well as cases where available therapies
do not directly impact the aspects of
disease that matter most to patients. The
extent of public comment for specific
disease areas was one of many factors
used to select the disease areas for
Patient-Focused Drug Development
during FY 2013–2015. In selecting the
disease areas of focus, FDA carefully
considered the public comments
received, the perspectives of reviewing
divisions at FDA, and the following
selection criteria, which were published
in the September 24, 2012, Federal
Register notice:

- Disease areas that are chronic,
symptomatic, or affect functioning and
activities of daily living;
- Disease areas for which aspects of
the disease are not formally captured in
clinical trials; and
- Disease areas for which there are
currently no therapies or very few
therapies, or the available therapies do
not directly affect how a patient feels or
functions.

FDA's selection also reflects the
Agency's desire to include a diverse set
disease areas that represent the wide
range of diseases the Agency encounters
in its regulatory decision-making. These
criteria, also published in the September
24, 2012, Federal Register notice, were
overarching considerations that the
Agency took into account in selecting
the set of disease areas:

- Disease areas that reflect a range of
severity, from diseases that are life-
threatening to those that are mild and
symptomatic;
- Disease areas that have a severe
impact on identifiable subpopulations,
such as children or the elderly; and
- Disease areas that represent a broad
range in terms of size of the affected
population, including common conditions
experienced by large numbers of patients and rare
diseases that affect much smaller patient
populations.

Patient-Focused Drug Development
was conceived as a mechanism to learn
more from patients where their
perspectives could be helpful to drug
development and FDA's review of
applications for new drugs in certain
disease areas. For FDA's review
divisions, this kind of input is most
helpful when the impact of a disease on
patients is not well understood or
endpoints for studying drugs for a
disease are not clearly defined or
established. The potential to fill these
information gaps by hearing from
patients was also a key consideration in
identifying the initial 12 disease areas.
FDA has selected the following
diseases to be addressed in FY 2013–
2015:

- Alpha-1 antitrypsin deficiency;
- breast cancer;
- chronic Chagas disease;
- female sexual dysfunction;
- fibromyalgia;
- hemophilia A, hemophilia B, von
Willebrand disease, and other heritable
bleeding disorders;
- HIV;
- idiopathic pulmonary fibrosis;
- irritable bowel syndrome,
gastroparesis, and gastroesophageal
reflux disease with persistent
regurgitation symptoms on proton-
pump inhibitors;
- lung cancer;
- myalgic encephalomyelitis/chronic
fatigue syndrome;
- narcolepsy;
- neurological manifestations of
inborn errors of metabolism;
- Parkinson’s disease and
Huntington’s disease;
- pulmonary arterial hypertension; and
- sickle cell disease.

A schedule of the meetings planned
for each year can be found at the FDA
Patient-Focused Drug Development Web
site described in the following section of
this notice.

FDA will initiate a second public
process to determine the list of disease
areas for FY 2016–2017. The Agency
recognizes that there are many more
disease areas than can be addressed in
the planned FDA meetings under
PDUFA V, and FDA will seek other
opportunities to gather public input on
disease areas not addressed through this
PDUFA V commitment. FDA also
encourages stakeholders to identify and
organize patient-focused collaborations
to generate public input on other
disease areas with regard to the types of
questions addressed through this
PDUFA commitment, using the process
established through Patient-Focused
Drug Development as a model. More
information on other opportunities for
gathering patient input can be found on
the Patient-Focused Drug Development
Web site.

III. Patient-Focused Drug Development
Web site

FDA has a Web site on Patient-
Focused Drug Development: http://
www.fda.gov/ForIndustry/UserFees/
PrescriptionDrugUserFee/
ucm326192.htm. This Web site contains
the general schedule of upcoming
meetings for FY 2013–2015, information
on how stakeholders can prepare for
upcoming meetings, and information on
how stakeholders may leverage Patient-
Focused Drug Development to generate
input on disease areas not addressed
through the Patient-Focused Drug
Development PDUFA V commitment.
The Web site will be updated as new
information becomes available.

Dated: April 5, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013–08441 Filed 4–10–13; 8:45 am
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions;
Availability for Licensing

AGENCY: National Institutes of Health,
HHS.

ACTION: Notice.

SUMMARY: The inventions listed below
are owned by an agency of the U.S.
Government and are available for
licensing in the U.S. in accordance with
35 U.S.C. 207 to achieve expeditious
commercialization of results of
federally-funded research and
development. Foreign patent
applications are filed on selected
inventions to extend market coverage
for companies and may also be available
for licensing.

FOR FURTHER INFORMATION CONTACT:
Licensing information and copies of the
U.S. patent applications listed below
may be obtained by writing to the
indicated licensing contact at the Office
of Technology Transfer, National
Institutes of Health, 6011 Executive
Boulevard, Suite 325, Rockville,
Maryland 20852–3804; telephone: 301–
496–7057; fax: 301–402–0220. A signed
Confidential Disclosure Agreement will
be required to receive copies of the
patent applications.

Lentiviral Vectors with Dual
Fluorescence/Luminescence Reporters

Description of Technology: Twelve
lentiviral vectors that express both
fluorescent and luminescent markers as
a single fusion protein under various
gene promoters were constructed.
Vectors have been developed previously
to monitor tumors or tumor cells via
bioluminescence or fluorescence alone.
However, bioluminescence is not
sensitive enough to sort individual
tumor cells and fluorescence cannot be
used effectively to view internal tumors.
By combining the two reporters into a
single fusion protein, the tumor can be
effectively visualized within the animal
as well as sorted from non-tumor cells
for post-necropsy experiments. The
added advantage of bioluminescent
visualization allows for in vivo
experiments that more closely simulate the biological development of tumors in organs rather than at the surface of the skin. Additionally, since twelve different vectors with different gene promoters were developed, they can be tested in individual tumor models to find the best vector for visualizing that particular tumor cell line. The vectors are able to sustain long-term expression of both visualization markers, depending on the cell type and promoter in each vector.

Potential Commercial Applications:
- The vectors will be extremely useful for experiments in which both in vivo and in vitro analysis is desired.
- The vectors can also be used for screening cancer cell lines and in tumor models for reporter gene activity.
- The vectors can be useful in drug development.

Competitive Advantages:
- The bioluminescent marker allows for effective visualization of deep (non-surface) tumors in mice.
- The fluorescence label permits efficient sorting of tumor cells from normal (non-labeled) cells after tumors are excised from the mice.
- The vectors allow in vivo experiments that more closely simulate the biological development of tumors in organs rather than at surface of skin.
- The vectors sustain long-term expression.

Development Stage:
- Early-stage
- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Dominic Esposito, Chi-Ping Day, Glenn Y. Merlino (NCI)


Potential Commercial Applications: Diagnosis of Age-related Macular Degeneration.

Competitive Advantages: This technology is potentially a more sensitive means of diagnosing patients with AMD.

Development Stage: In vitro data available.

Inventors: Lai Wei, Robert Nussenblatt, Baoying Liu, Chi-Chao Chan (NEI).


Licensing Contact: Jaime M. Greene; 301–435–5539; greenejaime@mail.nih.gov.

Dated: April 5, 2013.

Richard U. Rodriguez,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C., as amended), the grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial