False and Misleading Information in the US FDA's Adverse Events Monitoring System (1994-1999)

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The Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to define the term "dietary supplement" and establish a regulatory framework for products labeled as either a food supplement or dietary supplement. DSHEA was passed after three years of committee hearings in Congress without a single opposing vote by any legislator in either the U.S. Senate or House of Representatives, despite significant opposition by a coalition of powerful lobbying groups.

In passing the DSHEA, Congress acknowledged the importance of dietary supplements in promoting health and reducing the risk of disease. It also gave the Food and Drug Administration (FDA) authority to promulgate a rational regulatory framework to enforce the will of Congress.

Of particular interest within that framework is the authority Congress gave the FDA to remove from the market dietary supplements that pose a "significant or unreasonable" risk to consumers or that are otherwise adulterated or carry inaccurate labeling. In compelling cases, DSHEA allows the FDA to ban a dietary supplement if the agency finds it to be an "imminent hazard."

Proponents for the use of dietary supplements have argued for years that dietary supplements are among the safest oral products the public can consume. Evidence to support their assertion can be found in annual reports of the American Association of Poison Control Centers published since 1980 in the *Journal of Emergency Medicine*. Of the millions of cases of food poisoning, drug reactions, etc., reported annually by the Journal, dietary supplements are rarely attributed to significant adverse events.

In keeping with Congress's mandate in passing DSHEA, the FDA elected to establish an "Adverse Events Monitoring System" (AEMS) to record adverse events and make such reports public. AEMS began compiling adverse events reports related to infant formulas, medical foods, and dietary supplements in 1995.

Efforts to obtain information from AEMS database required knowledge of which center within FDA maintained the information. To make it easier to find the information, FDA placed the AEMS database on its website, easily accessible to the public beginning on May 21, 1998. At the time the FDA launched AEMS and added it to its website, there were 2,450 adverse reports involving 3,183 products. Most were minor, but many were alleged to be serious.

This easy access to AEMS provided researchers such as this author to review the accumulated data FDA had compiled and determine the frequency and severity of adverse events associated with the consumption of dietary supplements. So immediately upon the release of AEMS on FDA's website, this author examined the data and was more than surprised by its content, he was alarmed. The AEMS database reported numerous deaths and serious adverse events allegedly associated with the use of dietary supplements. These reports however were incongruous with the public domain literature that reported no such cases. Could people really have died, for example, and no case histories reported any of several hundred medical journals?

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Were These Reports Factual or False?

For this reason the author spent three days analyzing every single case reported in AEMS database. The result of that analysis was submitted in writing by this author to the Office of Dietary Supplements, Office of Disease Prevention, National Institutes of Health; the Office of Special Nutritions, FDA; and selected members of Congress. (p. 13-16)

The content of this letter is being published for the first time, although it technically has been available to the public through the FDA Docket Branch or NIH archives since its receipt from either Federal agency.

The author's findings are instructive and demonstrate the risk to public health policy of permitting inaccurate and misleading information to be included in what proved to be a passive reporting system with no quality controls to ensure that data included in the AEMS database was accurate and factual.

The intent of exposing serious problems with the AEMS database was not to discourage gathering information on adverse events related to dietary supplement consumption. Adverse events associated with dietary supplements, some serious, have been reported in the literature and should be included in such a database, but only if they are factual. Many who reviewed my letter at NIH and Congress confirmed my findings and agreed with my request for the agency to take action and remove errors in the database. So why wasn't it done?

The FDA itself acknowledges that it has had a contentious struggle for decades with the dietary supplement industry. Would it then not benefit from allowing a database that is full of inaccuracies and unverified claims of harm to consumers to continue to be available to the public? The media used cases found in the AEMS database to warn the public about risks associated with supplements. In their reporting they would cite AMES, giving the public the impression that the data was infallible. The media could then use the data to support arguments that supplements needed stronger regulation, exactly the kind of restrictions the pharmaceutical industry has been pressuring the FDA to administer to the supplement industry for decades.

In the hopes that this misuse of misleading data by the media would stop, the author contacted the United States Pharmacopoeia (USP) soon after the letter was sent out in the hopes that it this quasi-governmental agency founded in 1820, and headquartered a few blocks away from FDA's headquarters, would serve as an arbitrator and successfully urge the FDA to remove AEMS from its website.

