

The conference agreement includes language making Vessel Sanitation Program user fees available through September 30, 2013.

Working Capital Fund.—The conferees have included bill language that allows CDC to begin creating a Working Capital Fund (WCF) to achieve greater cost efficiencies across the administrative operations of the agency. The conferees expect this WCF to begin making disbursements no sooner than fiscal year 2014. CDC shall notify the House and Senate Committees on Appropriations prior to any funds being transferred to or deposited in the WCF.

The conferees direct CDC to create a strong auditing system for the WCF, which shall include annual auditing of the calculation by which programs are charged to ensure that WCF funds are used solely for administrative costs and that CDC Centers and Offices are not over-charged for services. The conferees instruct that the structure of the WCF shall assume no more than a 2 year availability of any funds within it, that no construction of facilities shall be allowable costs, and that all allowable costs are clearly defined. The conferees further direct that the governance system be designed to include a role for all Center Directors in overseeing the costs incurred. The Committees on Appropriations expect quarterly briefings on the progress being made in drafting the charter and the methodology being used to set up the WCF.

Within the amount provided for Business Services, the conferees have made \$30,000,000 available until September 30, 2013.

NATIONAL INSTITUTES OF HEALTH

The conference agreement includes \$30,689,997,000 for the accounts that comprise the National Institutes of Health (NIH) total appropriation. This total

does not include any funding for the Global Fund to Fight AIDS, Tuberculosis and Malaria; the conferees understand that all fiscal year 2012 funding for the Global Fund is provided through Division I (Department of State, Foreign Operations, and Related Programs). The conference agreement continues the allocation to NIH of \$8,200,000 in program evaluation set-aside funding. Appropriation levels for individual institutes and centers are described in the table at the end of this statement of managers.

The conferees recognize NIH's mission to invest in basic biomedical research and apply that knowledge to enhance our Nation's health and well-being, lengthen life, and reduce the burdens of illness and disability. NIH is strongly urged to ensure its policies continue to support a robust extramural community and make certain sufficient research resources are available to the more than 300,000 NIH-supported scientists at over 3,100 institutions across the country. The conferees affirm the critical importance of new and competing research project grants (RPGs) to the mission of NIH and are concerned that in the past few years, NIH has failed to support the number of new, competing RPGs that it estimated would be awarded in its annual congressional budget justifications. The conferees expect NIH to evaluate its new grant-estimating methodology to improve its accuracy and support as many scientifically meritorious new and competing RPGs grants as possible, at a reasonable award level, with the funding provided in this Act.

In recent years, extramural research has accounted for nearly 90 percent of NIH's budget. The conferees strongly urge NIH to maintain at least that level in fiscal year 2012. NIH should also establish safeguards to ensure the percentage of funds used to support basic research across NIH is maintained.

The Office of the Director (OD) shall ensure, as practicable, the programs and offices within OD receive increases proportional to the overall increase, unless otherwise specified. The conferees request quarterly notification on obligations from the NIH Director's Discretionary Fund to the Committees on Appropriations of the House of Representatives and the Senate.

The conferees expect NIH to continue the long-standing policy for Common Fund projects to be short-term, high-impact awards, with no projects receiving funding for more than 10 years. The conferees recognize that certain investigator-initiated programs such as Pioneer Awards may be exceptions to the 10-year limit. Any other proposed exceptions should be explained in the fiscal year 2013 congressional budget justification.

The conference agreement includes language to eliminate the National Center for Research Resources (NCRR) and create the National Center for Advancing Translational Sciences (NCATS).

NCATS will study steps in the therapeutics development and implementation process, consult with experts in academia and the biotechnology and pharmaceutical industries to identify bottlenecks in the processes that are amenable to re-engineering, and develop new technologies and innovative methods for streamlining the processes. In order to evaluate these innovations and new approaches, NCATS will undertake targeted therapeutics development and implementation projects. In all of these efforts, the conferees expect that NCATS will complement, not compete with, the efforts of the private sector.

While the conferees welcome the creation of NCATS, they were disappointed by the way the administration requested it. The President's proposed budget for fiscal year 2012 included a vague description of NCATS but did not formally

request funding for the restructuring or provide any details about which components of NIH would be consolidated into the new Center. The failure to do so caused unnecessary uncertainty about the proposal and contributed to the impression that it was being rushed. The conferees are also aware of concerns that the NIH process for evaluating the merits of the NCATS reorganization did not comply with the NIH Reform Act of 2006 with respect to the role of the Scientific Management Review Board (SMRB).

