MOU Number: 225-12-0038

MEMORANDUM OF UNDERSTANDING
BETWEEN
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE FOOD AND DRUG ADMINISTRATION
AND
AMERICAN SOCIETY OF NEPHROLOGY

I. Purpose

The Food and Drug Administration (FDA) and American Society of Nephrology (ASN) share interests in promoting scientific progress through exchange of scientific capital related to kidney health. Both institutions foresee benefits from the mutual exchange of expertise related to products affecting kidney health (both intentionally and unintentionally), diseases impacting kidney health, clinical trial design, clinical pharmacology, translational science, and regulatory science. This Memorandum of Understanding (MOU) establishes the terms for collaboration to promote these shared interests, which can be pursued through a variety of programs including collaborative education, research, and dialogue.

II. Background

FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended (21 U.S.C. 301, et seq.). In fulfilling its responsibilities under the FD&C Act, FDA, among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, and medical devices and the safety and security of foods, dietary supplements, cosmetics, and radiological products. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA must stay abreast of the latest developments in research and communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships within the ASN will greatly contribute to FDA’s mission. FDA’s centers and offices are more fully described in Appendix A.

ASN leads the fight against kidney disease by educating health professionals, sharing new knowledge, advancing research, and advocating the highest quality care for patients. ASN performs cutting-edge medical research; educates the next generation of health professionals; educates concerning health disparities related to kidney disease; advocates for increasing awareness of kidney disease within the federal government and among policymakers; and strengthens the pipeline of clinicians, researchers, and educators through advance patient care and research in kidney disease.
III. **Substance of Agreement**

This MOU forms the basis for development of scientific collaborations, outreach and educational initiatives and intellectual partnerships between FDA and ASN through a Kidney Health Initiative (KHI). The mission of the KHI is to advance scientific understanding of the kidney health and patient safety implications of new and existing medical products and to foster development of therapies for diseases that affect the kidney by creating a collaborative environment in which FDA and the greater nephrology community can interact to optimize the evaluation of drugs, devices, biologies, and food products. The specific objectives of the KHI are to:

1. Facilitate dialogue and research that informs regulatory processes with regard to the kidney health of patients being treated for kidney-related as well as other diseases.

2. Assess current medical therapies and diagnostics to identify areas in need of greater innovation and/or better defined regulatory pathways.

3. Develop innovative and efficient trial designs appropriate to answer the most important questions related to kidney health.

4. Establish expert consensus around common terminology and key definitions related to kidney health.

5. Develop approaches to the systematic collection of retrospective or prospective data, such as registries and/or global databases, and establishment of data standards.

6. Coordinate “think tanks,” public forums, educational exchanges, and other events to promote discussion and updates on topics in kidney health pertaining to drug, device, biologies, and food product development and evaluation.

7. Create transparent infrastructure and processes that facilitate collaboration and communication among the greater nephrology community and the FDA, including:
   - Seeking input from all stakeholders (including the FDA, industry, nephrologists and other health professionals, the public or patient groups, the National Institutes of Health, the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, and other federal agencies).
   - Leveraging previously conducted and ongoing clinical studies, research infrastructure, and databases.
   - Creating an open and efficient mechanism for encouraging and evaluating potential projects submitted to KHI and ensuring objective evaluation.
   - Involving consortium members in the selection and execution of projects.
8. Establish systems to optimize post-market surveillance of products that affect kidney health, either intentionally or via adverse drug reactions.

9. Draft white papers regarding key issues, describing opportunities and challenges and proposing solutions, as well as promoting execution of these solutions.

Under this MOU, FDA and ASN will seek opportunities to participate together in collaborative research and training as permitted under appropriate statutory authority. Before any specific collaboration is initiated or implemented, FDA and ASN will identify priorities, topics of mutual interest, and develop separate, written agreements for collaboration and sharing of resources. Where applicable, these agreements shall incorporate by reference this MOU. FDA may enter into a contract, grant or cooperative agreement with ASN to the extent authorized by law and available appropriations. The terms and conditions of any such awards will be in accordance with applicable federal law and regulations, and shall be negotiated and executed by appropriate representatives of institutions within ASN and FDA.

IV. General Provisions

1. Rights to any inventions resulting from collaborative research will be determined by the separate written research agreements governing the effort, based on current U.S. Government patent regulations and any other applicable statutes and regulations.

2. Institutions within ASN and FDA may decide to enter into Cooperative Research and Development Agreements (CRADA) specific to particular collaborative projects. The terms of such CRADAs will address Intellectual Property rights.

3. Proprietary and/or nonpublic information will not be disclosed under this MOU, unless such disclosure is governed by appropriate confidentiality disclosure agreements or to the extent such disclosure is permitted by law.

4. Each party (FDA and ASN) will comply with the other party's security procedures and policies regarding access to and use of facilities. Either party may restrict or limit access to its property and facilities at any time and for any reason. ASN individuals participating in activities under this MOU on FDA property will comply with all applicable federal statutes and regulations.

5. It is recognized that from time to time FDA and ASN may share expenses and may require compensation of either party by the other. As research projects are developed, details of how costs are to be shared will be agreed to in advance under other contractual mechanisms as appropriate and in compliance with all applicable federal requirements.
V. Resource Obligations

This MOU represents the broad outline of FDA's and ASN's intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and ASN. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements between FDA and ASN. This MOU does not create binding, enforceable obligations against either party. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA operates.

