92N-0297

Branded Pharmaceutical Association

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February 21, 2001

Ms. Margaret O'Rourke
Division of Prescription Drug Compliance & Surveillance
Center for Drug Evaluation and Research (HFD-333)
Food and Drug Administration
Metro Park North 1
7520 Standish Place
Rockville, MD 20855

Dear Ms. O'Rourke:

On behalf of the Branded Pharmaceutical Association I want to thank you again for meeting with Mr. Alan Minsk, Mr. Larry Blansett and me on December 11, 2000 to listen to our concerns regarding the newly enacted amendments to the PDMA that require drug companies to verify the state medical licenses of physicians prior to leaving prescription drug samples with the physicians.

One of our main concerns was the potential adverse financial impact drug companies would face in complying with this new amendment. At the conclusion of our meeting with you we agreed to gather certain financial information from our member companies to try and assess the financial effect of compliance. I am reporting our findings to you with this letter.

Although we assured our members that the information we were requesting would be kept completely confidential we only had 10 companies or about 25 % of our members provide the requested information to us. However I do believe we have an accurate sample due to the different sizes of the companies that did participate.

I have enclosed a summary of the results of our member survey. I have listed the 10 companies as respondents A through J. Their total U.S. sales representatives and administrative personnel are listed in columns two and three. Column four lists the additional personnel needed to comply with the amendment. Column five lists the company's total annual U.S. sales and column six lists the estimated additional cost incurred for compliance. The last column lists the number of states in which the company samples prescription drugs.

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Some of the companies that responded listed problems they have encountered in trying to comply with the new amendment. These problems have been listed for you to read.

This survey shows significant additional costs as a result of complying with the new amendment. The smaller companies face a greater burden than the larger companies as a percentage of total sales but all companies will face a financial burden in complying.

We propose that the FDA exempt the small businesses from compliance with the provision of the amendment that requires verification of state licenses of physicians prior to sampling prescription drugs to the physicians. Our understanding that "small businesses" are companies with annual revenues of five hundred million dollars or less.

Our other reasons and concerns for exempting small businesses from this provision were discussed during our meeting with you. Your understanding of our concerns and your assistance with our request will be truly appreciated. I look forward to hearing from you after you have had some time to consider our request.

Sincerely,

Perry N. Cole

Perry N. Cole
President

enclosure: BPA PDMA Amendment Member Survey

Branded Pharmaceutical Association
PDMA Amendment Member Survey

Respondent	Total US Employees Sales Reps	Admin.	Additional Personnel	Total US Sales	Estimated Additional Cost	No. of States
A	12	4	2	$4,000,000	$120,000	6
B	11	4	1	1,500,000	40,000	7
C	55	10	1	11,000,000	100,000	18
D	40	3	1	5,000,000	22,500	13
E	42	5	2	2,051,998	60,000	36
F	13	9	1	3,000,000	20,000	17
G	3	2	½	673,000	13,000	3
H	125	35	2	35,000,000	75,000	48
I	65	15	1	87,000,000	110,000	50
J	DND	DND	1	DND	15,000	DND

Problems encountered in trying to obtain prescribers' license information from the state medical boards and/or prescribers:

A Doctor resistance.

B Some physicians not willing to show license, some are.

C None. The information was purchased from a vendor.

D All states do not have the list readily available and/or the cost is substantial.

E Difficult for physicians and staff to locate license, very inconvenient. Information is costly to purchase from outside vendors. Purchased information is not always accurate. This situation adds an extra 5-10 minutes per call.

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F Cost from states very expensive. Not all states have the information assessable through the Internet. (i.e. Pennsylvania, Delaware, Kentucky, New Mexico, South Dakota, Virginia)

G Some physician offices want to know why asking for licenses is any business of drug companies. Physicians feel that is a waste of their time. Some have said "well you just keep your samples", which hurts our sales.

H The majority of states do not have web sites with the license information. Some prescribers will give a copy of their licenses to the reps and some will not. This procedure is very time consuming and we are not totally confident the information is completely accurate.

I No consistent availability. Not all are accessible through the Internet. Some states assess a per request fee for verification. States very slow to respond. Commercial vendor service is extremely expensive.

J Several states will not give out license numbers.