

CRN: Goldilocks and the regulatory bear: Avoiding the too-hot, too-cold pitfalls of supplement rules

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"CRN's job is to navigate the landscape and lead our companies toward a climate that fosters consumer confidence while preventing burdensome regulations that would stymie the industry," says the association's Steve Mister. (Getty Images)

In this guest article, CRN's Steve Mister reviews the year's big issues and CRN's initiatives and actions on multiple fronts.

As 2024 comes to a close, and I consider the events of the year, it feels a little like a Goldilocks moment, “This regulation is too hot; this one is too cold; and this one is just right.”

Thirty years after the passage of DSHEA, the foundational law that set the robust dietary supplement engine into motion, industry stakeholders are still trying to balance consumer access and consumer safety just right. As the leading trade association for the supplement industry, CRN’s job is to navigate the landscape and lead our companies toward a climate that fosters consumer confidence while preventing burdensome regulations that would stymie the industry.

In 2024, we had several reminders of where the regulation is too stringent. In April, New York’s law went into effect restricting the sale of a broad range of supplements marketed for either weight loss or muscle building to anyone under 18 years old. After vigorously opposing the legislation, CRN’s Board of Directors authorized the association to file suit against the State to challenge these restrictions on consumer access. We look forward to a successful resolution of the case in 2025.

The law places age restrictions on dietary supplements based on the claims made for the products in violation of the First Amendment. Although purporting to address the epidemic of eating disorders and body dysmorphia, proponents of the law can produce no evidence that restricting these products would have any impact on the scope of the problem, nor can they offer a scientific counterpoint to the [research](#) that shows that there is no causal connection between supplements and eating disorders. Instead, these age restrictions limit consumers’ ability to access safe and beneficial dietary supplements. In 2024, CRN strongly opposed the New York law (surviving efforts to dismiss the case by the New York Attorney General) and also fought similar bills in seven other states.

Another instance where the regulation is too strict is drug preclusion. In this regard, CRN has worked this year to right the balance between pharmaceutical interests and protecting innovation in the supplement space. CRN provided FDA in our recent Citizens’ Petition with a roadmap for how to apply the drug preclusion requirement in a manner that respects legitimate pharmaceutical investments without cutting off dietary supplement innovation. We look forward to FDA’s response before July of next year.

Meanwhile, our government relations team has been developing legislation clarifying when pharma companies can invoke preclusion. Suppose FDA's interpretation of the law does not strike a fair balance. In that case, our proposed changes to the statute itself will make strikingly clear when drug preclusion can be rightfully invoked to protect pharmaceutical investment and when supplement companies are entitled to invest in marketing new ingredients without worry that the ingredient will be withdrawn.

But sometimes, the regulation is too loose, and that can be troubling if it fails to protect supplement companies who play by the rules and want to protect consumer confidence in this industry. This year, CRN has urged strengthening FDA's oversight to protect responsible firms from bottom-feeders that would hijack our industry.

Mandatory listing & FDA's inspection authority



Steve Mister, President and CEO, Council for Responsible Nutrition (Portraits by Jared Wolfe/CRN)

That's one reason we have continued our support for mandatory listing. It's an issue CRN has continued to pursue because FDA can't regulate what it can't see. Without a requirement that when new products "pass go", their marketers must submit a copy of the product's label to FDA, the agency is flying blind and can't equally apply the requirements of DSHEA to all players. Retailers crave a way to know the products they sell are on FDA's radar as well. As states move to fill the perceived vacuum in enforcement of federal requirements, critics rightly point to the fact that when a new product enters the supplement market, FDA is not alerted. Mandatory listing changes that.

CRN is also exploring other revisions to DSHEA that will strengthen FDA's inspection authority by allowing it to access third-party audits and use these reports in setting its own inspection priorities. In addition, CRN has been navigating the industry's response to FDA's request to add a new Prohibited Act to the law that allows FDA to prosecute firms that market a product as a dietary supplement that does not meet the law's requirements for a dietary supplement. When the law is too lax or the agency has not kept up with the marketplace, responsible companies should help equip FDA with the tools it needs to provide the necessary oversight.

"We are Regulated"

Sometimes, the regulation is just right, but if no one knows, that must be addressed. In the coming months, CRN will be launching "We are Regulated," a social media campaign that underscores the fact that dietary supplements are regulated. In 2024, CRN stepped up its response to misleading media stories claiming that dietary supplements are not regulated, and this new program will further assure consumers that they can trust their supplements.

Self-regulation is another way that dietary supplements are regulated "just right". Voluntary programs permit companies to rise above the legal requirements and impose higher standards on themselves collectively in ways they couldn't individually. In 2024, CRN adopted a range of new voluntary programs and recommitted itself to its existing programs with our campaign "Responsible. It's our Middle Name."

CRN's voluntary guidelines for e-commerce call on all industry members to provide consumers with all the same information online that they would get if they were to purchase the product in a store.

I'm particularly proud of the members' decision to adopt voluntary requirements for melatonin-containing supplements, including child-deterrent packaging for melatonin supplements in a flavored form. Our members have committed to providing additional label precautionary statements and, separately, adopting considerations for manufacturing gummy dietary supplements. These self-imposed standards illustrate why voluntary regulation is more adaptable and more agile than waiting for the government to step in.

So, as we look at the past year's events and prepare for the one ahead, it's been about assessing where the regulation is too strong, where it's too weak, and where it's just right. We invite more companies to join us in tasting the porridge, making sure this industry sees a happily ever after.