Lessons learned with NCATS should guide NIH as it considers another proposed restructuring, one that would involve consolidating NIDA, NIAAA and components of other Institutes and Centers (ICs) into a new Institute devoted to research on substance use, abuse and addiction. The conferees understand that NIH plans to adopt a more deliberate approach in evaluating the need for this Institute. The conferees strongly recommend that this approach should include full consideration by the SMRB and that if the administration ultimately decides to seek such a restructuring, it should provide sufficient details in a formal budget request to Congress.

The following table provides the specific funding levels for the institutes and centers and displays the comparable adjustments related to the reorganization.

(Dollars in thousands)	FY 2011 Enacted*	Reallocation of Resources	FY 2011 Reorganization Comparable	FY 2012 Enacted
National Cancer Institute (NCI).....	\$ 5,058,577	-4,163	\$ 5,054,414	\$5,081,788
<i>Therapeutics for Rare and Neglected Disease (TRND)</i>		-4,163		
National Heart, Lung, and Blood Institute (NHLBI).....	3,069,723	-1,489	3,068,234	3,084,851
<i>Clinical Research Resources</i>		+995		
<i>Biotechnology Research Resources</i>		+29		
<i>Research Management & Support</i>		+14		

<i>TRND</i>		-2,527		
National Institute of Dental & Craniofacial Research (NIDCR)..	409,608	-337	409,271	411,488
<i>TRND</i>		-337		
Nat. Inst. of Diabetes & Digestive & Kidney Diseases (NIDDK).	1,792,224	-1,476	1,790,748	1,800,447
<i>TRND</i>		-1,476		
National Institute of Neurological Disorders and Stroke (NINDS).....	1,622,003	-1,335	1,620,668	1,629,445
<i>TRND</i>		-1,335		
National Institute of Allergy and Infectious Diseases (NIAID)...	4,478,668	-3,689	4,474,979	4,499,215
<i>TRND</i>		-3,689		
National Institute of General Medical Sciences (NIGMS).....	2,033,782	+338,010	2,371,792	2,434,637
<i>Institutional Development Awards (IDeA)</i>		+226,480		
<i>Biotechnology Research Resources</i>		+97,114		
<i>Research Infrastructure</i>		+8,853		
<i>Research Management & Support</i>		+7,237		
<i>TRND</i>		-1,674		
Nat. Inst. of Child Health and Human Development (NICHD)...	1,317,854	-1,085	1,316,769	1,323,900
<i>TRND</i>		-1,085		
National Eye Institute (NEI).....	700,828	-577	700,251	704,043
<i>TRND</i>		-577		
National Institute of Environmental Health Sciences (NIEHS)..	683,724	-555	683,169	686,869
<i>TRND</i>		-555		
National Institute on Aging (NIA).....	1,100,481	-906	1,099,575	1,105,530
<i>TRND</i>		-906		
Nat. Inst. Arthritis & Musculoskeletal & Skin Diseases (NIAMS).....	534,349	-440	533,909	536,801
<i>TRND</i>		-440		
Nat. Inst. on Deafness & Other Communication Disorders (NIDCD).....	415,155	-341	414,814	417,061
<i>TRND</i>		-341		
National Institute of Mental Health (NIMH).....	1,476,294	-1,215	1,475,079	1,483,068
<i>TRND</i>		-1,215		

National Institute on Drug Abuse (NIDA).....	1,050,542	-865	1,049,677	1,055,362
<i>TRND</i>		-865		
National Institute on Alcohol Abuse and Alcoholism (NIAAA)....	458,286	-377	457,909	460,389
<i>TRND</i>		-377		
National Institute of Nursing Research (NINR).....	144,381	-119	144,262	145,043
<i>TRND</i>		-119		
National Human Genome Research Institute (NHGRI).....	511,497	-421	511,076	513,844
<i>TRND</i>		-421		
National Institute of Biomedical Imaging and Bioengineering (NIBIB).....	313,802	+23,370	337,172	338,998
<i>Biotechnology Research Resources</i>		+22,977		
<i>Research Management & Support</i>		+651		
<i>TRND</i>		-258		
National Institute on Minority Health and Health Disparities (NIMHD).....	209,714	+65,757	275,471	276,963
<i>Research Centers in Minority Institutions</i>		+58,686		
<i>Biotechnology Research Resources</i>		+1,784		
<i>Research Infrastructure</i>		+2,578		
<i>Research Management & Support</i>		+2,882		
<i>TRND</i>		-173		
National Center for Research Resources (NCRR).....	1,257,754	-1,257,754	0	0
National Center for Complementary and Alternative Medicine (NCCAM).....	127,713	-105	127,608	128,299
<i>TRND</i>		-105		0
John E. Fogarty International Center (FIC).....	69,436	-58	69,378	69,754
<i>TRND</i>		-58		0
National Library of Medicine (NLM).....	336,733	-277	336,456	338,278
<i>TRND</i>		-277		0
Office of the Director (OD).....	1,166,963	+287,042	1,454,005	1,461,880
<i>Comparative Medicine (incl. Nat'l Primate Res. Centers)</i>		+194,921		
<i>Shared & High-end Instrumentation</i>		+64,114		
<i>Clinical Research Resources</i>		+769		

