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PERSPECTIVES ON FDA'S EPHEDRA RULE AND THE COURT ORDER

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These perspectives are offered based on the following assumption:

Proper implementation of DSHEA will result in safe and beneficial dietary supplement products, a greater selection of products for the consumer, more science-based innovation, and a larger industry – in short, DSHEA is a positive step forward for consumers, industry, FDA and the public health in general.

The injunctive effect of the Order is very narrow.

The Order enjoins FDA enforcement only with respect to the sale of Nutraceutical's products containing 10 mg or less of ephedra alkaloids per day. FDA proposed in 1997 to limit the dose of ephedra to less than 8 mg per serving. There is no real market impact from this Order since FDA had, in the rule banning ephedra, agreed to allow the marketing low-dose Chinese herbal remedies and ephedra teas to continue.

The court also remanded the ephedra ban to the FDA for rulemaking consistent with the finding that FDA's "risk-benefit" standard is unauthorized by law. However, there is no reason to believe that this will result any change of status with respect to higher-dose ephedra products, and FDA has already announced its view that the Order does not impact the ban with respect to such products.

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It is highly unlikely that ephedra will return to the market.

FDA regulates imports under a different legal standard that makes it very easy for FDA to detain ephedra imports entering the U.S, even after the court Order. Insurance coverage for dietary supplement products containing ephedra disappeared long before the ephedra ban. Existing state-imposed bans remain unaffected by the court's ruling. Finally, the fast-moving legislative effort both in the states and on Capitol Hill aimed at curbing the production of methamphetamine will also affect the ability to market ephedra, even though ephedra did not prove to be a useful source material for illicit meth manufacturers when ephedra was on the market.

The "risk-benefit" standard presented a real threat to continued marketing of most of dietary supplements.

FDA's risk-benefit standard was announced for the first time in the context of the final rule banning ephedra. In that rule, FDA used the risk-benefit standard to apply drug efficacy standards for weight loss to ephedra. Combining the risk-benefit standard and the drug efficacy standards as FDA did in the ephedra rule effectively bans any weight loss product that does not show long-term (two year minimum) weight loss benefits, assuming FDA can argue, creatively or otherwise, that there is even a slight risk of serious adverse health effects. Further, if FDA were to apply drug standards for other popular products and claims, such as glucosamine for maintaining joint health, saw palmetto for maintaining prostate health, antioxidants for various aging-related claims, and numerous ingredients for maintaining a healthy immune system, to name but a few, these claims of benefits would almost certainly fail to pass the FDA test, allowing FDA to ban products based on perceived risks, however small, of serious adverse effects. As a result, allowing the risk-benefit standard to remain in place would open the door to the same type of FDA overregulation that the industry experienced pre-DSHEA.

FDA should revise the rule, not appeal the Order.

FDA's rule banning ephedra has serious flaws in both the rule's legal and scientific analyses, possibly because the rule was hurriedly written in response to political pressure. The record, as the court found, contains essentially no scientific support for banning low-dose ephedra products. FDA cannot now supplement the record, and the agency would therefore lose this argument again on appeal.

This firm wrote the initial white paper analyzing FDA's risk-benefit standard and showing why this standard is not authorized by the Federal Food, Drug, and Cosmetic Act (FDC Act) as amended by DSHEA. FDA provided almost no legal analysis to support the risk-benefit standard either in the rule banning ephedra or in the agency's

defense of its rule in court. The court easily dismissed the few arguments FDA did raise as contrary to the clear intent of Congress. An FDA appeal on this issue will also likely result in a second defeat.

Further, there is no public health need for FDA to appeal the Order. FDA can, on remand, use the appropriate "risk" standard to evaluate the safety of ephedra. Assuming the agency can articulate a science-based cause for concern that higher-dose products might increase the risk of serious adverse events, FDA can reissue the regulation using the correct legal standard. Meanwhile, the return of ephedra to the market is highly unlikely as a result of the lack of insurance, and FDA can take action under the import provisions of the FDC Act to prevent the reintroduction of higher-dose ephedra should that become an issue.

Industry should not request FDA to appeal the Order.

A request from industry to appeal the court Order would have little if any impact on FDA's actual decision whether to appeal, but would send a signal to FDA that the industry is willing to tolerate FDA action that is neither science-based nor authorized by law as long as such action achieves a dubious "greater good." This would be a very damaging message to send to FDA. As the agency is finally taking the task of implementing DSHEA seriously, there will be numerous disagreements and even conflicts over very important policy issues, such as how to interpret the definition of "dietary supplement" and the provisions that relate to "new dietary ingredients." Industry acceptance of the type of legal and scientific analysis that led to the ephedra ban opens the door not only to other bans that are on equally shaky ground, but will encourage FDA to creatively interpret DSHEA in ways that will unacceptably limit innovation, consumer access, and in the end, the size of the industry.

There is no cause for industry to seek or support changes to DSHEA.

The current climate for DSHEA is very different than it was five years or even one year ago. Ephedra has effectively been removed from the market by lack of insurance and the FDA ban, FDA has acted to remove androstenedione, and legislation has addressed concerns over other steroid-like ingredients. After more than 10 years, FDA is close to issuing a final rule on GMPs, is finally enforcing the law to remove products that make unsubstantiated benefit claims, and is working to establish policy with respect to new dietary ingredients. As a consequence, the previously negative press on dietary supplements has subsided, and the future for the industry is looking brighter as science is supporting the benefits of a growing number of products while weeding out others. This "fine-tuning" of the regulation of dietary supplements, which will encourage funding of more studies and the development of new products with greater benefits, should continue.

Investing effort into legislation to amend DSHEA is only appropriate where serious flaws in the legislation are evident and the public health is at risk. Legislation to ban ephedra or to mandate the reporting of AERs is not a rational approach given FDA's early steps to successful implement DSHEA and the predictable improvement in public perception that increased regulation has created. FDA's system for generating warning signals from the voluntary reporting of AERs is working, which is why FDA does not want or need mandatory AERs (see attached article from Natural Products Industry Insider), and FDA can still act to prevent the unlikely return of ephedra to the market. Legislation now will only open the doors to broader press attention and the potential for wider revisions to DSHEA. The press coverage of the court's Order regarding the ephedra ban has been minimal compared to coverage of past ephedra events, and will rapidly die to nothing because of the lack of safety issues.

In the end, should ephedra or any other dietary supplement become a public safety issue, that issue should be addressed at the agency level. The FDC Act as amended by DSHEA provides more than enough enforcement authority for FDA to remove dangerous products from the market, as FDA has already established in numerous cases.