

Dated: September 1, 2009.

Richard U. Rodriguez,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, 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.

ADDRESSES: 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.

Rapid Diagnostic Applications of Phage

Description of Technology: The NIH has available for licensing two techniques for rapid detection of a particular bacteria strain. Similar detection using currently available technologies take 1-2 days; this technology reduces the time to less than one hour. These technologies utilize phage, which has no pathogenic effect on higher plants and animals and are part of approved food-preparation formulations, indicating their known safety profile and an existing regulatory pathway. The first technique involves a phage that incorporates a reporter gene (e.g., luciferase) that will be expressed only when the phage successfully infects a bacterium. This technique is particularly useful where only bacteria-killing ("lytic") phages are known because the method also deactivates the lytic genes, enabling infection and subsequent detection. The second

technique involves an engineered phage that will bind with quantum dots upon infection of bacteria; if a sample is treated first with this phage and then with quantum dots, the sample will only respond if the bacteria are present. Both techniques can be used to diagnose a clinical sample (tissue, blood, etc.) or an environmental isolate.

Applications

- Bacterial detection and diagnostics, including clinical or environment samples.
- Food safety and biodefense.

Advantages

- Detection methods are novel, rapid, and potentially applicable in many contexts (e.g., clinic, food preparation, bioterror response).
- Phage is easy and inexpensive to cultivate.
- Phage is on sale in the US for food-preparation formulations and thus has a known regulatory pathway.

Development Status: A range of phages have been synthesized, many of which have been tested proof-of-principle using major standardized testing systems.

Inventors: Dr. Carl Merrill (NIMH), Dr. Sankar Adhya (NCI), *et al.*

Publications

1. R Edgar *et al.* High-sensitivity bacterial detection using biotin-tagged phage and quantum-dot nanocomplexes. *Proc Natl Acad Sci. USA* 2006 Mar 28;103(13):4841-4845.
2. C Merrill *et al.* The prospect for bacteriophage therapy in Western medicine. *Nat Rev Drug Discov.* 2003 Jun;2(6):489-497.

Patent Status

HHS Reference No. E-169-2004—U.S. Patent Application No. 11/547,587 filed 05 Oct 2006.

HHS Reference No. E-281-2005—U.S. Patent Application No. 11/884,604 filed 17 Aug 2007.

HHS Reference No. E-318-2000—Research Materials (patent protection is not being pursued for this technology): "Method for Determining Sensitivity to a Bacteriophage."

Licensing Status: Technologies are available for licensing, either individually or as a package.

Licensing Contact: Bruce Goldstein, J.D., M.S.; 301-435-5470; goldsteb@mail.nih.gov.

Collaborative Research Opportunity: The NCI Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or

commercialize this technology. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Therapeutic Antibacterial Applications of Phage

Description of Technology: The NIH, in collaboration with others, has developed three groups of inventions related to the use of bacteriophages in therapeutic situations. The first group is a method of adapting phages to survive in the body substantially longer than wild-type phages, using serial passaging and/or genetic engineering. The second group involves phages designed to bind the toxins and cytokines that killed bacteria release into the bloodstream, reducing the pathogenic properties of the bacteria. The third group is a method of engineering a phage to have multiple binding sites, such that a single phage can target multiple types of bacteria.

Application: Therapeutic applications of phage to treat bacterial infection.

Advantages

- Improved efficacy through longer circulation.
- Additional antibacterial functions.
- Can be used independently or as an adjuvant to another antibacterial therapy.

Development Status: A range of phages have been synthesized and tested *in vivo*. A Phase 1 study of a phage targeting vancomycin-resistant *Enterococcus faecium* was completed by Exponential Biotherapies, Inc., with no adverse effects reported.

Inventors: Dr. Carl Merrill (NIMH), Dr. Sankar Adhya (NCI), *et al.*

Publications

1. C Merrill *et al.* The prospect for bacteriophage therapy in Western medicine. *Nat Rev Drug Discov.* 2003 Jun;2(6):489-497.
2. B Biswas *et al.* Bacteriophage therapy rescues mice bacteremic from a clinical isolate of vancomycin-resistant *Enterococcus faecium*. *Infect Immun.* 2002 Jan;70(1):204-210.
3. C Merrill *et al.* Long-circulating bacteriophage as antibacterial agents. *Proc Natl Acad Sci. USA* 1996 Apr 16;93(8):3188-3192.

Patent Status

HHS Reference No. E-110-1993—U.S. Patent No. 5,688,601 issued 19 Jun 1997; *U.S. Patent No. 7,332,307* issued 19 Feb 2008.