<i>Biotechnology Research Resources</i>		+8,505		
<i>Research Infrastructure</i>		+6,655		
<i>Research Management & Support</i>		+9,594		
<i>Science Education Partnership Award</i>		+18,480		
<i>Clinical Research Resources</i>		+534		
<i>Biotechnology Research Resources</i>		+552		
<i>Research Management & Support</i>		+716		
<i>Office of Rare Diseases Research</i>		-17,798		
National Center for Advancing Translational Sciences (NCATS).....	0	+563,405	563,405	576,456
<i>Clinical & Translational Science Awards (CTSAs)</i>		+457,700		
<i>Clinical Research Resources</i>		+27,879		
<i>Biotechnology Research Resources</i>		+18,633		
<i>Research Management & Support</i>		+16,316		
<i>NCBI/PA</i>		+1,079		
<i>TRND</i>		+24,000		
<i>Office of Rare Diseases Research</i>		+17,798		
<i>Cures Acceleration Network (CAN)</i>		0		

Note: The FY 2011 enacted level does not include transfers.

Cures Acceleration Network (CAN).—The conferees provide NCATS with up to ~~\$10 million~~ ^{10,000,000} to support the CAN Board and related activities. The conferees expect a high bar for any use of waiver authority for CAN grant matching funds; any use should be extremely limited to maximize funds towards the CAN goals. The conferees encourage the CAN Board to create general principles and measurable outcomes to track success. The conferees request NCATS to charter an Institute of Medicine (IOM) work group to review, evaluate, and identify issues related to the CAN authority and provide a report for use by the CAN Board to help it identify ways to accelerate and expand the number of cures. The report should include a survey and inventory of activities at NIH, FDA, AHRQ, CDC, the Patent and Trademark Office (PTO), and in the private sector that relate to the

CAN program. The conferees urge IOM to include balanced participation by the entities listed above as well as the representatives of the pharmaceutical and biotechnology industry and the biotech venture capital community. The report should address patent authority, marketability, use of high-throughput analysis, regulatory timelines, and cost structure issues related to the purpose of CAN.

Accelerating Commercialization of Therapies to Patients.—The conferees understand the need to develop models to assist research universities and institutes on the best ways to leverage and commercialize federally supported basic and applied biomedical research discoveries. This is a key reason why the conferees have agreed to create NCATS. The conferees note the market has started to develop public-private sector models that are beginning to show results in translating basic research far more quickly than traditional models. These types of models use pre-defined technology-licensing terms to rapidly license new products and build a core of options for commercialization partnerships with pharmaceutical and biotechnology companies to establish joint ventures to further advance products to the market. The conferees strongly urge NIH to study and foster these models.

The conferees expect any NIH-supported partnerships to expand translational pharmaceutical development in a manner that does not inhibit creative market models. Top priorities of the Center should include developing tools to improve the “de-risking” process and advancing the drug development process to the point at which it can reasonably be expected to be picked up by the private sector. The conferees suggest the selection of Center projects should consider future market acceptance as one component of the criteria to evaluate and selected potential Center projects. The conferees direct NIH to host a trans-NIH workshop with key research organizations, venture capitalists, pharmaceutical firms, the

PTO, the FDA, and a sample of research universities and institutes to work together with NIH and the drug development market. The workshop should also consider how existing NIH and government mechanisms can be used to encourage models around the country to speed commercialization of therapies through a market-based approach.

Clinical and Translational Science Awards (CTSAs).—The conferees are encouraged by the success of the CTSA consortium and recommends the program receive full funding as it nears full implementation. The conferees expect the NCATS Director to ensure the current focus on the full spectrum of translational research is maintained, and CTSA resources are not diverted. The inclusion of patient-centered research, community engagement, training, dissemination science, and behavioral research is extremely important to the translation and application of basic science discoveries and success of the CTSAs. CTSAs now represent an investment of half a decade of innovation in translational research. To ensure the benefits of this investment are maintained, the conferees urge NIH to support a study by the IOM that would evaluate the CTSA program and recommend whether changes to the current mission are needed. The review should include stakeholders' input and be available no later than 18 months after the enactment of this bill.

Therapeutics for Rare and Neglected Disease (TRND) Program.—The conferees continue support for TRND at a level of \$24,000,000 within NCATS. The conferees urge NIH to provide an annual report on the TRND program that identifies the number of projects started each year, cost per project, and the outcome of each project. The first report should be provided to the Committees on Appropriations by July 1, 2012.

