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GAO/OIG Supplement Adverse Event Report Implications: Opportunity/challenge for academic, regulatory and industry stakeholders.

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Six years after passage of the "Dietary Supplement and Nonprescription Drug Consumer Protection Act", all stakeholders are reviewing the progress made toward full industry compliance and successful implementation. Additionally, subsequent to enactment of the mandatory AE reporting law, Congress has charged the Government Accountability Office and the Office of the Inspector General to review FDA's use of AER's in its regulation and oversight of dietary supplements as well as Industry's compliance with adverse event surveillance and regulatory reporting in support of consumer safety. The March 2013 GAO report reviewed AER data submissions, actions taken by FDA using AER data, FDA's enforcement efforts, use of AER data to protect consumers and FDA's progress toward meeting GAO's 2009 recommendations. From 2008-2010, FDA received 6,307 supplement AER's, 71% were reports from companies under mandatory reporting and 83% of all events involved multi-ingredient products. The report acknowledged other reporting venues such as public poison control centers which reportedly received more than 7,000 supplement AER's out of more than 145,000 total events involving dietary supplements during the same reporting period. GAO also reviewed regulatory actions related and/or linked to AER's to determine if the data was being used for consumer protection. A number of FDA actions were identified in response to AER data, but the GAO could not determine the total number of actions taken in direct consequence to reported AER's. The report concluded that FDA's inability to monitor such actions is likely due to no mechanism being in place to monitor the relationship between AER's and potential consumer threats other than certain actions or consumer alerts initiated on a case by case basis. Still, GAO acknowledged that AER data may be useful in detecting and responding to emerging threats but other activities such as electronic reporting may enhance FDA's ability to use AER data to its full extent. Other limitations in AER data utility were identified in the GAO report including poor data collection practices and low reporting prevalence amongst identified/registered dietary supplement companies and no national compendium of products. Subsequent review by FDA officials have noted that only 257 individual dietary supplement companies have submitted reports through 2012, much lower than the estimated 4,000 firms in existence, and lower than what would be expected for a representative passive surveillance system within an industry subject to mandatory AER reporting. Based on its findings, the GAO made broad recommendations in five areas including; 1) exploring use of poison center supplement AE data 2) implementing mechanisms to measure AER utilization efforts in support of consumer safety 3) facilitation of electronic AER submissions 4) increased public outreach projects including collaborative demonstration projects with stakeholders (a recommendation made in 2009) 5) finalizing NDI guidance. Additionally, GAO continues to recommend legislation mandating reporting of all AER's not just those judged as serious. These recommendations highlight persistent challenges for both FDA and the regulated community regarding demonstrating sufficient regulatory oversight to insure both supplement safety and quality, and unfortunately, the report paints all of industry with one brush without highlighting those best practice companies that have implemented exemplary quality and safety programs. As mentioned in the report there is a need for outreach and stakeholder collaboration which should include research and demonstration projects between academics, industry and regulators. The focus of this presentation relates to step by step review of challenges and potential solutions and opportunities to address supplement/botanical quality, and safety including appropriate risk assessment enhancements through a national collaboration with academic, industry and regulator stakeholders.