HHS Reference No. E-257-2000—U.S. Patent No. 7,163,818 issued 16 Jan 2007.

HHS Reference No. E-178-1996—Research Materials (patent protection is

not being pursued for this technology): “Deletion of Lysogeny Genes and Toxin Genes from Bacteriophage Used in the Epidemiologic Control of Bacterial Illness.”

HHS Reference No. E-179-1996—Research Materials (patent protection is not being pursued for this technology): “Therapeutics Use of Phage Expressing Toxin-Binding and/or Cytokine-Binding Proteins and Elimination of Genes Associate with Lysogeny.”

HHS Reference No. E-196-1997—Research Materials (patent protection is not being pursued for this technology): “Antibacterial Therapy with Bacteriophage Genotypically Modified to Delay Inactivation by the Host Defense System.”

HHS Reference Nos. E-089-1998 and E-257-2003—Research Materials (patent protection is not being pursued for this technology): “Two Enterocin-Producing Strains of Bacteria and Their Enterocins, Both of Which Are Lethal to Vancomycin-Resistant *Enterococcus faecium*.”

HHS Reference No. E-012-1999—Research Materials (patent protection is not being pursued for this technology): “Long Circulating Phage Vectors.”

Licensing Status: Technologies are available for licensing, either individually or as a package.

Licensing Contact: Bruce Goldstein, J.D., M.S.; 301-435-5470; goldsteb@mail.nih.gov.

Collaborative Research Opportunity: The NCI Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: September 1, 2009.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0392]

Medical Devices: Neurological Devices; Electroconvulsive Therapy Device; Establishing a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a public docket to receive information and comments regarding the current classification process related to electroconvulsive therapy devices (ECT). The current classification process for this device pertains to the “Order for Certain Class III Devices; Submission of Safety and Effectiveness,” published in the **Federal Register** of April 9, 2009 (74 FR 16214). Under the Order, FDA required manufacturers of certain Class III devices, including ECT, to submit a summary of, and citation to, any information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information which has not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). For each device subject to the Order, FDA is reviewing the submitted information to determine whether FDA should maintain the device as class III and require the submission of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP), or whether FDA should reclassify the device into class II or class I. FDA is now inviting interested persons to submit comments that relate to the safety and effectiveness of ECT.

DATES: Submit written or electronic comments and information by January 8, 2010.

ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments and information to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Victor Krauthamer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., W066-1106, Silver Spring, MD 20993, 301-796-2474.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 9, 2009 (74 FR 16214), FDA published an “Order for Certain Class III Devices; Submission of Safety and Effectiveness Information” (“515(i) Order”). Under this Order, as mandated by section 515(i) of the act (21 U.S.C. 360e(i)), FDA required manufacturers of certain class III devices that were in commercial distribution before May 28, 1976, and devices found to be substantially equivalent to them that were marketed on or after that date, including ECT, to

submit to FDA by August 7, 2009, a summary of, and citation to, any information known, or otherwise available to them respecting those devices including, adverse safety or effectiveness data that had not been submitted under section 519 of the act (21 U.S.C. 360i). In addition, manufacturers were encouraged by FDA to submit a summary of the information previously sent to FDA under section 519 of the act. Currently, the agency is in the process of reviewing the information that has been submitted by the manufacturers subject to the 515(i) Order.

Based upon the review of this submitted information, FDA is considering whether to issue a proposed rule requiring the device to remain in class III, followed by the issuance of a regulation requiring submission of a PMA or PDP, or to revise the classification of the devices into class II, requiring the designation of special controls, or into class I, requiring only general controls. In determining whether to revise the classification of a device, or to require a device to remain in class III, FDA will apply the criteria set forth in section 513(a) of the act. If FDA decides to reclassify the device, FDA must determine that general controls alone (class I) or general controls plus special controls (class II) would provide reasonable assurance of the safety and effectiveness of the device. FDA’s proposed classification of ECT devices will be subject to notice and comment rulemaking to allow for additional public comment.

FDA has received a significant number of inquiries from members of the public and the health care community in response to this order to ECT manufacturers. In recognition of this significant public interest, FDA is opening this docket to permit individuals other than manufacturers to submit information related to the safety and effectiveness of ECT. If individuals wish to report an adverse event associated with the use of an ECT device, please use the MedWatch Online Voluntary Reporting Form available at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>. FDA will review information submitted through the MedWatch program prior to making any changes to the classification of ECT devices.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic