

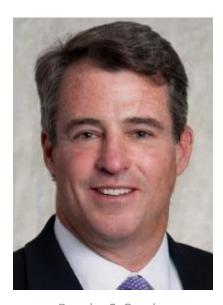
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Congress Could Be Coming For Dietary Supplements Soon

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The next chapter in the saga of New York State Attorney General Eric T. Schneiderman's investigation of the dietary supplements industry may take place on Capitol Hill. On April 2, Schneiderman and the state attorneys general of Connecticut, the District of Columbia, Hawaii, Idaho, Indiana, Iowa, Kentucky, Massachusetts, Mississippi, New Hampshire, the Northern Mariana Islands, Pennsylvania and Rhode Island sent a letter to Congress requesting it launch an investigation into the dietary supplements industry and to look into strengthening oversight from the U.S. Food and Drug Administration.[1]

Seeking "a broad-based solution," the letter — addressed to the chairman of the Senate Committee on Commerce, Science and Transportation, which is responsible for product safety and other consumer protection issues, the chairman of the Senate Subcommittee on Health and other ranking committee members — suggested Congress and the FDA "act in concert" to conduct a sweeping investigation of the industry and consider new legislation.[2]



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If Congress chooses to pursue the investigation proposed by the state attorneys general it will do so with a broad mandate. The state attorneys general suggested Congress investigate everything from product labels and marketing, to the effectiveness of existing quality assurance measures, to the quality of ingredients, fillers and finished products. As pledged in the April 2 letter, Congress would also enjoy the full assistance of the state attorneys general.

Unique Nature of Congressional Investigations

The specter of a congressional investigation adds yet another layer to the regulatory and enforcement challenges already facing the dietary supplements industry. A congressional investigation can begin at anytime and with no warning. Indeed, they often erupt at the most inconvenient of times, when a company is already being investigated by enforcement authorities, wrapped up in class action litigation or managing a public crisis. Once Congress gets involved, the stakes are raised even further and the collateral consequences can be devastating. It is thus imperative for any company facing a congressional investigation to be well-prepared to navigate the unique pitfalls ahead.

Unlike other regulatory and enforcement activity with which many companies are familiar, a congressional investigation may present some particularly unpleasant and unexpected realities. Congressional committees make their own rules and have tremendous control and discretion over their

investigations. This means, for example, that the committee could subpoen anyone within the company, all the way from a top executive to a low-level employee and, of course, anyone from outside the company as a witness.

Possibly even more troubling is that Congress is often not required to observe the same rights and protections that may be available to a company or individual in most other enforcement settings. For example, congressional committees will often not adhere to claims of attorney-client privilege, and may choose not to excuse a witness's refusal to testify based on the Fifth Amendment privilege against self-incrimination.[3] Presenting yet another difficulty is that Congress does not recognize claims of confidentiality. A committee may share the information it collects with other enforcement authorities, including by referring matters to the U.S. Department of Justice. More troubling, and difficult to address, is the fact that a committee may make information collected public in a formal hearing or report, or informally through leaks or press announcements.

It is also very difficult to stop a congressional investigation once it has begun. Congress wields an extremely broad subpoena power that will be upheld by courts as long as the subpoena has a "valid legislative purpose," which simply means that it relates to any subject that is, has been, or may be the subject of legislation.

In short, a congressional committee is allotted expansive latitude under Senate and House rules to conduct investigations into virtually any topic. And, as demonstrated by Schneiderman's request that Congress investigate the dietary supplements industry, a congressional investigation may be a powerful tool within an already ongoing investigation into the same subject matter.

Planning Your Response

While a congressional investigation presents unique and onerous challenges, it is possible for a targeted company to achieve a positive outcome. Industry members facing an investigation should remember that a committee may start an investigation and then abandon it, or shift its focus to other members of the industry, and that one company may receive better treatment than another in hearings or in a committee's report. Frequently, adopting a cooperative tone from the inception of a congressional investigation is more likely to achieve a positive result. This means opening a line of dialogue with the committee's staff and communicating the company's willingness to cooperate with the committee. Experienced counsel will often know when and how to push back if a committee is being unreasonable while avoiding being perceived as inflexible and evasive, which is only likely to draw more attention.

There are a few key opportunities to narrow the scope of an inquiry at the beginning of an investigation, first and foremost by preventing the issuance of a subpoena. A congressional investigation usually begins with a letter request and committee staff members generally have some discretion to narrow the scope of the letter request and to extend the deadline for responding, or even to accept a substitute for a witness initially called to testify. But if the staff is met with an outright refusal to comply, or grows frustrated in extended negotiations, a subpoena may be issued. Once that happens, modifications become much more difficult to obtain.

There are several options a company should consider in formulating its initial response to a letter request, but often a good first step is to have counsel brief the committee staff in person. A briefing can help the company identify a committee's true focus, frame the committee's understanding of the industry and areas of concern and provide an opportunity to ask the committee to honor any privilege issues that may be implicated. Making contact with both the majority and minority staff of the committee is also useful because it may reveal a sympathetic member. Identifying and working with such a member could lead to friendlier questions during the hearing or even a more favorable dissenting report, should the need arise.

Appearing before a congressional committee to testify is a unique situation. Careful preparation is important, from crafting a focused opening statement, to submitting additional materials for context, to anticipating likely questions. Such preparation with experienced counsel is essential for both voluntary and compelled appearances. And this is particularly true when the situation, like that currently facing the dietary supplements industry, involves a variety of cross-currents and parallel matters, such as state attorneys general investigations.

Interest from the public and press is another hurdle a company must sometimes face when involved in a congressional investigation. Schneiderman's investigation into the dietary supplements industry and request for congressional involvement are already generating intense media attention. And that attention will only intensify if Congress becomes actively involved. Ultimately, preparation is the key to facing not only the sometimes antagonistic questioning that may take place at a hearing, but also the accompanying media attention. Companies should also be mindful that preparation alone is not enough. A company must be able to adapt quickly as the tone and focus of a congressional investigation and media attention can move much more quickly and be much less predictable than in other contexts.

In the end, there are many strategies to help companies and witnesses fare better during an investigation. However a company chooses to proceed, it must tread carefully and remember that strategies that have worked well in litigation and other enforcement arenas may backfire in the context of a congressional investigation.

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- [1] http://www.ag.ny.gov/press-release/ag-schneiderman-and-ag-zoeller-lead-bipartisan-group-14-attorneys-general-calling
- [2] http://www.ag.ny.gov/pdfs/Final%20Letter%20Re%20Herbal%20Supplements.pdf
- [3] See Morton Rosenberg, Investigative Oversight: An Introduction to the Law, Practice and Procedure of Congressional Inquiry, CRS Rep. No. 95-464, at 46-47 (1995), available at: http://www.fas.org/sgp/crs/misc/RL30240.pdf

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