Preliminary Analysis of DEA Annual Needs Assessment

Testimony of
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On Behalf of the
American Council for Regulatory Compliance

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Subcommittee on Crime, Terrorism, and Homeland Security

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Good morning. My name is Dr. Edward J. Heiden. I am president of Heiden Associates, Inc., an economic consulting firm specializing in health and safety issues and located in Washington DC. For the past 26 years, Heiden Associates has been assisting companies and trade associations in examining the economic impact of government regulation. A statement of our corporate capabilities and my resume is attached.

Early this year my firm, Heiden Associates, and I were retained by the American Council on Regulatory Compliance (ACRC)—an association representing manufacturers, importers, and distributors of pseudoephedrine and ephedrine-based products such as over-the-counter cough and cold and asthma relief medications, whose members sell primarily to convenience stores and other non-mass-merchandiser channels. Our assignment was to help them respond to a draft report, prepared by DEA and published for comment in the Federal Register, containing DEA's 2007 national estimate of legitimate medical need and use for ephedrine and pseudoephedrine in prescription drug and over-the-counter (OTC) products.

We were asked to examine two issues: (1) the soundness of the data and methodology used by DEA to prepare its report and estimate; and (2) whether the legitimate supply needs of ACRC member firms for ephedrine-based products to sell had been adequately taken into account by the DEA draft needs assessment. ACRC members were seriously concerned that their needs had not been adequately considered, if at all. For instance, members indicated they had never been consulted as the needs assessment was being prepared. A few also indicated, after initially examining the DEA analysis, that the entire estimate of national need for ephedrine contained in the report was far lower than the supply need represented just by what they knew to be their own sales to convenience stores and other non-mass-merchandising channels.

We briefly report below on the results of our work, and the conclusions and recommendations we have drawn from it.

Summary of Our Work

Analysis of DEA Methodology and Treatment of Ephedrine Needs for Product Sellers to Convenience Stores and Related Market Channels.

DEA's assessment relied on a study by its contractor, IMS Health Government Solutions (IMS), to estimate medical needs for ephedrine and pseudoephedrine based on data that the company routinely collects and offers annually to customers. IMS used several types of data for its study–sales to retail establishments (including pharmacies), sales by retail establishments to patients, and medical insurance claims. However, the DEA report itself provided very sparse and incomplete documentation as to how this data was used, and lacked much of the evidence that an interested and engaged professional analyst would need and expect to have in order to determine exactly how the methodology was actually applied. Elementary supporting materials, especially the data files and calculations that would show the key procedures used, were missing, and in one important instance the agency refused to provide us with access when we made a request.

Likewise, DEA's treatment of exactly how the needs of the convenience store market channel was treated in the national estimation process is vague, confusing, and even contradictory in several important respects. For example, even though convenience stores are mentioned by DEA as a market channel included in the study, there is no way that an analyst can tell how the major data sources used by DEA actually treat the sales of such stores in their role as suppliers of ephedrine and pseudo-ephedrine products for sale to the public. Without any documentation, explanation, or citation to source data, the report simply states that the convenience store channel had less than 0.1 million grams of legitimate OTC ephedrine-based product purchase needs.

Development of Independent Estimates of Ephedrine Needs for Convenience Store and Related Market Channels.

Because of this lack of documentation or explanation by DEA of its estimates, and the strong view by ACRC members that DEA's estimate of less than 0.1 million grams to convenience stores and other non-mass-merchandiser channels lacked foundation, Heiden Associates conducted an independent examination of the need for ephedrine-based products in these market sectors. As a starting point, we obtained from DEA, through the ACRC, a copy of the product code listing used by DEA's contractor for the study, IMS, to develop its estimates. Once we received this listing, we asked ACRC industry members to review it. **Review by industry members showed that not one of the ACRC member products was included in the initial DEA product inventory used to develop sales estimates for the ephedrine and pseudo-ephedrine needs assessment. This means that none of these products was considered to be "in scope" for purposes of development of the DEA needs assessment. Further, ACRC members indicated that not one of them had been interviewed or queried by DEA or its consultant as part of the needs assessment development process.**

Consequently, since it was clear that DEA and its consultant IMS were not adequately capturing the sales of legitimately marketed ephedrine-based products, we felt it was necessary to work directly with ACRC staff and member firms on a confidential reporting basis to develop preliminary estimates of ephedrine-based OTC products to convenience stores and related channels. Specifically, we asked individual participating manufacturers, importers, and distributors to provide 2005 estimates of their total unit sales of ephedrine-based products for medical use and the channels through which they distributed these products. We also interviewed ACRC Board members to obtain their best assessments of the overall size of ephedrine-based product sales to convenience stores, the sector accounting for the largest portion of ACRC member industry sales. In addition, we consulted various extrinsic data sources to develop a profile of the economic importance of convenience stores and other non-mass-merchandising distribution

channels that appeared not to have been adequately captured in the DEA consultant's study.