After careful review of the author's letter, USP invited the author, then Clinical Professor of Natural Products Research at the National College of Naturopathic Medicine in Portland, Oregon, along with toxicologists, public health specialists, the FDA, and other interested parties, to attend the USP's "Open Conference on Dietary Supplements: Current Issues on Quality and Evidence Supporting Claims", held August 16-18, 1998, on the campus of the University of California at Los Angeles (UCLA).

A copy of the author's letter was circulated to each participant invited to a special meeting on "Data sources for information relating to safety." Copies were also given to anyone registered for the meeting who expressed an interest in attending the session.

After considerable discussion by participants at the meeting, there emerged a consensus that the AEMS database was a passive reporting system with inadequate safeguards to insure the information was accurate and thereby useful. Some participants commented that it fell so far short of being a reliable source of information that it could cause FDA to remove a

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May 26, 1998

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Re: Problem with FDA Database Report on Adverse Events Related to Dietary Supplements

Dear Dr. Marriott:

I wish to bring to your attention a rather serious matter of concern to me as a scientist studying natural and medicinal products.

Today I was searching for information on the FDA's website when I came across the announcement of a "new" Special Nutritionals Adverse Event Monitoring System (SN/AEMS). In the past it has been difficult to ascertain the number of adverse events related to the consumption of dietary supplements on a timely basis from the FDA. Often an FOIA was required. However, the new SN/AEMS report on their website lists 2,450 adverse events on a total of 3,183 products recorded since 1993 through May 26, 1998.

In reviewing the data in SN/AEMS, I came across a remarkable number of errors and questionable data. For example, "deaths" were attributed to company products that the companies in question did not manufacture or market. In at least one case, an alleged "liver failure followed by death" was attributed to the use of a vitamin C product. The same death was later discovered in another company's profile to be caused this time by vitamin E. Never in my nearly 30 years as a professional in this field have I have come across a case of liver failure resulting in death due to either vitamin C or vitamin E or the combination of the two. (The cases I am referring to have an asterisk after them. This asterisk indicates that additional products were reported in association with the adverse event. However, these other products should be shown on the same screen since they may be drugs.)

In another company profile I discovered that the FDA had attributed 9 deaths to a variety of products from one company. I contacted that company CEO and discovered that they had never heard of even one death related to any of their products, much less than nine. In addition, a number of the products claimed by FDA to have been caused by their company's products, none have ever been sold by them, such as "EDTA" or "Black Walnut Hull Tea." I continued my contacts with CEO's of other manufacturing companies and discovered the same degree of surprise and consternation with the information they examined found in the FDA's SN/AEMS database.

It is my strong opinion that the NIH Office of Dietary Supplements should take an interest in this matter and discuss the need for corrections with the FDA's Office of Special Nutritionals before FDA continues to release its records to the public through its Website. Incorrect information should be expunged from these records or corrected, since it may be a source of information in the future in conjunction with ODS's efforts to inform the public about dietary supplements. ODS should be assured that such information is reliable and accurate before relying on FDA's database. Another reason for asking that some effort be made in a timely fashion is that ODS's new IBIDS website is linked to FDA's website, which may imply that NIH believes the data in the SN/AEMS to be accurate and reliable, which I contend it is not.

I appreciate your willingness to look into this matter with the urgency it demands.

Sincerely,

Alexander G. Schauss, PhD
Director, Life Sciences Division,
Natural and Medicinal Products Research
(Clinical Professor of Natural Products Research)

cc: Dr. William Harlan, M.D., Director of the Office of Disease Prevention
Dr. Wayne Jonas, M.D., Director of the Office of Alternative Medicine

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June 1, 1998

Dr. Elizabeth Yetley, PhD
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Re: SN/AEMS Report on Website

Dear Dr. Yetley:

I reviewed the Adverse Event Monitoring Report (SN/AEMS) recently placed on the CFSAN's website in preparing a paper for publication on this subject and for a forthcoming lecture at an international conference on nutrition. I am also a Clinical Professor of Natural Products Research at the National College of Naturopathic Medicine.

A considerable amount of misleading information and errors were found in the SN/AEMS Report. Let me provide you with ten examples of what I discovered while reviewing the SN/AEMS Report database when using the search feature for the identifier word "death."

