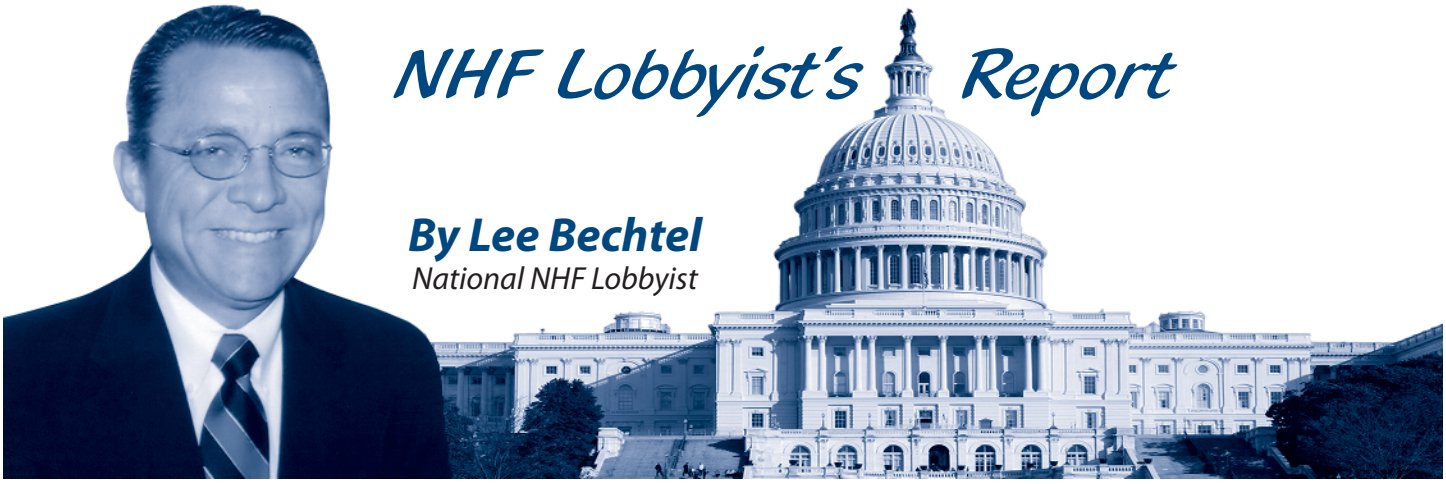

NHF Lobbyist's Report

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AER SUPPLEMENT GUIDANCE RELEASED – PROPOSES ABHORRENT ERRONEOUS REQUIREMENTS

The Food and Drug Administration (FDA) has released a Draft Guidance for Adverse Event Reporting (AER) and recordkeeping for dietary-supplement manufacturers, packers, and distributors, as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 (Pub. L. 109-462). The NHF lobbied against this legislation, even up to the late-night final passage in the House in December of 2006. These efforts fell 5 votes short of defeat. There were no other health-freedom groups, or their lobbyists, hanging around the halls of Congress when this happened. Many were quick to report on the bad news, but the efforts of the NHF largely went unheralded.

This Guidance raises many of the very same issues raised in opposition by us in 2006, not the least of which was that mandatory reporting was not needed in the first place. Among other things, the legislation would hurt small nutritional and dietary-supplement companies, would unnecessarily raise the cost of dietary and nutritional supplements, and reduce consumers' access to a range of products.

The Guidance is "intended to assist the dietary-supplement industry" in complying with this law. When finalized, it will represent the FDA's regulatory thinking. It does not, however, establish any legally enforceable responsibilities on the regulated companies nor on the FDA. Guidance documents are best viewed as being recommendations, unless specific regulatory or statutory requirements are cited. It is always this last bureaucratic "boilerplate" language that gives pause to the practical outcomes of industry Guidance documents.

In this case, the AER Draft Guidance proposes an "Abhorrent Erroneous Reporting" (AER) system for dietary-supplement manufacturers, packers, and distributors. In several instances, the FDA's interpretation/recommendations do not even correspond with the new Federal law's stipulated authorizing language. On these matters the Agency's instructions instead misrepresent Congress' intent when it passed the law, misdirect dietary-supplement manufacturers, packers, and distributors into violating the law, and do not give clear guidance on how to comply with the serious adverse event reporting requirements in the law.

