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A Practical Path -- Does the First Amendment Matter?

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Effects of First Amendment Cases

- **Office of Compliance personnel are now aware of the First Amendment rights of companies and consider it in their enforcement actions**
- **But, FDA still wants to protect its approval/clearance franchise**
  - If companies can advertise a new indication without approval, perhaps they will not do clinical trials to advance knowledge
- **FDA is shifting to control of indications as a result**

Central Hudson

- **Established a four-part test, as discussed by Rich Samp**

1. **Threshold issue: Does the commercial speech involve unlawful conduct or is it misleading?**
   - If so, the commercial speech is not protected by the First Amendment
2. **If speech passes the threshold issue:**
   - Is the governmental interest substantial?
3. **If so, does the regulation directly advance the governmental interest?**
4. **Is the regulation more extensive than necessary to serve that interest?**

My view is slightly more forgiving than Rich Samp's

1. There is a substantial government interest: protecting the PMA approval system and protecting the scope of indications for both 510(k) and PMA products
2. Silencing companies directly advances that goal
3. However, FDA runs wild in its violation of criteria four: FDA wants total and absolute control of speech

What do we do?

- **Even though WLF wishes for us to be more combative and to face down the FDA's unconstitutional behavior:**

WHO WANTS TO BE FIRST?

So, how do we balance FDA's desire to unconstitutionally control us, without suing them?

1. **Get tight control of your process**
   - Use a Standard Operating Procedure (SOP) for promotion
   - Train early and often to keep accidents from determining your ad policy
2. **Use all tools FDA provides**
3. **Mention the First Amendment in any compliance activity**

SOP

- **Build your promotion into your quality process**
- **Start with a claim chart at the inception of product planning and update continually as testing either proves or disproves parts of your claims**

SOP (cont.)

- **Have a written process for all parts of development of promotional material**
  - What are the standards
  - Who signs off
- **Have a process for all modes of dissemination**
  - Oral
  - Written
  - WLF distribution of articles

Using the Tools

- **Work with your lawyer and regulatory staff to use every mode FDA allows for early dissemination**
  - Press release
  - CME conference support (thanks to WLF)
  - Dissemination of articles
  - Notice of Availability announcements

How to Express your Rights

- **When an inquiry or enforcement action comes from FDA, express the First Amendment issues**
  - I am not advocating belligerence or threat of litigation
  - However, stress that your communication is true and not misleading, and therefore not a violation
  - Push the Central Hudson buttons

Indications or Intended Use – A New Battleground?

- ***Indications for use.*** **A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended (21 CFR 814.20 (PMA))**

Intended Use (510(k))

- A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended (21 CFR 807.92)

"GENERAL"

- Note that the PMA indications and the 510(k) intended use both use the term "general"
- These statements have morphed from "general" to sort of holy text

Untitled Letter

- **A client received a letter saying that an ad was violative because the exact words in the ad were not in the 510(k)!**
  - This is not the Food, Drug, and Cosmetic Act standard of "not false or misleading"
  - This clearly is not what is thought of as the meaning of going outside your indication

Another Letter

- **One FDA missive stated that it was not sufficient for the words to be in the application:**

THE WORDS HAD TO BE IN THE INDICATIONS FOR USE

What happened to our definition?

- **FDA is shifting the game, looking for turf on which is can avoid its constitutional difficulties**

Be Prepared

- If you get into these discussions with FDA, remember to express the First Amendment standards in some manner
- Get the discussion back to the law and not one of new definitions

Summary

- As much as WLF and its cheerleaders want legal challenges to FDA advertising policy, many of our clients justifiably do not want to go first
- In the meantime, express your First Amendment rights
- Control your promotion with SOPs
- Use all available tools