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ZERHOUNI FACES WIDE RANGE OF QUESTIONS AT HOUSE HEARING

On March 25, the House Energy and Commerce Health Subcommittee held the fifth in a series of hearings on the National Institutes of Health (NIH) to focus on how the agency is conducting clinical research and highlight areas for improvement.

Noting that the "NIH has not been reauthorized in over ten years," Subcommittee Chair Michael Bilirakis (R-FL) explained that he "firmly believes that [the] investment in biomedical research through NIH is probably one of the wisest uses of our limited Federal resources." It is incumbent upon the Congress, however, "to continue to ensure that taxpayers' dollars are used in the most effective manner," the Chairman stated.

Expressing his approval of NIH Director Elias Zerhouni's leadership in developing the NIH Roadmap, Bilirakis articulated his belief that the Roadmap "will help NIH re-focus its priorities and improve on its already impressive track record." (See *Update*, October 6, 2003).

In his testimony before the Subcommittee, Zerhouni recognized the support of Congress and the White House for NIH. That support, he noted has allowed for "unprecedented knowledge." He also asserted that the discoveries that have resulted from the support of NIH will "have far less meaning if we cannot translate them into prevention methods and treatments for disabilities and diseases." This translation, sometimes referred to as the "bench to bedside" process, cannot happen without clinical research, Zerhouni explained.

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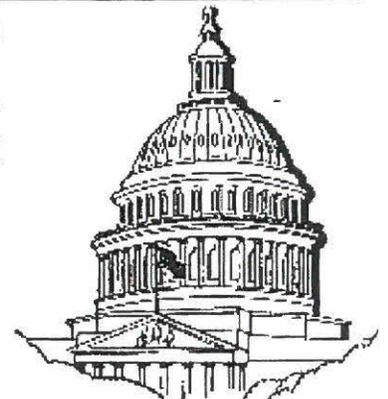
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COSSA SEMINAR HELD ON DETECTING DECEPTION

In the midst of Washington headlines dominated by the work of the National Commission on Terrorist Attacks Upon the United States (also known as the 9/11 Commission), COSSA focused its first Congressional Briefing of 2004 on a related topic. The March 19 seminar, *Detecting Deception: Research to Secure the Homeland*, highlighted three experts who have been studying techniques and approaches that security agencies can use to uncover threats to the nation.

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ZERHOUNI, (Continued from Page 1)

He noted that clinical research, broadly defined, involves the participation of human subjects in various aspects of research. According to the NIH Director, approximately one-third – \$8.4 billion – of the grants awarded by the NIH support clinical research. The agency continues to expand its clinical research program and provide resources for infrastructure, he told the Subcommittee. Zerhouni emphasized that one of the key goals of the Roadmap is to re-engineer the clinical research enterprise to overcome the obstacles to the conduct and translation of clinical research by transforming its very structure. Accordingly, he noted, there are four main components to this provision of the Roadmap. These include: 1) facilitating translational research; 2) enhancing the clinical research workforces; 3) integrating clinical research networks; and 4) coordinating clinical research policies.

Congress Should Be Careful About Micromanaging the NIH

Also declaring herself a proud supporter of the NIH, Rep. Lois Capps (D-CA) observed that “the NIH supports the best research in the world,” the “direct result of the amazing job that the NIH has done.” Capps, however, lamented the recent House-passed budget resolution which provided “for minimal increases.” She expressed her fear that the lack of adequate resources for the agency would cause the loss of scientific gains made as a result of the recent five-year doubling of its budget.

Further, emphasizing that the research supported by the agency has “dramatically improved the lives of many Americans,” Capps warned against the tendency by some in Congress to attempt to “micromanage science.”

Anticipating a return to the discussion that dominated a joint hearing of the House Energy and Commerce Committee and the Senate Health, Education, Labor and Pensions Committee on October 2, 2003, Capps noted that “some members have raised questions about NIH grants on human sexuality. While I do think it is important for Congress to conduct oversight, it is also important for us to keep politics from interfering with science.” She cautioned Members of Congress against engaging in “witch hunts.”

