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Summary Comments
Hugh H. Tilson MD, DrPH
Senior Advisor to the Dean, UNC School of Public Health and Chair, Steering Committee, Centers for Education and Research in Therapeutics (CERTs)
FDA Meeting: Leveraging -- Collaborating with Stakeholders
Duke University, April 12, 2000

There are numerous opportunities for the FDA to leverage opportunities with the CERTs and professional organizations to support its efforts.

Pharmacoepidemology

Pharmacoepidemiology is a field that is rapidly evolving to help FDA and society address the pressing needs of post-marketing drug safety. The CERTs centers have bold strategies to build on or develop partnerships with large automated multipurpose population-based database systems to study post-marketing drug safety issues. Beyond the important contributions of the databases, the CERTs also provide a much-needed leverage opportunity for developing innovative and more effective means of monitoring adverse reactions in populations, and to advance much needed training in the techniques of pharmacovigilence.

Health Outcomes Research

The second of the major new leverage opportunities presented by the CERTs is in the sphere of health outcomes (or quality) research. Leveraging the research and demonstration efforts of the CERTs will expedite pilot testing and better understanding of effective means to assure monitoring of medical errors involving therapeutics and development of effective system strategies for their reduction.

Professional Organizations

The FDA already participates actively in professional organizations such as the American Academy of Pharmaceutical Physicians (AAPP), the International Society for Pharmacoepidemiology (ISPE), and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). In addition to the leverage opportunities that exists through relationships with these organizations, the Forum of International Professional Societies, created jointly by ISPE and ISPOR, represents a similar opportunity to ensure intelligent coordinated development of both pharmaceoepidemiology and health outcomes research.

Local Collaboration Opportunities

Research Triangle Park (RTP) is a perfect metaphor for the sorts of leverage and collaborations the FDA is seeking. The RTP is home to strong research universities, global contract research organizations, small and large pharmaceutical firms, several co-located federal research establishments, and the Research Triangle Institute (which is itself a collaborative of many of the area's partners). Through collaboration with CERTs, the FDA is able to ensure constructive partnerships with many of these organizations that are partners with CERTs centers. In addition, both Duke University and the University of North Carolina house AHRQ based Evidence-Based-Practice Centers, to help with the evidentiary underpinnings of education and research in therapeutics.

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SUMMARY:

The AHRQ CERTs Program provides an excellent opportunity for FDA to leverage substantial efforts and raised awareness in pharmacoepidemology and pharmaceutical outcomes and quality of care research. Notable are the efforts to target proactive drug safety surveillance and evaluate the impact of therapeutics improvement educational efforts using large automated population-based databases by the CERTs.

DETAILED COMMENTS:

One of the newest national programs of the Agency for Healthcare Research and Quality (AHRQ), the CERTs program provides a real and powerful vehicle for FDA partnering and leverage. Created under Congressional mandate as part of the FDA Modernization Act of 1997, the CERTs initiative creates centers within academia to assist in the development and improvement of the therapeutics sector. Four (4) centers have already been funded (Duke, Georgetown, University of North Carolina, and Vanderbilt) and others are under evaluation. In his separate remarks, Dr. Robert Califf, Principle Investigator of the Duke CERT and Director of the National Coordinating Center for the CERTs program, will depict some of the leverage opportunities in clinical pharmacology and clinical research.

In addition, these centers already possess expertise and valuable programs in two other areas critical to FDA's mission: pharmacoepidemiology and pharmaceutical outcomes research. The first of these is the field which is rapidly evolving to help FDA and society address the pressing needs of post-marketing drug safety highlighted in the Commissioner's Risk Management initiative. Specifically, the CERTs centers have bold strategies to develop, or already possess, access to and partnerships with one or more of the nation's large automated multipurpose population-based database systems. The recently released Healthy People 2010 emphasizes the promise of these database systems to provide more accurate drug utilization/population exposure data, better ascertain real-time information about potential drug related safety problems, and provide richer information about attendant risk factors to permit the sorts of early and accurate interventions which are needed in the post marketing environment. FDA needs these resources to be developed, needs a larger and better national academic expertise to perform needed research and surveillance using them, and needs a trained workforce in industry and the Agency to develop the partnerships necessary for population based proactive safety surveillance.