The proposed Guidance (which can be revised) has at least seven key abhorrent and erroneous reporting (AER) definitions and recommendations. These will increase the costs of dietary and nutritional supplement products to consumers. A summation of these follows.

Erroneous Reporting of Serious Adverse Events

The FDA's thinking/recommendation is that any person seeking treatment at a hospital emergency room, without actually being admitted, who informs the admitting medical professional (a Nurse Practitioner, an Emergency Room Physician) of supplement use, should be considered to have experienced a serious adverse event. As such, without hard medical evidence, an AER using the FDA's MedWatch Form 3500A, should be filed, by the health professional or filed by a person, via the phone number on the label of a supplement. The policy/legal issue on this point is that there is **NO** clarification for the MedWatch instructions for this. This occurs because, incredibly enough, the authorizing law did not instruct the FDA to make a distinction between supplements, on the one hand, and nonprescription drugs and prescription drugs, on the other hand. Further, if a person is not admitted to a hospital, how could it be interpreted as being a "serious adverse" medical outcome?

Patient Versus Injured Person

In the Guidance, there is the consistent use of the term "injured person," as opposed to the use of the word "patient."

That may not sound like much, but it is when employed in actual reporting by healthcare professionals. The Statute stipulates that adverse-event reporting for supplements fit within the existing MedWatch instructions for filing a MedWatch report. Yet, MedWatch's own terminology used for prescription drugs – unlike the Guidance – refers to an adverse medical outcome as happening to a "***patient***."

Taken together, then, the term of art "injured person" means an outcome where a person may not be admitted to a hospital for a "serious medical outcome" caused by a dietary supplement. In other words, a wider net is being cast for AER-supplement reporting ("injured persons") than for AER-drug reporting ("patients") ***and*** the round peg of the supplement-induced injury must be pounded into the square hole of the exact same MedWatch form that was designed for drug-induced injuries.

For example, a person could show up at a hospital emergency room with symptoms of a viral infection. He or she is obviously an "injured person," but the emergency-room physician does not necessarily have to admit him or her to the hospital as an inpatient because it may not be a serious condition. Instead, they are sent home. For AER-drug reporting, though, the injured person must also be a patient to trigger the reporting requirement. So, the proposed "injured person" standard for filing a MedWatch report for supplements is inconsistent with that used for drugs, leaving the door wide open for erroneous reporting by physicians accustomed to filing drug and not supplement AERs.

Unfortunately, the FDA's ability to misinterpret federal law in the drafting of the Guidance gets even worse.

Serious Adverse Medical Outcomes from Supplements

The Dietary Supplement and Nonprescription Drug Consumer Protection Act specifically lists five conditions or medical outcomes caused by supplements or nonprescription drugs that are to be reported by dietary-supplement manufacturers, packers, distributors, and healthcare professionals, when reported by consumers to them. These are (1) death; (2) a life-threatening experience; (3) inpatient hospitalization; (4) a significant disability or incapacity; or (5) a congenital anomaly or birth defect. The Guidance lists these five, but importantly it fails to include any instructions to the reader on its thinking or recommendations on any of these. This is a crucial part of the AER requirements that will be often referred to. So, if a responsible company is required to file an AER related to a dietary supplement, why is this matter not adequately addressed so as to avoid confusion? The FDA's ability to misinterpret – or ignore – key aspects of federal law in the drafting of this Guidance gets worse, yet again.

Waiting to Submit Reports

The AER law requires a "responsible person" – which means a dietary supplement manufacturer or distributor – to file a MedWatch within 15 days of its receipt of an adverse event from a "reporter." Under the law, a reporter could be a person, a physician, or another healthcare professional. When filing a report, there is minimum data information required to be provided on the filed report. Yet, the Guidance document says that a responsible person can ***wait*** to submit a serious adverse event report to the FDA until the minimum data set information has been obtained. (Under the federal HIPPA law, this cannot include a person's name.)

