August 8, 2022

Dear Members of the CRN Community,

I write to update you on the progress being made toward passage of federal legislation to enact a product registry for dietary supplements. I want to reassure you that we continue to advocate for advancing this legislation and honor the guiding principles for this initiative directed by CRN's Board of Directors. On the other hand, I am distressed to see so much disinformation being promoted that reflects lack of understanding of the complicated Congressional process, intentional misdirection and false information about what is in the bill, and intentional efforts to deceive the industry about the consequences of this legislation. So I would like to set the record straight.

We are Still at the Table

Contrary to what you may have heard, the negotiations for dietary supplement product listing continue with progress made each day toward getting a final bill that CRN can support. The press reports you may have read about a "stripped-down, user fee only bill" are still a possibility, and in fact, if CRN is not able to reach agreement on the "must have" changes to the Senate Committee passed bill, CRN would even support that bare bones reauthorization of the user fees without any mention of dietary supplements. But we are not at that juncture yet, and for now, we continue our discussions with the Hill.

Some Say Dietary Supplements Have No Place in this Discussion—They are Wrong

Recent articles have quoted sources who say that the provisions related to dietary supplements should not be included in the FDA Safety & Landmark Advancements (FDASLA) Act. They have insisted that legislation should be limited to only pharmaceutical and device issues. That opinion is both naïve and ill-informed. Drug user fees have been reauthorized five times since the Prescription Drug User Fee Act ("PDUFA") was first enacted in 1992. Since then, this must-pass piece of legislation every five years has been both tacked on to other larger bills (in 2002, it was part of a much larger bioterrorism bill) and been a vehicle for a variety of other FDA-related proposals including devices and food (in 2017, it even included prohibited acts related to food). So the notion that FDASLA must remain "pure" to drugs and devices only is an effort to deflect attention from the real issues.

Moreover, given the sharply divided, partisan environment in Congress today, very little legislation is able to advance to the President's desk. These "must-pass" omnibus bills are one of the few ways to get anything done, and members of Congress seize on these packages of bills with anything that is germane. For people who know how to get things done in Washington, it's the manner of doing business (for "Hamilton" fans, it's being in the room where it happens). We are fortunate to have FDASLA advancing with an opportunity to hitch a ride.

Dietary Supplements Will Not Be What 'Tanks' the Bill

Some stakeholders are promoting the notion that the dietary supplement provisions of the FDASLA Act (the Senate version of the user fee bill) could potentially doom the user fee reauthorization to defeat. That is a wildly over-inflated estimation of the role dietary supplement issues will have in this legislation. While important to our industry, other drug-related issues are likely taking precedence in the FDASLA negotiations. Dietary supplement issues will not be responsible for shutting down FDA or any of the other parade of horribles that are being trotted out. If the legislation does not pass, it will be over an impasse on drug issues. We would get jettisoned very quickly.

Moreover, Senator Richard Burr (R-NC) recently introduced his own version of the reauthorization bill that, unlike FDASLA, includes only language to reauthorize the drug and device user fee programs. He explained his

reservations about FDASLA, stating, "The policies added to this bill endanger the development of drugs for rare diseases, imperil intellectual property rights, threaten Americans' access to breakthrough treatments and cures, and deter private sector innovation. In effect, this proposal would compromise the FDA's overall ability to keep pace with advancements in the industry it regulates. And Democrats' recently released drug pricing proposal would further reduce private sector investment, making it more difficult for Americans' to access new, lifesaving medicines." These objections are all related to drugs and devices, not supplements. The alternative bill gives him a point of leverage in those user fee negotiations. But to be clear, his statement explaining his bill doesn't even mention supplements (or cosmetics—another provision of FDASLA). It is inaccurate to suggest that he is conceding to the will of the supplement industry with this alternative legislation.

Why CRN Supports A Dietary Supplement Registry

It's also worth reminding ourselves why CRN has so strongly supported legislation to establish a product registry for dietary supplements. CRN's Board of Directors first expressed support for this initiative in 2018, shortly after CRN created the ***Supplement OWL***, the industry's voluntary version of label transparency. Since then, the *Supplement OWL* has grown to over 13,000 labels, but it's clear that without a mandatory component, neither our efforts, nor even the NIH's ODS label database, will fully capture the marketplace. FDA cannot properly regulate the industry if it doesn't have visibility to know what products are on the market.

Since 2019, we have written extensively about the need for a mandatory product listing, and our reasons for supporting it, in trade press, consumer press and regulatory journals. These include:

- Supplemental blog: What If There Were a Registry?
- Mandatory Product Listing: It Won't 'Wash the Windows' Either!
- Op-Ed: 80% of Americans take dietary supplements. Better oversight and safety are musts
- A Mandatory Dietary Supplement Registry: Transparency as 'disinfectant'
- Mandatory Product Listing: Beneficial, or Burdensome?

