Comments in Response to the European Commission Public Consultation

May 9, 2008

PUBLIC CONSULTATION IN PREPARATION OF A LEGAL PROPOSAL TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE

KEY IDEAS FOR BETTER PROTECTION OF PATIENTS AGAINST THE RISK OF COUNTERFEIT MEDICINES

I am Katherine Eban, a journalist and author of the book Dangerous Doses (Harcourt Inc., May, 2005). Dangerous Doses: a true story of cops, counterfeiters and the contamination of America's drug supply is a detailed journalistic account of the pharmaceutical counterfeiting problem that surfaced in the United States in the time period 2000-2005. With that knowledge and my continuing involvement in this issue, I wanted to share my perspective on the Commission's efforts to prevent and control a similar problem now unfolding within the European Union.

I want to begin by recognizing the fine efforts that the Commission is taking in this area. The counterfeiting of medicines is one of the most heinous of crimes. It puts those most at risk in further peril by subjecting them to unknown and potentially lethal materials. The Commission's recognition of this risk and its comprehensive movement of crack down on criminals and other parties that would facilitate this crime is to be commended.

The Consultation sets forth a number of technical, process and legal proposals that all appear well conceived and should, if implemented, make counterfeiting more difficult in the first place and easier to identify and disrupt when it occurs. Therefore, I add my support to these initiatives.

There is one particular issue that the Commission identifies where I would like to comment further. That is its perception that complexity in the medicine distribution chain facilitates counterfeiting. The Consultation document states: "counterfeiters seem to veil the source of the product by selecting highly complicated distribution concepts." Based on three years of intensive on-the-ground reporting, and my reconstruction of the path that counterfeit Epogen took to reach a 16-year-old boy on Long Island, contained in a chart in my book and available on my website, www.dangerousdoses.com, I fully agree.

In my investigation of numerous counterfeiting incidents, including that of Epogen, Lipitor, Procrit, Neupogen and Serostim, it became clear that one common essential element was that the counterfeits entered the medicine supply through a poorly regulated and opaque distribution system that required minimal documentation of a drug's origin. I cannot help but see the challenges the EU is facing with repackaging and parallel trade as being virtually identical to the issues that lay at the heart of the problem here in the US.

Additionally, as this problem of a veiled distribution chain came to light in different states and within the federal government, another similar situation began to arise: different states began to adopt laws to attempt to control this problem in the absence of

strong federal requirements. Again, the Commission appears to be concerned about the same situation developing within the EU: "there is evidence that Member States are starting to consider taking unilateral action to address the problem of counterfeit medicines. … Indirectly, this kind of way forward could encourage counterfeiters to target Member States with lower levels of protection of the legal distribution chain." Hence, the less regulated member states within the EU have effectively become the secondary wholesalers of your distribution chain.

Here in the US, once again, as one state (Florida) began to take stronger measures to control weaknesses in the distribution chain through more rigorous screening of registered wholesalers, the questionable wholesalers merely moved to states with more relaxed rules. Therefore, I believe that it is essential for regions like the US and the EU to have strong uniform standards. A drug supply is only as clean as its dirtiest link, therefore it does no good to lock the front door while leaving the back one open.

As a final comment, I would like to add what I think is an obvious endorsement of the Commission's suggestion to use antitamper seals for packs of medicines. If individual packs of medicine can be opened and manipulated in the distribution chain, virtually all control of the authenticity and quality of the medicine itself is lost. Product can be substituted, diluted, tampered, and otherwise compromised. Therefore, I believe the Commission is correct in its suggestion for using, and legally protecting, such seals as product moves from the manufacturer to the patient.

Thank you again for opening comments on this important issue.

Katherine Eban