Capps praised Zerhouni for his thoughtful response to Members that resulted from the generation of a list of approximately 150 grants submitted to NIH by the Energy and Commerce Committee (See *Update*, February 9, 2004). “Many of my colleagues advocate for the use of so-called ‘sound science,’ which seems more about

advancing political goals, not science. But when the world’s best scientific institution makes a decision based on truly sound science some of them object to the results.

“Our job in Congress should not be to micromanage scientists about how to conduct their research. Our job should be to make sure that they have the support and resources they need to advance medical science. We can and should make sure that NIH is run effectively, and that its procedures meet quality standards. . . There is no question that some Americans engage in self-destructive behavior. If we want to help them make their lives better we cannot pretend the behavior does not exist. We must come to understand it and its effects on public health so that it can be addressed more effectively. That is what scientific research is for,” Capps emphasized.

Protection of Human Subjects

Rep. Diana DeGette (D-CO), who recently reintroduced legislation (H.R. 3594) aimed at shoring up the human subjects protection system and creating harmonization between the various Federal agencies, particularly the U.S. Food and Drug Administration (FDA) and NIH, expressed her pleasure with Zerhouni addressing the issue in his testimony.

Rep. Jim Greenwood (R-PA), who joined DeGette in introducing human subjects protection legislation in the 107th Congress, echoed her support for harmonization. Zerhouni responded by explaining that he is working in collaboration with the other Federal agencies to analyze the regulations and find common ground between the FDA, NIH, and the Office of Human Research Protection, among others.

According to Zerhouni, the “NIH is working in concert with regulatory agencies, research communities, and patient advocacy groups to catalyze Federal-wide coordination of policies pertaining to clinical research, to develop better processes, and to standardize requirements for reporting adverse events, human subjects protections, privacy and conflict-of-interest policies, and standards for electronic submission.”

Rep. Steve Buyer (R-IN) expressed his desire to see the NIH engage all Federal agencies, and specifically the Veterans Administration, which does clinical research. Zerhouni reassured him that the NIH’s harmonization effort does indeed involve a trans-agency look.

Buyer also noted his surprise at learning from reading the Centers for Disease Control and Prevention's (CDC) website that genital herpes is very common in the United States. According to the CDC's website, said Buyer, 45 million people, 1 of every 5 adults have genital herpes. "Shocking," he declared. He then asked the NIH Director how do you define an epidemic, and noted that 1 of every 4 women is infected. "Is it prudent to go after this virus?," he asked, noting that currently there is not a cure for genital herpes.

Observing that there are 65 million people with sexually-transmitted diseases (STDs), with an additional 4 million people a year acquiring a STD, Buyer declared "we have a public health issue." He also noted that while most of the research investment is in HIV, there are increasing numbers of individuals with HPV (human papillomavirus); there is a similar increase in the rate of syphilis, along with an increase in STDs in the senior population. He inquired as to whether or not the NIH has a plan to combat this trend.

Zerhouni responded by emphasizing the need for research in this area, "both biomedical and behavioral research. . . We need both." The problem, he explained "relates to the environment as much as to the biology."

AHRQ COUNCIL MEETING FOCUSES ON MEDICARE LAW

On April 2nd, the National Advisory Council for the Agency for Healthcare Research and Quality (AHRQ) convened at AHRQ headquarters in Rockville, MD to hear an update on the status of Agency's current budget, research, and program initiatives and discuss building a science base for evaluating the effectiveness of health care interventions, the Hospital Consumer Assessment of Health Plans Survey (HCAHPS), and the Agency's new mission.