1) Out of the 2,450 adverse events for 3,183 products the SN/SEMS Report claims to have received, 156 reported deaths were reported to be associated with the consumption of dietary supplements. In tracking each case history according to its ARMS number I discovered an extraordinary number of people died more than once. For example, ARMS (case) number 11444, died 11 times. ARMS number 11578 died 9 times. So did ARMS number 10649. Altogether, there were only 94 deaths, not 156 as implied by compiling the number of "deaths" due to all causes related to the use of dietary supplements. Many of these "deaths" do not have an asterisk after the ARMS number, which if indicated would imply that other products were associated with the adverse event. And when asterisks are shown after the ARMS number, there is no way to tell if the associated products are dietary supplements, OTC products, prescription drugs, or poisons. So if someone drank a bathroom cleansing product in an attempt to commit suicide or by accident, and happened to also consume vitamin E that day, there is no way to determine if the cause of death was due to the bathroom cleaner or vitamin E. And if this hypothetical case were real, why would anyone include vitamin E as the cause of death when a far more plausible cause is evident, namely, the bathroom cleaner?

2) Some deaths are improbable and should not appear unless there is good evidence that the association is even possible. For example, I could not find anywhere in the scientific literature of a case of death associated with Ester-C, a vitamin C product. Yet ARMS number 12330 claims that this occurred as: "Shortness of breath, acute respiratory failure, renal failure, leukopenic and thrombocytopenic, necrotic tissue in bone narrow; followed by death." The same case #12330 is also claimed to have died due to: Klamath Blue green algae; ginseng; garlic and parsley; Pycnogenol; cat's claw; and, gelatin, despite the fact that no death could be found that would link any of these supplements to such a death in the scientific literature.

3) Even more improbable are cases such as #12597, wherein four separate deaths are reported for one person, in which it is claimed that "liver failure followed by death" was due to: fresh dandelion root; natural dry vitamin E; Ester-C with bioflavonoids: and, St. John's Wort. Vitamin E causing liver failure leading to death? How could CFSAN allow such information to get into its adverse monitoring database without some evidence to substantiate such an implausible association for which no mechanism of toxicity as claimed is known?

4) The SN/AEMS reports on products that are not manufactured by the companies claimed to be the manufacturer of record for the product. For example, I was surprised to see "EDTA" listed as produced by "Nature's Way Products Inc." I contacted the company and discovered that they do not or have ever sold "EDTA", as I suspected. So why is that company listed as the producer of that product? Similarly, Nature's Way is also listed as the company of record for "wormwood", but again, it does not manufacture or distribute this product. Nor does it manufacture wormwood oil, which is reported in the literature as associated with the death of a person in Europe. So again why is it claimed that wormwood herb caused death in the same person who is also claimed to have died due to the ingestion of red raspberry leaves, black walnut hull tea, peppermint leaves, EDTA, echinacea with goldenseal, echinacea with mushrooms, red clover, and ginseng? I could not find any evidence in the scientific literature of these botanicals causing death, nor could the company whose products was named for this case (#11578) recall ever hearing of such a death attributed to its products. Further, there is no information as to whether the "EDTA" was taken orally, or administered intravenously. The "EDTA" could have been an excipient in a product. However, there is no evidence in the scientific literature that such a minute amount could cause toxicity, much less a "death".

5) There seems to be a considerable lack of knowledge among natural products manufacturers about the deaths attributed by the FDA as reported by SN/AEMS. I contacted five companies mentioned as the manufacturers of products alleged to be implicated in various deaths to find out what they know about them as reported in the SN/AEMS Report. In each case, none had ever heard of the deaths reported in the database. I would assume that if someone died of a dietary supplement, the manufacturer would hear from the deceased family's lawyers? Or is it possible that 94 people died and only a handful filed legal claims, thereby leaving the implicated companies in the dark as to the possibility of their products presenting a public health threat? Isn't it FDA's responsibility to investigate a death due to a regulated product? And if such investigations are carried out, why did five companies know nothing about any deaths related to their products?

6) I note that Similac and Ensure Plus (produced by Ross Products Division of Abbott Laboratories) and Enfamil (produced by Bristol-Myers Squibb Company/Mead Johnson Nutrition Group) are listed as products causing death. In the case of Enfamil four deaths are reported (ARMS #11876; #10484) including three infants. Yet these three infants are listed as one death not three. Why were the deaths of 3 infants underreported in the SN/AEMS Report, yet when there are herbs involved they are reported as multiple deaths?

