try to develop an evidentiary record to support whatever the agency's going to do. I'm not going to presuppose to tell you what's in the back of their mind or whether they want to undo restrictions and totally open up the agency to broad notion of the First Amendment that ends what the agency's able to do. But the agency has to conduct this assessment at this time, and it's good to get people's views on this issue, and I think that's what they're doing.

AUDIENCE PARTICIPANT: My question is a follow-up on the flecainide and encainide issues. It seems to me that the current restrictions on dissemination of off-label use either by doctors or by other people in the marketplace is reasonable. So, the flecainide-encainide situation actually occurred in the circumstance where such off-label promotion would be illegal.

If the company were able to discuss the alternative use and the limitations and provide disclaimers, then the argument could be made that in fact a circumstance that existed in this situation was made worse by the agency's restrictions of speech, rather than permitting dissemination, especially when the restriction is on doctors.

MR. SAMP: I agree with you. And I think there's nobody who knows more about a product, generally, than a manufacturer. Yet, doctors can say anything they want about the product, the one person who generally prohibited from giving unsolicited speech is the manufacturer, and they kind of have to wait by the phones for somebody to call up and ask. I suspect they'd have a lot more accurate information out there, if they were a larger player in the field.

MR. ADAMS: The answer is that might have been true; perhaps, it probably would have been true. But in many cases, it wouldn't be true. And in many cases, you know and I know, having worked at FDA and seeing usually the worst things that go on in the world, there's quite often an inclination of companies not to really provide the most balanced view of what the science is, because they want more use of their product, because shareholders want greater profits. And that's what FDA's concerned about.

I think FDA's view on that might be, okay, it might have been better if we'd let the company disseminate information which would be balanced information. And maybe FDA will now say we're going to go the next step and come up with rules about how companies give that out to make sure companies give balanced information. That might be their response to your question.

AUDIENCE PARTICIPANT: Since the Federalist Society is a conservative/libertarian organization, or at least it purports to be, I'm a little perplexed — I've been perplexed at other Federalist Society meetings — that I rarely hear true libertarian positions. I'm wondering whether anybody on the panel is willing to address the issue of what type of government regulation at all is justified in the FDA area. We all seem to just argue about the nuances and positions of various forms of regulation, without getting to the basic question of whether the free market tort system is adequate to deal with the issues that the government and the FDA face.

MR. SAMP: As somebody who shades toward being a libertarian, I can tell you that there are a lot of government agencies that I would vote to abolish, but I don't think I would vote to abolish FDA. I think the public demands somebody out there so that they can rely on to do something. And if there's ever a food scare or a health scare, always the first question is, where was the government protecting us?

People demand something like this, and I think it definitely leads to a lot more increased confidence in the market and we have a much smoother securities market in this country because of the SEC, and we have a better food and drug delivery system in this country because of the FDA. That's not to say that I like the agency all that much, but it's better than no

agency.

MR. ADAMS: And I can't help you. Bill told me I'm supposed to be here as the guy you throw tomatoes at. I'm not really a libertarian. I would be worried if there wasn't an FDA out there policing the industry and what they say and making them do good studies.

[1] William B. Schultz and Michael R. Taylor, Editorial, *Hazardous Hucksters,* Wash. Post, May 28, 2002, at A17.

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