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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2003N-0361
Comments for the Anti-Counterfeiting Task Force

Thank you for the opportunity to comment on the FDA anti-counterfeiting initiative. The task force members requested elaboration on a number of the points in my comments at the October 15, 2002 FDA public hearing. The comments below are directed at these points. My comments specifically avoid naming any specific company or its technology or service and focus on several points that, in my view, are applicable to the FDA's effort. Please feel free to contact me if you would like additional information, or my company could be of assistance.

SCA's experience in the security industry stretches back over two decades, with the last 10 years spent actively working with brand owners to protect their products, as well as their customers. We work across a wide range of industries and geographic areas and my comments are based on our experience not just in pharmaceuticals but also in spirits and beverages, spare parts, apparel, audio/video, imaging supplies, luxury goods and others both in the US and abroad.

From time to time, SCA also provides analytical information about various aspects of the authentication industry. I recently authored a study on anti-counterfeiting and brand protection in the pharmaceutical industry for PIRA International in the United Kingdom.[1] The study provided an opportunity to investigate in depth a number of aspects of brand protection and security packaging specifically in the pharmaceutical industry and to

[1] The Future of Anti-Counterfeiting, Brand Protection and Security Packaging for Pharmaceuticals, published by Pira International Ltd, (www.pira.co.uk), United Kingdom, Spring 2003.

2003N-0361 C31

speak with players involved in various aspects of the industry. My comments also reflect some of the insights we gained conducting that study.

I. Secure business practices (Options 7 & 10-13)

In all industries, good management of the supply and distribution chain is, in our experience, the single most important factor in product protection. We see the most positive results in product protection from brand owners that feel they can trust the companies with whom they do business, and refuse to do business with those they cannot trust. Some brand owners have solved much of their counterfeiting and diversion problems with positive changes in the way, and with whom, they do business.

It certainly does make sense that all stakeholders, regardless of their position in the supply and distribution chain, formally address product security. Top management must be committed to a product protection program and insist on their staff's compliance with the program. Every entity in the chain must be part of the solution. If they are not part of the solution, then they are, by definition, part of the problem.

We urge brand owners in all the industries where we work not only to engage their supply and distribution chain in the process, but also to engage them in a positive fashion. Their communication strategy should:

- Communicate the manufacturer's commitment to the concept of product protection
- Communicate the manufacturer's commitment to their specific product protection program itself
- Communicate their expectation of those companies they do business with to buy-in and cooperate, and
- Communicate the value to their business partners of buying into the program

Guidelines, as suggested already by the FDA or other industry groups, on secure business practices are relevant. Some manufactures already utilize software to streamline the complicated and labor-intensive process of evaluating clinical research organizations (CRO). This same data framework can be used to make it easy and efficient to know and manage vendors and distributors.

Option 7 in the interim report, suggests limiting the supply chain for those drugs "at high risk of being counterfeited" as an interim measure. We would suggest that it should not be ruled out as a long-term measure.

II. Technology (Option 3)

SCA is a long-term supporter of product marking programs and has seen them be effective for a wide variety of companies in many industries. One topic that has come up

repeatedly by brand owners in pharmaceuticals (as well as other industries) is to develop a program around an overt, secure anti-counterfeiting feature for product authentication by the end user. Overt features are important and useful. However, in our experience a product security program that relies solely on the end user is a weak program at best, and potentially leads the buyer into a false sense of security. In our view, covert security features are essential part of any well-monitored and effective product protection program. No one feature is appropriate for all applications or, from a security perspective, desirable. Fortunately there is a wealth of alternatives available in the market.

III. Education and Public Awareness

When it comes to public awareness of the dangers of counterfeits we urge the FDA to ally their education efforts with those of industries outside of pharmaceuticals. Counterfeiting, at least counterfeiting whose purpose is economic gain, is very often an organized multi-line criminal business of which drugs are only one of the profitable products. The best defense for all of us is for US consumers to understand the interaction of seemingly harmless counterfeit items such as fake t-shirts and sunglasses, readily available from street vendors and flee markets, and potentially dangerous fake products like pharmaceuticals and automobile parts. When the United States is a poor market for all types of counterfeits, everyone wins.

There are a number of individual industry associations as well as multi-industry organizations that currently address this topic. The FDA will find allies both here in the US and in Europe and useful information on successful, and not so successful, programs they have utilized in the past. Organizations that cover a wide range of industries and are specifically devoted to the issues of counterfeiting and diversion include: the International Anti-Counterfeiting Coalition (IACC) in Washington D.C., the Anti-Counterfeiting Group (ACG), and the Counterfeiting Intelligence Bureau of the International Chamber of Commerce in London, and the Union des Fabricants in Paris.