7) ARMS #11876 is a death due to salmonella poisoning. The product in question is an oatmeal cereal manufactured by Gerber. Oatmeal cereal is a food, under FDA regulations, not a dietary supplement. Why is it included in the SN/AEMS report for dietary supplements?

8) Of 156 deaths reported, 33 cases report the cause of death due to a specific ingredient or list of ingredients, yet cite as "unknown" the name of the manufacturer. How can someone supply the FDA with detailed information about the contents of the product off the label yet not be able to supply information about the name of the manufacturer off the same label? One of the primary reasons for having an adverse monitoring system is to help identify emerging public health problems. How is this possible if there is no information about the name of the manufacturer in question in 33 cases of death claimed to be due to the consumption of a dietary supplement?

9) In 9 cases of death attributed to a dietary supplement, no information is provided about either the name of the manufacturer or the ingredients in the product. Of what value is such information? How does such a lack of information help the FDA identify emerging public health problems?

10) There are 36 cases of death reported in the SN/AEMS Report that is missing crucial information about the product in question. In each case the name of the manufacturer is reported but the ingredient content is reported to be "unknown." How can someone report the name of the manufacturer of the product in question off the label, yet offer no information on the contents of the ingredient when reading from the same label? Again, how does such a lack of complete information help the FDA identify emerging public health problems?

I could cite many additional examples to support my request to temporarily remove this database from CFSAN's Website. Adverse event monitoring systems are designed to identify emerging public health problems associated with the use of marketed products, in this case, dietary supplements. If there are serious questions about the veracity of the data in the SN/AEMS database, how can it be of any public health benefit to those who are engaged in such risk assessments? Why do so many companies have no knowledge of any deaths associated with their products, if FDA is responsible for monitoring deaths associated with products the agency regulates?

Considering the examples cited above, I would respectfully request that the SN/AMES Report be temporarily removed from the FDA's Website until errors are removed and misleading information is corrected. As it presently stands the SN/AEMS Report is unreliable and of limited use as a source of information for those engaged in risk assessment of dietary supplement products.

In making this request, I fully recognize that the adverse event monitoring system is required by Federal law. However, that law does not require that erroneous and misleading information be included in the SN/AEMS database or placed for public inspection on the FDA's website.

Respectfully yours,

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dietary supplement when no real risk to public health actually existed. The author urged those attending the meeting to work with the FDA to develop a workable monitoring system that resulted in including only serious adverse events and then only those that could be authoritatively verified. Given that representatives of FDA were at the meeting, it was everyone's hope that the agency would recognize the database's shortcomings and inaccuracies and simply have it removed and work with the public health community until a system for monitoring was developed that accurately reflected adverse events.

This did not happen. Day after day the AEMS database continued to appear on FDA's website and be used by critics of dietary supplements both in academia and the media who were intent on using its inaccurate information to paint a negative picture concerning the safety of dietary supplements. Nor did the FDA make any effort to post a disclaimer on the site acknowledging the specific cases that were inaccurate, have them removed, or qualified other cases to such a degree that it would discourage the reader from relying on these case histories given the lack of substantiation.

Beginning in September 1999, the author repeatedly urged members of Congress, the NIH, and the FDA, to consider the opinion of experts in toxicology and information systems who attended the USP meeting to review my letter and have the agency remove the AEMS database. Once removed, to provide a statement acknowledging that the database was flawed and contained inaccurate information, especially related to serious adverse event reports. Such a posting would have the effect of creating dissonance in the minds of those who relied on the information at face value.

Congress Intervenes

After much lobbying and the support of various stakeholders disturbed by the misinformation that was constantly available to the public, the US House of Representatives' Committee on Government Reform held a hearing on March 25, 1999, at which the FDA would be challenged to explain why it persisted in posting the AEMS database having learned of its problems.

The Committee hearing was titled, "The dietary supplement health and education act: Is the FDA trying to change the intent of Congress?" Chaired by Representative Dan Burton (R-Indiana), the Committee listened to testimony from individuals representing academic institutions, supplement manufacturers, nutraceutical trade associations, and the FDA.

At the hearing, the FDA was represented by Jane Henney, MD, Commissioner of the FDA, Joe Levitt, Director, Center for Food Safety and Applied Nutrition (CFSAN), which oversees the regulation of dietary supplements under DSHEA, and Margaret Porter, Chief Counsel for the agency.

