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The Standard of Quality℠

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April 9, 2010

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

Re: Docket No. FDA-2009-N-0247-
Food and Drug Administration Transparency Task Force

Dear Sir/Madam:

The Food and Drug Administration (FDA) Task Force has requested comments on how FDA can make improvements in "Maintaining open channels of communication with industry routinely and during crises."

The United States Pharmacopeial (USP) Convention[1] recognizes fully the importance of addressing this issue. FDA certainly has a huge challenge in better addressing communication needs. It has some successes upon which to build, including FDA's recent collaboration with us in updating drug quality standards. I cite this example because this sort of partnership underscores the positive role FDA *can play* in encouraging the more complete and timely dissemination of information, and how it can and should bring together industry and other parties.

Working closely with USP, the pharmaceutical industry, and other regulatory and scientific bodies, FDA played a pivotal role in helping USP revise public quality standards for heparin in 2008 after adverse reactions and deaths resulted from heparin intentionally adulterated with over-sulfated chondroitin sulfate (OSCS). Through the work of dedicated scientists and regulators collaborating successfully and in an expedited manner in the interest of protecting patients, FDA and USP moved quickly to confront this crisis, and this work is ongoing. See: http://www.usp.org/hottopics/heparin.html. We have seen similar beneficial results in working with FDA to update our standards on glycerin.

***This kind of change requires no modifications of statute, rules, or regulation. It requires no reorganization and no new funding. In fact, to the contrary, it demonstrates how FDA can cut across its organizational boundaries and can leverage the scientific and communications resources of others, including non-profits, to address urgent public health needs*.**

[1] As a private, non-profit organization, USP has worked since 1820 to improve the health of people around the world through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods. For more than 100 years, we have worked closely with the FDA developing and revising drug quality standards that are enforced by that agency. Assisted by more than 1,000 volunteers worldwide, USP engages in open, public processes to ensure unbiased, independent, authoritative, science-based decision-making.

We hope that FDA will expand its efforts and encourage these types of positive relationships to help update other USP standards. Clearly, the growth of economically motivated adulteration of medicines worldwide is a tragic by-product of global supply chains, and safety nets must be constantly reassessed and improved.

Sincerely,

Roger L. Williams, M.D.
Chief Executive Officer