Institutional Development Awards.—The conferees provide \$276,480,000 to increase support for the Institutional Development Awards (IDeA) program. The conferees recognize the importance of the Centers Biomedical Research Excellence (COBRE) and the IDeA Networks of Biomedical Research Excellence (INBRE) programs ~~and expect NIH to maintain the planned level of \$150,598,000 for COBRE and \$80,000,000 in the request.~~ The conferees believe the IDeA program has made a significant contribution to biomedical research and creating a skilled workforce. Therefore, the conferees provide a \$45,882,000 increase and recommend it be divided equally toward a new COBRE competition and to support new awards for the IDeA Clinical Trial and Translation Program to develop infrastructure for clinical and translational research in IDeA States. The conferees encourage the NIH Director to expand the program to support co-funding of IDeA projects across NIH ICs to foster the development of efforts in IDeA State programs. Further, as an Office of Experimental Program to Stimulate Competitive Research (EPSCoR) program, the focus of IDeA should continue to be on improving the necessary infrastructure and strengthening the biomedical research capacity and capability of research institutions. Unfortunately, many institutions in EPSCoR-qualifying States who could benefit from the IDeA program are ineligible for funding. The conferees encourage NIH to revise current eligibility criteria to take into account how the decreasing success rate for R01 grants NIH-wide is affecting IDeA eligibility. In particular, the conferees believe the IDeA Director should have the authority to consider funding institutions in any State that is EPSCoR eligible. The conferees urge NIH to develop criteria to incorporate flexibility into the program to address these concerns. The conferees request an update on both the IDeA eligibility criteria proposals and funding level by State and major activities, to include the co-funding activity, in the fiscal year 2013 congressional budget justification.

Third Party Collections 3-Year Pilot.—Since fiscal year 1997, Congress has included bill language authorizing NIH to “collect third party payments for the cost of clinical services that are incurred in NIH research facilities.” NIH has not yet exercised that authority. A recent study released in September that was conducted by PricewaterhouseCoopers LLP (PwC) found that there are numerous potential advantages as well as potential disadvantages to implementing a third party billing program. “The potential use of third party billing represents a significant investment and enduring change for the NIH Clinical Center,” the study states. “As such, additional efforts beyond the 14-week study represented in this report may be undertaken to more fully consider the challenges associated with the use of third party billing and the opportunities that may exist.” The conferees concur with this observation and therefore direct NIH to conduct a 3-year pilot study to assess the viability of third party reimbursement at NIH by looking at one of the services commonly used by a significant number of outpatients at some point in the patient’s protocol. One possible example would be radiology services, but this is not the only option. The Committees on Appropriations expect to be briefed on the proposed subject area and scope of the pilot before it is finalized. The conferees include \$10,000,000 for the Clinical Center for the costs of building the billing infrastructure for the pilot.

Neuroblastoma.—The conferees note the promising results of a recent clinical trial using a chimeric antibody to treat newly diagnosed neuroblastoma patients. The conferees support efforts to facilitate access to this new therapy for relapsed patients and request an update in the fiscal year 2013 congressional budget request.

Clinical Trials.—The conferees are aware of a 2010 IOM study on clinical trials that identified a number of concerns which may apply across all ICs.

The conferees direct NIH to conduct a trans-NIH review of the applicability of the 12 IOM recommendations to all NIH ICs that conduct clinical trials. The review should examine ways to develop and strengthen NIH-wide policies with a focus on opportunities to improve the incorporation of innovative science, increase speed of initiation and completion, improve the means of setting priorities, and develop better incentives for participation in clinical trials.

The conferees note the report found it takes over 900 days to open a clinical trial, but trials supported with other resources [REDACTED] developed methods to open studies within 90 days. The conferees encourage NIH to consider guidance to incorporate the 90-day opening model into other NIH-wide clinical trial activity.

through the American Recovery and Reinvestment Act

The review should examine the policies of each IC regarding funding for variable accrual costs per case, and ensure consistent guideline across NIH. Specifically, the review should examine the viability and effect on speed of opening trials of a multi-tier system in which payments for cost-per-accrual vary according to the time required to open the trial. Furthermore, the review should examine the methods and processes ICs use to prioritize clinical trials based on peer-review input, funding, and other ways to optimize selection of studies.

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The conferees request a report by September 30, 2012, that identifies the findings, proposed policy changes, implementation timeline, and key measures NIH will use to monitor clinical trial activity.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

The conference agreement includes \$3,354,313,000 for the Substance Abuse and Mental Health Services Administration (SAMHSA). In addition, the