AHRQ Director Carolyn Clancy opened the conference by reiterating for council members the highlights of the Agency's FY 2005 budget request (See *Update*, March 28, 2004) and the 2003 Health Care Quality and Health Care Disparities reports (See *Update*, January 12, 2004). She also noted that AHRQ, in conjunction with the Institute of Medicine, has prioritized developing strategies to address diabetes and respiratory disease in priority populations such as children, asthmatics, smokers this year.

Clancy also detailed AHRQ's role in the execution of four provisions written into the Medicare Modernization Act of 2003 (MMA): 1) designing and evaluating Medicare Care Management Performance Demonstrations; 2) coordinating with the Centers for Medicare and Medicaid Services (CMS) and the National Institutes of Health to design the Medicare Health Care Quality Demonstration; 3) administer support efforts and undertake research and provide other scientific support to improve quality, effectiveness, and efficiency of health care items and services provided by CMS; and 4) identify options available to improve information available to health care providers, patients, and policymakers.

Gail Wilensky, a Senior Fellow with Project Hope and former head of the U.S. Health Care Financing Administration, the predecessor to CMS, discussed the role she envisioned AHRQ and other government health organizations would play in implementing the MMA. Her main premise was that the Medicare law "should not be changed to allow the government to negotiate directly for lower prices" since it already "sets the prices for the thousands of types of physician visits and procedures that Medicare covers." Wilensky also asserted that a better plan for the government in the long term would be "to combine the effects of group purchasing with efforts by the government to make good information available about both the clinical effectiveness and cost effectiveness of new drugs that come on the market."

Moreover, she maintained that the best way to decrease the cost of pharmaceuticals is to provide better information to patients and physicians about the therapeutics that can best meet the patients' needs and align "the information with financial incentives" for the patients and the physicians' practices. Getting good information will take time, and Wilensky emphasized her regard for AHRQ as a "key government player" in reforming Medicare because it is an agency with "some bipartisan support" and has been authorized by Congress "to modestly expand work" on prescription costs and impacts. She stressed how important it was for the Agency to try to provide this kind of information to consumers and physicians so impediments to quality health care could be removed and people could make informed decisions about their health care.

Following Wilensky, Charles Darby of the AHRQ Center for Quality Improvement and Patient Safety and Thomas Reilly of CMS presented an updated overview of HCAHPS, a standardized survey designed to allow meaningful comparisons of hospitals nationwide and to provide consumers with qualitative information about the hospitals they receive treatment from. HCAHPS administrators have finished revising the survey to meet

the concerns/suggestions provided during the initial public response phase and a pilot program for HCAHPS has been launched in three states: New York, Maryland, and Arizona. They are also preparing for the survey to be implemented nationally by (1) making implementation practical to hospitals and vendors by holding stakeholders meetings, presentations, and web chats to elicit suggestions; and (2) partnering up with hospitals and vendors to collect data and the government to analyze and report it to the public. Darby and Reilly told council members that revisions to HCAHPS will be made after another round of public comment and that the survey should be released in 2005.

The afternoon session featured a discussion of AHRQ's new mission. Clancy asserted that the Agency intends to adopt a more activist framework, one which "focuses on improvement through new research partnered with delivery of care to organizations." She expressed a strong desire to make the research more relevant but conceded that the metrics of success are presently unclear.

ACADEMY REPORT EXAMINES MEASURING DISCRIMINATION

The National Academies' Committee on National Statistics recently issued a report on *Measuring Racial Discrimination*. The Panel on Methods for Assessing Discrimination, chaired by Rebecca Blank, Dean of the University of Michigan's Gerald R. Ford School of Public Policy, convened scholars to "consider the definition of racial discrimination, assess current methodologies for measuring it, identify new approaches, and make recommendations about the best, broad methodological approaches."

In defining race, the scholars agreed that it is a "complex concept," best viewed for social science purposes "as a subjective, social construct based on observed or ascribed characteristics that have acquired social significant meaning." It is also a social construct that evolves over time, the committee contended, noting that Italians and Eastern European Jews were regarded as distinct racial groups in the late nineteenth and early twentieth centuries.

Race is also difficult to define consistently for certain populations and in some situations, according to the report. For example, some Hispanics in the United States consider themselves part of a distinct racial group; others do not. The panel decided to

include Hispanics in their discussion of racial discrimination.

The panel strongly recommended that data on race and ethnicity are necessary for monitoring and understanding evolving differences and trends in outcomes among groups in the U.S. population. Therefore, the Federal government and state and local governments should continue to collect such data. The report suggested that Federal standards for racial categories should be responsive to changing concepts of race among the population. The Federal government modified its racial definitions in the late 1990s to include a multi-racial category.

In addition, the report concluded that data collectors, researchers, and others should be aware of the effects of measurement methods on reporting of race and ethnicity, which may affect the comparability of data for analysis. It called on Federal agencies to seek ways to test the effects of such factors as data collection mode, location, and question wording and ordering. The importance of collecting and analyzing longitudinal data was also stressed.

With regard to racial discrimination, the panel noted that social scientists define this concept in two ways: 1) differential treatment on the basis of race that disadvantages a racial group; and 2) treatment on the basis of inadequately justified factors other than race that disadvantages a racial group (differential effect).

The report discusses and evaluates four major methods used across different social and behavioral science disciplines to measure racial discrimination: 1) laboratory experiments; 2) field experiments; 3) analysis of observational data and natural experiments; and 4) survey and administrative record reports. The panel concluded that "no single approach...allows researchers to address all the important measurement issues or to answer all the questions of interest." They urged public and private agencies and the research community to embrace a multidisciplinary, multi-method approach to the measurement of racial discrimination and seek improvements in all major methods employed.

The committee also endorsed the need for more research that would "model and analyze longitudinal and other data in order to study how discrimination's effects may accumulate across domains and over time in ways that perpetuate racial inequality." It gave strong support to such surveys as the Panel Study of Income Dynamics, the National Longitudinal Survey of Youth, and the General Social Survey.

The full report is available at www.nap.edu/catalog/10887.html.

found on the web at: <http://www.cossa.org/CPR/cpr.html>.

SCIENTISTS ENCOURAGED TO SUPPORT PEER REVIEW

On April 15, the Coalition to Protect Research (CPR), a partnership of organizations committed to promoting public health through behavioral and biomedical studies, began a petition encouraging Congress to respect the integrity of the peer review process and the National Institute of Health's (NIH) human sexuality research portfolio. CPR is asking scientists and health care professionals to sign the petition, which will be shared with Members of the House and Senate.

The petition drive stems from a July 2003 amendment to a House appropriations bill that would have cut off funding from five specific peer-reviewed NIH grants that some Members deemed unworthy of Federal funding. The primary target of the amendment, which failed by a 210-212 vote, was studies investigating sexual health. In response to related congressional inquiries, NIH Director Elias Zerhouni conducted a comprehensive review of the NIH's human sexuality research portfolio and concluded that the more than 150 grants under question were appropriately reviewed and that sexual health research is not funded disproportionately to the public health burden of diseases linked to sexual behavior and function, such as HIV/AIDS, other STDs, or infertility.

Zerhouni, who was appointed by President Bush in 2002, has noted that "the peer review process, which is fundamental to the ability of NIH to conduct effective and high quality research, has worked properly and provided a level of valuable and independent review in this important area of research." The Director has also asserted that, in looking at the public health relevance of sexual health grants, ". . . there was no question that these projects should have been funded and should continue to be funded."

