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Department of Government & Professional Affairs

May 9, 2007

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

Dear Sir or Madam:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to comment on the proposed establishment of a national Sentinel Network for post-market surveillance for medical devices and pharmaceutical products.

ACCP is a national professional and scientific society representing almost 10,000 clinical pharmacist practitioners, researchers and educators. Our members have been among the profession's leaders for almost three decades in developing and providing professional services, consultation, cutting-edge clinical research, and education programs that improve the quality of medication use in the health care settings in which they practice.

ACCP members are well aware of the consequences of inappropriate or suboptimal use of medical products, which include the:

- Negative impact on public health through direct injuries to patient
- Erosion of public trust and confidence in the governmental oversight of medical products,
- Over cautious use of treatments among health care providers and patients resulting in diminishing usefulness of effective therapies.

ACCP also recognizes the challenges that face the FDA under the current system of post-market surveillance due to limitations in the quality, quantity, and timeliness of available data as well as limitations in the agency's capacity to quickly conduct post market studies.

Why the American Public needs a "Sentinel Network"

For health care professionals to make informed decisions regarding the safe and effective use of medical products, they must have access to timely, up-to-date and accurate information about those products. With efforts already underway to develop and harmonize health information standards - such as electronic health records - and to make

use of available health information technologies, the need to formalize a collaborative project network between government agencies and the private sector is even greater.

Defining an Effective Sentinel Network

An effective Sentinel Network would comprise a virtual, integrated electronic network that would foster the seamless, timely electronic flow of medical product safety information from electronic databases and surveillance reporting systems, through risk identification and analysis processes, to health care practitioners and patients at the point of care, while protecting patient privacy. Such a network would focus on three main actions:

- Data collection
- Risk identification and analysis
- Risk communication.

The Sentinel Network should also include measures to improve the scientific underpinnings of the safety system, increase monitoring for hazardous side effects and expand communication with patients, pharmacists and other health care providers.

Moving Towards More Effective Post-Market Surveillance

Pre-market clinical trials cannot identify all potential risks from a medical product. At the same time, the FDA approval process must not inhibit the availability of new medical products on the market or restrain innovation.

Drugs in development are tested on several hundred or a few thousand human subjects, but rare side effects may emerge only after tens of thousands of patients have taken a medication. Many academic experts think new drugs should be considered "experimental" even after successful completion Phase I-III testing.

For these reasons, effective and ongoing post-market surveillance efforts are essential. The FDA and other Federal agencies should expand post-market surveillance efforts, including adverse drug reporting systems used to assess known risks and to identify previously unknown risks, and the use of population-based data sets to help assess whether such risks are directly related to specific medical products.

Just as with pre-market trials, without the necessary quality, quantity and timeliness of available data, and the appropriate capacity to rapidly conduct post-market safety studies when needed, the effectiveness of these post-market activities will be limited.

Adverse Drug Events Database

While ACCP fully supports the development of the Sentinel Network, the College is concerned over the challenges that exist in rapidly and efficiently collecting the required information and applying it to the proper care of patients.

The extent of these challenges was demonstrated by the delayed upgrade to the FDA's Adverse Event Reporting System (AERS). According to a report [1] conducted by the Breckenridge Institute, the FDA spent a total estimated cost of $25,000,000 on the planned upgrade, yet the system now faces a four-to-five year delay, and will not be operational until 2009 or 2010.

In its 2006 report - The Future of Drug Safety: Action Steps for Congress, the Institute of Medicine (IOM) described the AERS as "outdated and inefficient." [2] It is therefore vital that the development of the Sentinel Network also encompass the modernization of the AERS database — which now captures only a small fraction of problems — to make it easier for researchers to recognize that something was going wrong.

ACCP fully recognizes the efforts that have been made to enhance the capabilities of the AERS. In addition, ACCP recognizes the success of the MedWatch program in:
- Increasing public awareness about the importance of reporting adverse reactions
- Educating health care professionals on reporting requirements
- Standardizing reporting formats
- Providing a single point of entry for the public and practitioners to report adverse events related to medical products.

However, the success of MedWatch has created an enormous information technology challenge that the current AERS can no longer handle. A comprehensive overhaul of the AERS system is therefore necessary to the success of the Sentinel Network.

Other Recommendations

ACCP also recommends that the proposed Sentinel Network addresses key issues, including:
- Increasing funding to ensure that the agency has the resources necessary to carry out its stated mission
- Congressional action to grant broad new legal powers for the drug safety program reforms.

ACCP welcomes the announcement [3] that the FDA would partner with Veterans Affairs, Medicare and other government agencies to share extensive information that those agencies collect on doctors' prescribing patterns and their patients' outcomes, and urges the agency to continue to expand and enhance these, and other, data collection activities.

Conclusion

In response to the IOM Committee on Identifying and Preventing Medication Errors [4], ACCP suggested that the current "system" – involving disjointed processes for prescribing, dispensing, and monitoring of medications, combined with a lack of

[1] Available at: http://finance.senate.gov/press/Bpress/2007press/prb030707a.pdf (accessed 3/22/2007)
[2] Available at: http://www.iom.edu/Object.File/Master/37/331/11750_report_brief_congress.pdf (accessed 3/22/2007)
[3] Available at: http://www.fda.gov/oc/reports/iom013007.html (accessed 3/26/2007)
[4] Available at: http://www.accp.com/position/com_IOMErrors.pdf (accessed 3/22/2007)

consistently-delivered, standards-based, and quality-focused practice activities that evaluate, manage, and deliver better medication use outcomes in individual patients – must be acknowledged to be fundamentally flawed.

In addition, substantial change in provider responsibilities, care processes, and the systems and procedures that constitute the current medication use process must occur if meaningful improvement in the quality of medication use, including the prevention of avoidable medication errors, is to be achieved.

In summary, ACCP and its members thank the FDA for holding the open meeting on the Sentinel Network. ACCP supports the development of this network and the ongoing efforts by the FDA to improve and enhance:

- Opportunities for collaboration between patients, health care providers and government agencies
- The utilization of health information technology
- The collection and analysis of medical product safety information
- The dissemination of this information to health care practitioners and patients at the point of care.

Please feel free to follow up with us at any time if the College and its members can be of assistance in this important effort.

Sincerely,

M. Madd

C. Edwin Webb

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Executive Director   Director, Government & Professional
Affairs

Cc: ACCP Board of Regents