**Oral Testimony**

**Coalition for Healthcare Communication**

**New Jersey Division of Consumer Affairs**

**Oct. 19, 2017**

I'm John Kamp, the executive director of the Coalition for Healthcare Communication. Our members include the medical professional communicators and medical journal and Internet media publishers that are the marketing partners to the nation's life sciences industries. Our members take seriously their role in the delivery of healthcare information, knowing full well that a pill can be a poison if not fully accompanied by information about how, when, and most importantly, in whom to use it safely and effectively. As such, our members work with medicine and device companies and medical professionals from the clinical and research industries to fully engage in communication with prescribers throughout America.

First, know that the CHC members recognize that there is an opioid crisis in the United States and that it is important to establish public polices to effectively combat it. Indeed, we support many state efforts to limit prescribing to a seven-day course in most circumstances, education and other initiatives by the U.S. Food and Drug Administration, and other such efforts to combat opioid misuse and addiction. But we also acknowledge that acute and chronic pain is commonly undermanaged, which is a reason for the dilemma we are facing.

We note that while the proposed rules discussed this morning are premised on the public health need to combat opioid abuse, the rules themselves apply broadly to all prescribers and prescriptions without either an expression of need or evidence that the rules would meet their goal.

Indeed, we fear that as written the rules may be counterproductive in that they will curtail the significant communication programs aimed at safe, proper and effective prescribing of all medicines.

Second, we note that without significant revision, these rules may have the unintended consequences of not just restraining the business activities of senior clinicians, researchers and educators inside the State of New Jersey, but may lead these doctors, their deputies and medical student mentees to practice medicine outside of New Jersey. This could unfortunately move many research and education dollars out of the state to the detriment of its now-growing industrial and educational programs.

Note, of course, that research and education are central to the development and effective use of all products, including, of course, medical products. This drug development and medical education in clinical care will be done somewhere, but if this rules remain as written, much less of it will be done in New Jersey. It would be unfortunate if New Jersey, the nation's medicine chest, would cease to be the choice of researchers, teachers and medical students looking to design, develop and spread the appropriate use of life-enhancing and life-saving medicines.

There are at least two reasons for this potential exodus of drug research and medical education from New Jersey:

1. Despite the regulatory impact analysis in the proposal, the rules will create a significant burden on prescribers. The burden will be directly on the prescribers themselves, but also inevitably will affect the life science companies that engage them, as well as their communication partners, the members of the Coalition.

2. As intended, the rules will not just limit the annual compensation received by prescribers who specialize in research and clinical education, but also dampen their career potential. When faced with a choice, these skilled professionals will look outside New Jersey to advance their careers.

However, perhaps the most important reason to reject these rules as drafted is that the proposals may undermine one of the most important avenues to combat the opioid epidemic – the provision of FDA-regulated education events, sometimes called promotional education.

Before elaborating on that, I want to provide two notes of praise to the drafters, i.e., thank you for exempting certified CME education, and for including medical journal editorial materials among those items clearly intended to lead to enhanced patient care.

But, in contrast, the proposal clearly limits and discourages FDA-regulated education, which generally are education sessions done in restaurant private rooms during lunch or dinner. The proposal does so in at least two ways: (1) It directly limits the number of meetings each prescriber can attend each year that are sponsored by a single company; and (2) It indirectly limits the sites where meetings can be held through the unrealistic $15 per meal limit. The limit on the number of meetings per company artificially limits large companies with multiple products, while the $15 limit nearly eliminates the ability to hold such meetings in high-cost New Jersey.

Instead, New Jersey should encourage these FDA-regulated events because they provide incredible opportunities for the companies to give clinicians information on when and how to use drugs safely and effectively. By FDA mandate, these presentations must be both truthful and not misleading about the advantages of the drug, but also be fairly balanced and provide a full accounting of limitations, side effects and contraindications. In fact, they are only communicating content that is supported by the label of the approved product. Discouraging these meetings practically cuts off one of the most important avenues of education about drugs available to clinicians.

In sum, while the Coalition for Healthcare Communication agrees that opioid addiction is a significant public health issue deserving industry and government attention, these proposed rules will not only fail to alleviate the crisis, they may in fact make it worse.

We strongly encourage the State of New Jersey to withdraw and revise the current version.

Thank you.