CPR organizations represent scientists, physicians, health care providers, patients, and advocates that support Federal investments in basic biomedical and behavioral research in human sexual development, sexual health, HIV/AIDS, and sexually-transmitted diseases. The petition drive will continue as long as NIH and these important studies remain under attack on Capitol Hill. The petition can be

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Automated Detection

Judee Burgoon, Professor of Communication, Professor of Family Studies and Human Development, and Director of Human Communication Research for the Center for the Management of Information at the University of Arizona, discussed "Automating Detection of Deception and Hostile Intent." She noted that her presentation was built from her work on two major, multi-institutional projects: 1) a five-year multidisciplinary project funded by the Department of Defense on detecting deception in the military infosphere; and 2) an automated identification of intent project funded by the Department of Homeland Security.

For purposes of her work, Burgoon defined deception as "messages that are knowingly transmitted to create some kind of false impression," often with hostile intent. Intent can be defined as a cognitive state that causes external behaviors to be exhibited, which can then be interpreted by others. Key issues, according to Burgoon, are whether we can tie noted behaviors to intent, whether we can accurately determine if a person is being deceptive or truthful and whether they pose a risk.

Traditionally, she stated, "humans have very poor ability to detect deception." To this end, one objective is to automate detection to augment human capabilities. This could especially enhance efforts to detect deception in electronic, audio, and video messages – all common forms of communication in this day and age.

One aim of Burgoon's research has been to go beyond typical methods of judging deception. For example, many people correlate speaking more rapidly or in a higher pitch with deception. The same can be said for emotional indicators that show fear or guilt. But not all deceivers, of course, feel these emotions or experience the type of arousal that causes changes in speech quality. As a result, Burgoon and her collaborators have had to consider other possible signs, such as lacking details, the absence of emotional language, and false smiles.

Burgoon also discussed analyzing text messages in the context of an experiment involving a mock theft. She noted that, in responding to questions, deceivers use much longer responses in text format than in face-to-face contact. As a result, her team concluded that "text-based deception allows for planning, rehearsal, and editing in

ways that are not possible in spontaneous, face-to-face communication and deceivers can use text communication to their advantage.”

Based on what they learned, Burgoon explained that her team developed a set of automated tools to detect deception in text messages. This set of tools, dubbed Agent 99 (after the character from the “Get Smart” television show), has scored between 61 and 91 percent in judging truthful messages as the truth and between 61 and 88 percent in judging deceptive messages as deceit.

Burgoon also discussed a form of video analysis based on motions made by an individual’s hands and face. It can measure levels of agitation, and using an algorithm, differentiate between individuals telling the truth and those trying to deceive.

In conclusion, Burgoon asserted that “humans are very fallible at detecting deception and hostile intent, but we think we can develop automated tools to augment human judgment that can greatly increase detection’s accuracy by using them.” This can be studied across cultures and developed as more research is done over time.

Cross Cultural Deception

Charles Bond, Professor of Psychology at Texas Christian University, focused his presentation on “International Deception.” He noted that his research has focused on judgments of deception across cultures and that “international judgments of deception might in principle prevent future terrorist attacks.” Bond also explained that the key questions for his research are whether there are universal cues of deception – “behaviors that liars display in every culture” – or if there is a good way to detect lies across cultures.

To give some context, Bond stated that deceptive behaviors have primarily been studied in the U.S., Western Europe, Japan, and Australia. He did the only study to date on deceptive behavior in the Arab world – it was done a long time ago involving Jordanians. Bond has also done work about *judgments* of deception involving citizens of Jordan, the U.S., and India. Individuals of all three nationalities were videotaped and other people from all three countries watched and were asked to judge whether they were watching a liar or a truth teller.

Bond’s results were statistically significant: people have an ability to detect lies told not only by people from their own country, but also “a highly significant ability to detect lies across cultures.” In fact, he explained, people

could detect lies across cultures when they were listening to a language that they couldn’t understand.

Bond noted that his current work is a very large study with 88 collaborators on beliefs about deception in 75 different countries. For the first part of this study, which involves 4,800 participants, people were asked “How can you tell if people are lying?” Common beliefs (in response to this question) are that liars are inconsistent, they shift their posture often, their speech is somewhat incoherent (i.e. their speech contains “uh”s, “ah”s, and long pauses), and liars tend to show signs of nervousness. “The most common belief about deception worldwide, however, is that liars can’t look you in the eye,” Bond explained.