During her testimony Dr. Henney stated that, "Dietary supplement manufacturers are not required to provide safety information to the FDA before marketing a product. The FDA has the responsibility for gathering information before the Agency can take action to restrict the sale of a dietary supplement product for safety reasons. This means that the Agency must rely on adverse event reports, product sampling, information in the scientific literature, and other sources of evidence."

The FDA's unwillingness to remove inaccurate information from AEMS was revealed during an exchange of questions and answers that transpired between Representative Mark E. Souder (R-Indiana) and Ms. Porter:

Mr. Souder: "One of the difficulties you have at FDA is if you have products out there that are unsafe and then you are held accountable. But I was curious also about the liability that FDA might have if you list a company in this area as having killed someone when they may not have manufactured the product. And, also, if the report is incorrect, then what do you do to correct it in the cite? In other words, what is your liability if you have false information or information that would say that, in effect, a distributor was responsible when they didn't manufacture? Have you run into the liability question?"

Dr. Henney: "Mr. Souder, I would love to be in a position to answer your question, but I have a feeling that my Chief Counsel is in a better position to answer your question about the liability."

Ms. Porter: "Mr. Souder, if you are talking legal liability and you are referring to the agency's adverse event reporting system, I think under ordinary circumstances, the agency's good faith effort to receive and evaluate adverse events would be viewed as a discretionary act and, therefore, exempt from tort liability in the legal sense. If you are referring to the agency's efforts to do its best to assure within its authority and its resources constraints that the reports are correct, well then, of course, the agency would try to do that."

Mr. Souder: "And if there was a

false report, would you make an effort on your Internet site to correct that and is there not just a legal liability, but also an ethical liability if you have damaged a company?"

Dr. Henney: "Mr. Souder, when we are made aware that there is not even the extreme of false, but information that would appear to be full or complete, when we are made aware of that, we do have an ability to at least footnote those reports in that way. We do not change in any way the original report that we would have received, but we would footnote it as having received information to the contrary. And that is how we would handle that."

Ms. Porter: "Mr. Stouder, let me also add that the adverse events that are reported to the agency as a general matter are made available under the Freedom of Information Act. We try to keep confidential the AEMS of the reporters and the AEMS of the individual patients, but the rest of the report is, in fact, legally available. So I think that would be another reason why the agency wouldn't be held legally liable. But, as is indicated, without our constraints, we want to be sure consumers have accurate information."

Mr. Souder: "Why, if a report is false or incorrect, wouldn't it be deleted? Why would it just be footnoted?"

Ms. Porter: "I can't – I am sorry."

Mr. Stouder: "The response was that if the report was proven to be false or just incorrect or you got additional information, you would footnote it. Why wouldn't you delete the false information?"

Ms. Porter: "It is part of the entire record. I think that would be the answer."

Testimony by Annette Dickinson, PhD, Vice President, Scientific and Regulatory Affairs for the Council for Responsible Nutrition, pointed out that:

"The FDA does not have adequate staff or other resources to properly evaluate the adverse event reports, and the reports are released without comment regarding the likelihood of any actual causal relationship between the product named and the event which occurred. This places every company at risk of being held 'guilty until proven innocent', without investigation. The industry is at risk of being charged with causing a large number of adverse events, many of which may be minor complaints and many or which may not, in fact, be due to dietary supplement use."

At the time this hearing was held, the FDA had the skills and ability to scientifically evaluate the accuracy of adverse event reports. As Dr. Dickinson pointed out at the hearing, in 1997 the FDA received about 3,000 adverse event reports regarding veterinary drugs. The FDA saw fit to verify each report, which revealed that only 1% of the veterinary adverse events were definitely associated with product use; 31% were probably associated, 45% were possibly associated, and 12% were definitely not related to the product in question. Had the FDA applied the same effort to reports they collected for dietary supplements as they did for veterinary drugs, it would have been interesting to see what the percentages would be. Certainly, they would have noticed that one person died nine times, or that reports attributed to harm to a product that was produced by the company they claimed manufactured it never was manufactured by that company. All these dubious entries created a highly unreliable, inaccurate, and misleading database.