…and many others available on our website. So I was surprised to hear some industry stakeholders assert that the concept was being rushed through Congress and that it came as a surprise to the industry. You could say we have been exceedingly transparent on our position on the issue of transparency!

Making Progress

We are making remarkable progress on the legislation and the issues that have raised consternation of our members. As some examples, when Senator Durbin first approached CRN with his interest in developing legislation, several items were proposed, including registration fees on dietary supplements, a requirement to include a registration number on the label, and much more non-label information that would have to be disclosed. None of those items made it into the bill.

Since then, CRN has negotiated other elements either into or out of the language. For example, when some industry stakeholders falsely alleged that the legislation "would require premarket approval," we approached the HELP committee for further assurances. The committee-approved version of FDASLA now contains the provision that "*Nothing in this section shall be construed to grant the Secretary authority to require the approval of a dietary supplement prior to marketing.*" The committee bill also includes some protections for confidential business information (although we are asking for more). Our most recent discussions suggest that there is opportunity for dialogue on our remaining issues.

Myths and Facts: Breaking Through the Misinformation

But much disinformation and gaslighting continue about what a dietary supplement registry would and wouldn't do. CRN has debunked many of those arguments in previous forums, so I urge you to take a look at this byline, Ignore the Red Herrings: Myths & Facts about Mandatory Product Listing, or this slide deck: Mandatory Product Listing Reality Check Deck. Our work on the Supplement OWL has also demonstrated that even small businesses can comply with a listing requirement.

One item that has attracted attention is the inclusion of a new "Prohibited Act" in the legislation that would make illegal the "*introduction or delivery for introduction into interstate commerce of any product marketed as a dietary supplement that does not meet the definition of a dietary supplement under section 201(ff)*." Some stakeholders have questioned if this provision would give FDA new power to prosecute products containing CBD or NAC. Miriam Guggenheim, CRN's outside counsel, and I rebutted these concerns in a published article last week, CRN says furor about new prohibited act is much ado about nothing. The envisioned dangerous "new power" being conjured up about this new provision is actually authority FDA already has. The impact of the provision is to allow FDA to address more efficiently illicit substances—the very thing industry has been asking FDA to combat.

Two other recurring arguments against mandatory listing are that FDA doesn't need a mandatory registry because the NIH's ODS Label Database is sufficient, and that plaintiffs' attorneys would misuse a mandatory registry to troll for new cases. What's odd is that these two arguments are directly inconsistent—they cannot both be true. If the ODS database is so thorough and complete, then plaintiffs' attorneys already have access to all these labels and creating a new registry doesn't create a new threat at all…or…the ODS database is actually not complete because it is not mandatory and marketers have no accountability for keeping their entries current, which is exactly why FDA needs an accurate and complete registry for visibility of the marketplace.

The Truth About DSHEA 2.0

Finally, some stakeholders continue to say that mandatory listing should wait and be included in a much broader package of reforms to DSHEA. While CRN certainly has a wish list of other items we would like to change in the current law, that has to be balanced with pragmatism and a dose of what realistically can be accomplished in this Congress—or even in the next one. Changes to the law would likely have to be enacted with the cooperation, or at least not the opposition, of FDA. Many of the ideas being proposed, like private third-parties deputized to conduct facility inspections, do not have FDA buy-in yet and will require extensive negotiations to get FDA on board. Then the industry has to convince a deeply divided Congress to enact these reforms. These things take years—mandatory listing is achievable in this Congress.

Still others are introducing the notion that complete pre-emption of all state laws related to dietary supplements should be a trade-off for a federal product registry. That is unrealistic and unattainable in this political climate. Just like the earlier argument that FDASLA should be limited to drug issues, this is a red herring to make the bill unpassable and to deflect attention from the real issues.

Final Thoughts

For almost 50 years, CRN has been the champion, innovator and thought leader for our members. Our early support for the adverse event reporting law in 2005 and Designer Anabolic Steroid Control Act in 2011 led to their passage. CRN has been a pioneer for product listing with our *Supplement OWL*, which serves as a model for how a dietary supplement registry could work. As long as there is a meaningful opportunity to advance our policy agenda, we will continue these negotiations toward a product registry.

We value the trust our members place in us to sustain and expand this incredible industry. And we are driven by the direction recommended by our members through our committees and adopted by CRN's Board of Directors. So I encourage you over the next few months to be scrupulous consumers of information and maintain a healthy skepticism when you read or hear that the product listing can't be achieved or would doom the industry. If you have questions about CRN's policy making process or the state of play, please let me know, SMister@crnusa.org.

With warm regards,

Steve Mister
President & CEO