American Medical Association
Physicians dedicated to the health of America

November 3, 2003

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

RE: Anti-Counterfeit Drug Initiative [Docket No. 2003N-0361]

The American Medical Association (AMA) is pleased to offer comments to the Food and Drug Administration (FDA) on the *FDA Counterfeit Drug Task Force Interim Report.* The Task Force should be commended for its efforts to date in addressing the growing threat of counterfeit drugs. The Task Force has done an excellent job in identifying the vulnerabilities in the United States drug distribution system, and it has laid out a comprehensive set of potential options to attack the counterfeit drug problem using a multi-pronged approach.

It is clear from the Task Force report that widespread adoption of new anti-counterfeiting technologies (i.e., authentication and track-and-trace), improvements in secure business practices, and electronic pedigrees provide great opportunities to combat counterfeit drugs. It is also clear that improved communications and education with everyone involved in the drug distribution chain, including physicians, could make a significant difference.

The AMA believes that it can best help the Task Force and the FDA in the areas of rapid alert and response systems and in professional and public education and awareness. In particular, as an umbrella organization for multiple specialty and state medical societies, the AMA can serve to convene physician organizations and facilitate an enhanced communications network among medical societies on drug counterfeiting. In fact, the AMA has already scheduled an initial meeting this month of FDA officials and representatives from national medical specialty societies to discuss drug counterfeiting.

The AMA agrees with the Task Force that reporting of potential counterfeit drugs (through MedWatch or other means) needs to be improved and that mechanisms must be established to alert physicians, other health professionals, and patients about the existence of counterfeit drugs. The AMA would be pleased to discuss the concept of a counterfeit alert network with the Task Force and/or the FDA to help determine the best role for the AMA in helping physicians to report suspected counterfeit drugs and disseminating information to physicians about counterfeit drugs that have been identified.

Awareness and education of physicians about counterfeit drugs is important and will be essential if physicians are to be effective stakeholders in identifying suspected counterfeit drugs and responding to counterfeit drugs once they are identified. Again, the AMA would be pleased to discuss with the Task Force, the FDA, and other stakeholders (e.g.,

pharmacists and the pharmaceutical industry) how it could most effectively meet the educational needs of physicians.

While the AMA is most supportive of the work of this Task Force, we are concerned that illegal importation and illegal Internet purchases of prescription drugs by American citizens potentially could have a profound negative effect on the FDA's ability to confront the counterfeit drug problem. From our perspective, the importance of these two problems cannot be overemphasized. Although we understand the limitations of the Task Force to effectively deal with these issues, the AMA believes that greater emphasis should be placed on the threats posed by illegal importation and illegal Internet sales in the final report.

In summary, the AMA encourages the Task Force to issue its final report as soon as possible and we look forward to working with the FDA and other stakeholders to address the problem of counterfeit drugs.

Sincerely,

Michael D. Maves, MD, MBA