In recommending that a supplement manufacturer or distributor wait to submit a report until all of the data elements have been collected, the Guidance document actually proposes a violation of the AER statute. The statute, though, does not provide an option for a responsible person to refrain from filing because one or another of the minimum data elements has not been made available by the reporter. There is no clarification in the Guidance that states that a dietary-supplement manufacturer or retailer who follows this recommendation will not find itself facing any kind of legal complaint, i.e. non-compliance.

Over-Filing Burden

The AER law requires that *either* a supplement manufacturer or a distributor be designated as the responsible party charged with filing serious adverse event reports with the FDA. And this is to be done by way of an agreement made between these two parties. However, the Guidance instructs that "reports of serious adverse events received by a responsible person in which the initial reporter identifies the suspect dietary supplement as one manufactured, packaged, or distributed by another responsible person, should be promptly forwarded to that other responsible person."

Once again, this additional reporting requirement is without statutory basis. In other words, there is no requirement that a responsible person who receives a report forward this to another party when they have had nothing to do with the supplement product in question. This is just the opposite of what Congress intended, and what the statute stipulates.

Physician Employment Requirement

Unlike other Guidance provisions, the physician-employment requirement does comport with the AER requirements. Having had first-hand knowledge of the authorizing legislation, I labeled this the "physician full employment provision." The FDA's recommendation is that the party responsible for filing serious adverse medical outcome reports with the FDA – that is, either the supplement manufacturer or the distributor designated as the responsible person – use a trained healthcare practitioner to review and make a medical judgment on whether a prescription drug or a supplement, individually or from a joint-use interaction, was or was not the cause of a serious adverse medical outcome.

The Guidance would appear to allow the use of trained staff employing computer-assisted technology or questioners as an

adjunct to a physician, but does not recommend the use of the former instead of the latter to ensure that complete information is obtained from persons contacting a supplement manufacturer or a retailer about a serious adverse medical event. Regardless, the real issue here is the typical inherent anti-supplement bias of most physicians, a bias that will inevitably color their assessment of the cause of the serious medical event.

FDA Recordkeeping Burden

As with all things involving dietary supplements and the FDA, this section of the Guidance that discusses recordkeeping is not surprising. In short, the FDA's stated recordkeeping burden for dietary-supplement reporting is, as it always has been, poorly substantiated by third-party scientific, peer-reviewed data. The generally agreed-upon number of adverse medical events caused each year by dietary supplements is around 500. This covers all types of adverse-event reports, almost none of which are ever fatal or even long-term disabling. Without really knowing, the Guidance suggests that there will be an increase on the order of at least a hundred times per year, or 50,000 AERs.

Neither of these figures are adjusted to reflect just the filing of reports for cases of an expected serious adverse medical outcome that can be medically documented as actually being related to supplement products. These are cases that may have caused (1) death, (2) a life-threatening experience, (3) inpatient hospitalization, (4) a significant disability or incapacity, or (5) a congenital anomaly or birth defect—the five conditions for mandatory reporting. This is yet another example of extreme data inflation by FDA bureaucrats. The FDA's use of these numbers is predictable. It is inevitably all about more money from Congress, from taxpayers, and directly from the dietary supplement companies. There already are industry User Fees for human prescription drugs, medical devices, and veterinary drugs and devices. AERs for serious medical events for dietary supplements will, I predict, lead to supplement industry User Fees in the future.

Final Analysis

Having been a lobbyist, policy analyst, and student of the FDA for twenty years, both inside and outside of government, my judgment on the AER Draft Guidance is that it is still a work in progress. I have never seen such a poor work product produced by FDA bureaucrats. This is both good and bad for dietary-supplement companies of all shapes and sizes. There is a possibility that this Guidance will not be finalized for months or even years, which would translate into extended confusion for the industry. In fact, there are examples of this with other FDA-regulated products. On the other hand, it could be finalized on a faster track. Sometimes it is better to know than to not know. Time will tell. Either way, there will be increased costs to companies and to consumers as a result of more FDA regulation of commerce that was not needed in the first place. And, as always, with more regulation comes less freedom. HFN