Numerous industries have coalitions devoted to anti-counterfeiting. While they work on issues that effect their industry, many have utilized effective public education programs. Some industries have formal organizations, other have informal groups of key brand owners that share information on effective efforts in countering their common problem of counterfeiting. To name just a few of the organizations here in the US:

Motion Picture Association of America (movies)
IFPI/RIAA (recording industry)
Imaging Supplies Coalition (printers/ink cartridges)
Business Software Alliance and Software Publisher Association (software)
Coalition Against Piracy of Sports Logos (CAPS) (licensed sports products)

Virtually all of these groups have addressed public education, with varying degrees of success. There is a lot to be learned from their experiences.

IV. Developing and Maintaining Analytical Data

The interim report addresses the need for up-to-date databases in several different contexts, including a database on authentic products and their packaging and product tracking databases. However the report does not address the current gap in both micro and macro data of strategic value to companies and their regulators.

On the micro level, real time information on global drug pricing, from the manufacture all the way to the end user, is clearly of strategic as well as operational value to firms. Analyzing where money can be made between countries, between drugs, and at various points between manufacture and final sale provides several important things. It provides key real time data for cost saving adjustments for the drug company, but equally important it provides crucial objective data on vulnerable points in the system.

My recent review indicates that while such a real time database is not widely used, it is currently available and capable of effectively managing even the complicated pricing situation of products of large global manufacturers. The FDA interim report talks to "drugs at high risk of being counterfeited"; equally useful is identifying "points at high risk". Real time information has obvious immediate operational value, and provides a base of information that allows companies to undertake anti-counterfeiting and diversion measures selectively and on a preemptive basis.

On the macro level, missing from the report is any discussion of providing a reliable database to evaluate the actual extent of the problem. Providing this type of data is essential for sound program planning and evaluation of program effectiveness. Such information would give pharmaceutical companies and the governments and agencies that monitor drugs valuable information not only on whether the situation was improving or deteriorating but also provide useful information on pockets that are particularly troublesome.

As counterfeiting becomes more and more of an issue across a wide range of industries, there are increasing efforts to find better ways to track the problem. One very interesting recent effort is by the Centre for Economics and Business Research (CEBR) for the European Commission Directorate-General Single Market.[2] The study analyzed various methods of collecting and comparing counterfeiting data across a range of industries. The study, published in July 2002, is an excellent first step in getting a handle on the scope of the problem. The authors of the study looked for realistic and cost effective methods of collecting reliable data on counterfeits in 19 different product areas, including pharmaceuticals. In each case they considered the way products are bought and sold in that particular industry.

The variety of permutations and methods of counterfeiting pharmaceuticals (no active ingredients, fake packaging, incorrect quantity of active ingredient, etc.) make the task of

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[2] Centre for Economics and Business Research, Counting Counterfeits: Defining a method to collect, analyze and compare data on counterfeiting and piracy in the Single Market, July 15 2002,

determining the size of the problem among the most difficult industries to monitor. Added to this are the numerous stages and participants in the pharmaceutical distribution chain, providing a large number of potential entry points for counterfeit drugs.

The authors determined that seizure data and reported cases, while sometimes available, were not reliable as there was no way to determine the rate of detection relative to the size of the problem. In the end the authors recommend the use of mystery shopping and expert evidence on a range of pharmaceuticals purchased from a sample of different outlets. Samples would presumably be laboratory tested, perhaps by the legitimate pharmaceutical producers. A consumer survey would be conducted at the same time to weight the results of the mystery shopping to reflect existing consumption patterns (percentage of drugs purchased at retail pharmacies, on-line, via institutional pharmacies, etc.).

While the pharmaceutical distribution system in EU countries is not identical to the US, there are sufficient similarities that the proposed methodology seems reasonable for use in North American markets as well as Europe. I personally think there is a great deal to be gained from a unified inter-country approach to data collection, especially given the fact that the problem is a global one.

At a time of tight budgets I know it is difficult to find support for data programs. However, given the character of the problem and the potential risk to the population, it seems that a major role for the U.S. government is in providing reliable information. Any public education effort should be based on sound information, not isolated sensational cases. The recent FDA and U.S. Customs joint spot examination of mail shipments of foreign drugs is an excellent example of the importance of collecting reliable data. I urge the FDA to consider expanding their efforts to provide an accurate picture of the situation industry wide.

Thank you again for the opportunity to provide these comments.

Sincerely,

June Shelp