This Town Hall meeting occurs on the same day and in the same area as the mid-year meetings of the International Society for Pharmacoepidemiology (ISPE)... a key leverage partner in this important global arena. In its annual meetings, ISPE provides a vital forum for scientific accountability among the partners in this critical enterprise. A complex scientific field, pharmacoepidemiology requires partners among the epidemiology, clinical, pharmacology, and computing communities; a global activity, it mandates international cooperation; and a field which intersects the public health, medical, industry and government sectors, it cries out for the sorts of public/private partnerships and ability for FDA to leverage which this Town Hall embraces. Often taken for granted (though certainly not by the FDA) is the partner field of Pharmacovigilence, known by the pharmacoepidemiologists as 'epidemiologic intelligence'. Beyond the important contributions of the databases, the CERTs also provide a much-needed leverage opportunity for developing innovative and more effective means of monitoring adverse reactions in populations, and to advance much needed training in the techniques of pharmacovigilence.

The second of the major new leverage opportunities presented by the CERTs program is in the sphere increasingly known as health outcomes (or quality) research. Among critical areas to advance, through FDA's partnership in the CERTs program and leverage of the resources already available, the CERTs will emphasize an understanding of the translation of the evidence generated in CERTs and elsewhere into effective medical practice improvement. The recent Institute of Medicine Report, 'to Err is Human', underscores the continuing challenge of detection and development of constructive, non-punitive systems to address errors in medical practice. Again, this emphasis is already part of FDAs commitment to Risk Management. Leveraging the research and demonstration efforts of the CERTs will expedite pilot testing and better understanding of effective means to assure monitoring of medical errors involving therapeutics and development of effective system strategies for their reduction. A recently convened cross-Society sector development activity, the Forum of International Professional Societies, created jointly by ISPE and its partner organization, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), represents a similar leverage opportunity to ensure intelligent coordinated development of both fields.

A third organizational resource for FDA leverage is the American Academy of Pharmaceutical Physicians (AAPP), with national headquarters just up the road in Raleigh, NC. This organization is working collaboratively with at least one of the CERTs to assist in translating the evolving education and research initiatives into effective initiatives with America's practicing physicians.

The FDA already participates actively in ISPE, ISPOR, and AAPP; this leadership needs to continue and be expanded. In the CERTs program, FDA's CDER is a central partner with AHRQ, through the excellent representation of OPDRA Director, Dr. Peter Honig. Through your collaboration with the CERTs, therefore, you are able to ensure constructive partnerships with the groups with which the CERTs partner. For example, also here in the Research Triangle Area, both Duke and UNC house AHRQ based

Evidence-Based-Practice Centers, to help with the evidentiary underpinnings of education and research in therapeutics. Indeed, RTP is a perfect metaphor for the sorts of leverage and collaborations you are seeking in that the RTP based CERTs have strong neighborhood partners among the strong research universities, global contract research organizations, small and large pharmaceutical firms, several co-located federal research establishments, and Research Triangle Institute ... itself a solid collaborative of many of the area's partners.

The opportunities to find and pursue leverage opportunities within the CERTs for FDA's implementation of its objectives in Risk-management and Quality Improvement, including its commitments to QuIC include: better coordination of FDA's extramural pharmacoepidemiology grants program, the planned improved proactive surveillance activities (e.g. hospital based surveillance, pregnancy exposure monitoring), needed improvements in pharmacovigilence practice and training, and error reduction initiatives. Progress on these vital initiatives is already being substantially enhanced by FDA's commitment, along with all others involved in the CERTs to ensure proper, mutually accountable partnerships.