The second part of the study involved responses to a questionnaire on beliefs about deception. Again, the participants indicated that liars make less eye contact than truth tellers. Other common responses emphasize that liars tell long stories and touch and scratch themselves and shift their posture more than usual. The questionnaire also asked how many lies the typical person tells in a week and how accurate the participants thought they were at detecting lies. Results varied widely across countries.

Bond concluded by asserting that “We should be researching deception in the countries of greatest interest to the U.S. security community. Studies there might in principle prevent future terrorist attacks.”

Face-to-Face Intelligence Gathering

Mark Frank, Associate Professor of Communication at Rutgers, addressed “Practical Approaches to Detecting Deception in Counter-Terrorism.” To introduce his topic, Frank told the audience that “Prior to September 11, 2001, human to human intelligence gathering had been seen as the weird uncle of the intelligence gathering world.” With the “limits of technological approaches to gathering intelligence laid bare on September 11,” however, “there has been a renewed interest in gathering information from people in situations where two people meet face to face.”

Obviously, it is vital for the agents collecting face-to-face intelligence to be able to judge whether they have been told the truth. Frank explained that the key questions are how we know when we are being lied to and if there’s any technology that can assist in this assessment.

In trying to answer these questions, Frank has taken care to look at situations involving “minimally implicit,

but better explicit, rewards or punishments.” (i.e., not white lies) This makes the studies more applicable to real counter-terrorism situations. In addition, Frank noted that he has worked closely with individuals from counter-terrorism and intelligence fields in the planning, design, and interpretation of results.

To determine how individuals can best detect lying, Frank conducted extensive studies of human expressive behavior. Research has shown conclusively that certain muscles, including ones in the face, are “reliable muscles,” ones that are very hard to control. These muscles can give away someone’s attempting to conceal his or her feelings. Frank’s work has shown that a person’s ability to spot these micro-expressions is correlated with their abilities to spot high stake lies.

Frank also discussed individuals in his studies who have been able to detect deception at a rate of 90 percent or better. He is working to determine why these people are particularly gifted and urged that those in law enforcement and related communities with this ability should be identified and utilized in critical interviews and situations.

Touching on the technology question, Frank stated that the Facial Action Coding System (FACS), developed by Paul Ekman and Wally Friesen, has been used by over 300 scientists in about a dozen countries and can identify micro-expressions that even highly qualified and trained experts have missed. The problem is that it can take up to three hours to code one minute of behavior into FACS. Thus, developing a fast-working computer system capable of the same identification could be a key to detection efforts.

Franks has been working towards this goal with help of an NSF grant and has been able to replicate “90 percent agreement for all upper face units.” He noted that it is still a work in progress, but that it could be ready for field use within five years.

To conclude, Frank mentioned that ongoing collaborations between law enforcement personnel and those in academe have proven successful and should be continued and expanded. He urged renewed attention to and funding for these efforts.

COSSA will prepare edited transcripts of the seminar, which included a lively question and answer period. These should be available by late May. If you would like to request a copy, please e-mail coffa@coffa.org.

BUSH ANNOUNCES INTENTION TO NOMINATE WEINSTEIN AS ARCHIVIST OF THE UNITED STATES

On April 8, President Bush announced his intention to nominate Allen Weinstein to serve as Archivist of the United States. Weinstein, who holds a Master’s and Ph.D. in History from Yale, currently serves as Senior Advisor for Democratic Institutions and Director of the Center for Democratic Initiatives at the International Foundation for Elections Systems. He previously served as President of the Center for Democracy and as a professor at Boston University, Georgetown, and Smith College. The position will require Senate confirmation.

If confirmed, Weinstein will replace John W. Carlin, who was appointed by President Clinton in 1995 and has been at the National Archives since.

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