



FACT SHEET

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OPPOSE: DURBIN LEGISLATION S 722
SUPPORT: HARKIN AND HATCH LEGISLATION S 1538

DSHEA: Let's make it work!

S 722 - Durbin's legislation would:

- Impose an onerous system for Adverse Event Reports (AERs) that goes well beyond the requirements for drugs
- Trigger a process that could permit the FDA to remove products from the market based on one AER.
- Make it almost impossible to return a product to the market once any action has been taken against it.
- Require premarket approval for some supplements
- List steroid hormone precursors in the Controlled Substances Act
- Create unnecessary burdens for industry, which could result in higher consumer costs for beneficial dietary supplements.

While Durbin's legislation provides some points to consider, it makes more sense to deal with those within the context of DSHEA.

We don't need to reinvent the wheel!

New laws aren't needed!

We need FDA to more fully enforce the laws already on the books!

Don't make them start all over again!

S 1538 - Harkin and Hatch's legislation would:

- Provide more funds to FDA to enforce DSHEA
- Provide additional enforcement funds for the next 5 years
- Require the FDA to submit an annual report on dietary supplements
- Provide more funds to the Office of Dietary Supplements for research
- Ensure that the goals of the Dietary Supplement Health and Education Act of 1994 are met by authorizing appropriate funds to fully enforce and implement the law.

DSHEA: It Makes Sense...Let's Make it Work!