How many of the approximate 2,450 events on a total of 3,183 dietary supplement products would have definitely been associated with product use had similar criteria been used as was applied to veterinary drug adverse event reports? We will never know. One could guess that since the public domain scientific literature, including the *Journal of Emergency Medicine,* reports remarkably few serious adverse events annually, and same

incidence and prevalence is reported for dietary supplements sold in other countries including, Canada, the 28-member European Union countries, non-EU Scandinavian countries, and Australia and New Zealand, the incidence would clearly have been found to be extraordinarily rare, and remarkably rare when compared to OTC's, drugs, and food.

But how can this author's opinion, based on over 30 years of experience in researching dietary supplements and evaluating their safety based on countless toxicology studies, be documented to the degree that the media, public health officials, legislators, and consumers will know this is so? The breakthrough came when a bipartisan coalition of members of Congress decided to create legislation to establish a new adverse event monitoring system.

New Law Passed By Congress in December 1999 Establishes New Adverse Events Reporting for Dietary Supplements

On June 21, 2006, Senator Orrin Hatch (R-UT), the original primary sponsor of DSHEA, introduced Senate bill 3546 (S. 3546): The Dietary Supplement and Nonprescription Drug Consumer Protection Act. At the time the bill was introduced, Sen. Hatch was joined by five co-sponsors: Sen. John Cornyn (R-TX), Sen. Richard Durbin (D-IL), Sen. Michael Enzi (R-WY), Sen. Thomas Harkin (D-IA), and Sen. Edward Kennedy (D-MA). On September 25, 2006, Representative Chris Cannon (R-UT) introduced the companion bill, House Resolution 6168 (H.R. 6168), in the House of Representatives. On December 9, 2006, the Senate passed S. 3546, by unanimous consent. Three days later, on December 9th, the House bill passed by roll call vote: 203 ayes, 98 nays, and 132 not present or not voting.

December 12, 2006, any difference between the two bills was resolved, at which time the House suspended the rules requiring further debate. On December 18, 2006, 15 minutes before Congress suspended all work on legislation under consideration, the House passed S. 3546. The bill was presented to the president on December 20, 2006, and signed into law by President George Bush, on December 22, 2006. Thereafter, the Dietary Supplement and Nonprescription Drug Consumer Protection Act became Public Law number 109-462. Responsibility for promulgating regulations and enforcement of the law was given to the FDA. Enforcement begins on September 23, 2007.

This bill affects not only dietary supplements, but also over-the-counter (OTC) products. It requires reporting to the FDA serious adverse events associated with either OTC or dietary supplement product use.

Under this new law, the manufacturer will be required to: submit a serious adverse event (SAE) report to the FDA within 15 business days; submit, within 15 business days, any related medical information that is received within one year of the initial report; maintain records related to each report for six years from the time the report is received by the company; and, permit inspection of such records.

Such an event is defined under the new law as an adverse event that results in death, a life-threatening experience, in-patient hospitalization, a persistent or significantly disability or incapacity, or a congenital anomaly or birth defect.

The law defines an "adverse event" as an event that occurs after overdose, abuse, drug withdrawal and failure of expected pharmacological actions of the drug. When a SAE is reported, the manufacturer must file the report no later than 15 business days after it is received using the MedWatch form that FDA has made available to the public for drug adverse event reports for many years, easily found on the FDA's website (www.fda.gov). An

interesting provision in the law permits retailers of dietary supplements whose name appears on the label to authorize the contract manufacturer who manufactured the product to report the SAE on their behalf.

All labels of dietary supplements will require a phone number or domestic address a consumer can use to report a SAE. If a label lacks this information, the FDA can deem the product mis-branded and take enforcement action.

A particularly important provision of the law protects companies from civil lawsuits that might arise from the information in the SAE. Submission of a SAE is required under the law but "shall not be construed as an admission" that the product caused or contributed to the adverse event.

It is fascinating to look back over the last eight years and monitor the effect that data analysis and one letter have had on improving the system of monitoring adverse events associated with dietary supplement products sold in the United States.

My hope is that the new monitoring system, which for the first time also requires the reporting of adverse events of OTC products in the United States, will document the perceived rarity of serious adverse events associated with dietary supplements compared to foods, OTC and drug products. If this one objective can be acheived, then contributing to the demise of one monitoring system and seeing it replaced by a mandatory evidence-driven gathering system that verifies the data will have been well worth those three days of analysis performed during May 1998.

References

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