Eight ACRC member firms in all, of varying size and type (manufacturer, importer, and distributor) responded to our request for relevant sales data. In all, these eight firms sold more than 1.5 billion doses of 12.5 and 25 mg ephedrine-based products in 2005 to the public. About 80 percent of these sales were made through "bricks and mortar" outlets such as convenience stores and small independent grocers, with the remainder reported through mail order and online channels. Collectively, these products contained approximately 27,880 kilograms of ephedrine, or more than seven times the amount DEA proposed as its preliminary 2007 annual needs estimate.

In reviewing DEA's own statistical data, it has become clear to me that these products are not the major source of diversion for the production of methamphetamine. According to DEA Administrator Tandy's recent testimony before the Senate Foreign Relations Committee: ". . .super labs, which are primarily controlled by Mexican drug trafficking organizations … are supplying the majority of the methamphetamine consumed in this country." The vast bulk of the products found in small toxic methamphetamine laboratories are name brand pseudoephedrine cough and cold products, such as Sudafed, purchased in large chain pharmacies and mass merchandisers. The products distributed by the ACRC and other small distributors are off brand combination ephedrine asthma relief products, which are not found in these illicit laboratories as a precursor to make methamphetamine.

How is it possible that the DEA/IMS study missed such a large portion of the overall market for ephedrine-based products in its estimates? It is not as if the convenience store and online/mail-order market sectors are inconspicuous: according to the most recent source data available, convenience stores and online/mail order firms sold an estimated $644 million of non-prescription medicines in 2002, with more than 38,000 convenience stores selling non-prescription medicines.

There are several possible reasons why DEA might have missed so much ephedrine-based product sold through non-mass-merchandising channels.

First, many of the companies involved in manufacturing and marketing ephedrine-based asthma products are also in the business of producing and distributing dietary and nutritional supplements, sales of which are tracked under a separate product code than under the code for non-prescription medicines. It is very possible that retail establishments might bundle products distributed by ACRC members and other similar firms under a product code such as vitamins, minerals, and other dietary supplements, or even general merchandise, that is not defined as within the scope of the IMS study.

Second, many convenience stores and independent grocers, particularly smaller ones in center city and rural locations still do not have the ability to scan individual product purchases. Non-scanning convenience stores are not likely to have been included in the databases used for the DEA needs assessment, which rely heavily on scanned data.

Third, the participants in the DEA needs assessment data base used to track OTC drug purchases (Homescan) may have under-represented poorer, lower health status households in urban and rural areas, as is sometimes the case with national consumer market panels that we have worked with in past studies. In this connection, it is important to note that it is convenience stores and small retailers in these less completely-tracked locations who are most likely to make products available to asthmatics where other retailers are non-existent or are open only during daytime and early evening hours. IMS does not have the ability to accurately capture convenience store data.

Conclusion

The lack of access to data that serve as the foundation of the IMS study estimates and the sparse, non-transparent, confusing, and in some cases seemingly contradictory

documentation of the procedures used to derive the annual needs assessment from these data make it difficult to determine whether the DEA has correctly characterized the volume of ephedrine requirements for prescription and non-prescription products sold in chain drug stores, large grocery chains, and mass merchandisers. However, it is obvious that the IMS study failed to incorporate any data on ephedrine-based products lawfully marketed by a substantial and economically significant sector of manufacturers, importers, distributors, and retailers who market primarily through convenience stores and online/mail-order channels. This failure has caused the DEA to propose an unrealistically low preliminary estimate for the amount of ephedrine required for legitimate needs in 2007. Should this estimate stand as the basis for DEA decision-making, substantial hardships are likely to result not only for numerous suppliers in the distribution chain and those who are employed by them, but also for the many asthmatics and others in legitimate medical need who rely on convenience stores and small retailers in locations where other retail outlets (such as mass merchandisers) are non-existent or only open during daytime or early evening hours.

We encourage the DEA to revisit this issue and make the data and analysis that underpin the IMS study estimates available for review under appropriate restrictions to ensure confidentiality and limit the use of the data. With access to these materials, we are confident that we would be able to work with DEA and/or IMS analysts to develop a fuller and more complete picture of the market needs for ephedrine-based products.