VI. Liaison Officers

A. For the American Society of Nephrology

Individual's name: Tod Ibrahim

Organization: American Society of Nephrology

Title: Executive Director

Address: 1510 H St, NW Suite 800 Washington, DC 20005

Telephone Number: (202) 640-4676

B. For the Food and Drug Administration:

Individual's name: Patrick Archdeacon

Organization: US Food and Drug Administration

Title: Medical Officer

Address: 10903 New Hampshire Ave, Silver Spring MD 20993

Telephone Number: (301) 796-3952

Each party may designate new liaisons at any time by notifying the other party's liaison in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a
new liaison within two weeks and notify the other party through the designated liaison.

VII. Term, Termination, and Modification

This agreement will be effective when accepted by both FDA and ASN. This agreement may be modified or terminated by mutual written consent by FDA and ASN or may be terminated by either party upon a 60 day advance written notice to the other.

VIII. Statutes, Regulations, Rules, and Policies

This MOU and all associated agreements will be subject to the applicable statutes, regulations, rules, and policies under which FDA and ASN operate.

APPROVED AND ACCEPTED FOR THE AMERICAN SOCIETY OF NEPHROLOGY

Ronald J. Falk, M.D.
President of American Society of Nephrology

9/6/2012
Date

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
HHS Food and Drug Administration

8/30/12
Date
APPENDIX A

FDA Centers/Offices

The Food and Drug Administration (FDA) is comprised of an Office of the Commissioner, six product-oriented centers, a center for toxicological research, and a nationwide field force. FDA is a scientific regulatory agency responsible for the safety of the nation’s domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products. It is one of the oldest federal agencies whose primary function is consumer protection. The agency touches and directly influences the lives of everyone in the United States. FDA is recognized internationally as the leading food and drug regulatory agency in the world. Many foreign nations seek and receive FDA’s help in improving and monitoring the safety of their products. FDA is part of the Executive Branch of the United States Government within the Department of Health and Human Services (DHHS) and the Public Health Service (PHS).

FDA Centers/Offices include:

Office of the Commissioner (OC) – OC is committed to providing the overall scientific and regulatory policies for the entire agency, including special FDA initiatives. OC includes the Immediate Office, the Office of Women’s Health, Office of Minority Health, Office of the Chief of Staff, Office of Policy and Planning, Office of Legislation, Office of International Programs, Office of the Chief Counsel, Office of the Counselor to the Commissioner, Office of Special Medical Programs, Office of External Affairs, Office of Foods, Office of Operations, Office of Medical Products and Tobacco, Office of Global Regulatory Operations and Policy, and the Office of the Chief Scientist.

Center for Biologics Evaluation and Research (CBER) - CBER is committed to advancing the public health through innovative regulations that ensure the safety, effectiveness and timely delivery to patients of biological products. CBER protects and enhances public health through regulating of biological and related products including blood, vaccines, tissue, allergenic and biological therapeutics.

Center for Drug Evaluation and Research (CDER) - CDER is committed to promoting and protecting public health by assuring that safe and effective drugs are available to Americans. Opportunities exist for faculty and students in pharmaceutical science, biochemistry, chemistry, biotechnology, bioengineering and chemical engineering, as well as many other scientific and engineering disciplines to engage with research and regulatory scientists in flexibly structured programs within the Center.

Center for Devices and Radiological Health (CDRH) - CDRH assures that new medical devices are safe and effective before they are marketed. The Center also monitors devices throughout the product life cycle, including a nationwide post-market surveillance system, and assures that radiation-emitting devices meet radiation safety standards.
Center for Food Safety and Applied Nutrition (CFSAN) - CFSAN, with the Agency’s field staff, is responsible for promoting and protecting the public’s health by ensuring the nation’s food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

Center for Veterinary Medicine (CVM) - CVM is a consumer protection organization that fosters public and animal health by approving safe and effective products for animals and by enforcing other applicable provisions of the FD&C Act and other authorities.

Center for Tobacco (CTP) - CTP is responsible for planning, managing, directing and coordinating major tobacco program objectives to implement the Family Smoking Prevention and Tobacco Control Act. This law gives FDA authority over tobacco products by adding a new chapter to the FD&C Act for tobacco products. Some of the Agency’s responsibilities under the law include setting performance standards, reviewing premarket applications for new and modified risk tobacco products, requiring new warning labels, and establishing and enforcing advertising and promotion restrictions. The law gives FDA the authority to regulate tobacco products and manufacturers - not growers.

National Center for Toxicological Research (NCTR) - NCTR conducts peer-reviewed scientific research that supports and anticipates FDA’s current and future regulatory needs. This involves fundamental and applied research specifically designed to define biological mechanisms of action underlying the toxicity of products regulated by FDA. This research is aimed at understanding critical biological events in expressing toxicity and at developing methods to improve assessment of human exposure, susceptibility and risk.

Office of Regulatory Affairs (ORA) - ORA is the lead office for all FDA Field activities as well as providing FDA leadership on imports, inspections, and enforcement policy. ORA supports the six FDA Product Centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States. ORA develops FDA-wide policy on compliance and enforcement and executes FDA’s Import Strategy and Food Protection Plans. ORA staffs are dispersed throughout the United States. Over 85 percent of ORA’s staff work in five Regional Offices, 20 District Offices, 13 Laboratories, and more than 150 Resident Posts and Border Stations. ORA Headquarters is comprised of the Office of Resource Management; Office of Regional Operations; and the Office of Enforcement located in Maryland and the Office of Criminal Investigations located throughout the United States. FDA maintains offices and staff in Washington, D.C., the U.S. Virgin Islands, Puerto Rico, and in all States except Wyoming. In addition to executing its mission through its Federal workforce, ORA works with its State, Local, Tribal, and Territories counterparts to further FDA’s mission. ORA funds grants and cooperative agreements to perform State inspections and provide technical assistance to the States in such areas as milk, food, and shellfish safety.