




*Presentation for the*  
**Research Advisory Committee on  
Gulf War Veterans' Illnesses (RAC)**  
*Hosted by the*  
U.S. Department of Veterans Affairs  
*at the*  
Capital Hilton, Washington, DC - April 28, 2016

**“GULF WAR RESEARCH  
RECOMMENDATIONS”**

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*“Gulf War Research Recommendations”*

**BACKGROUND: PAST TO PRESENT**

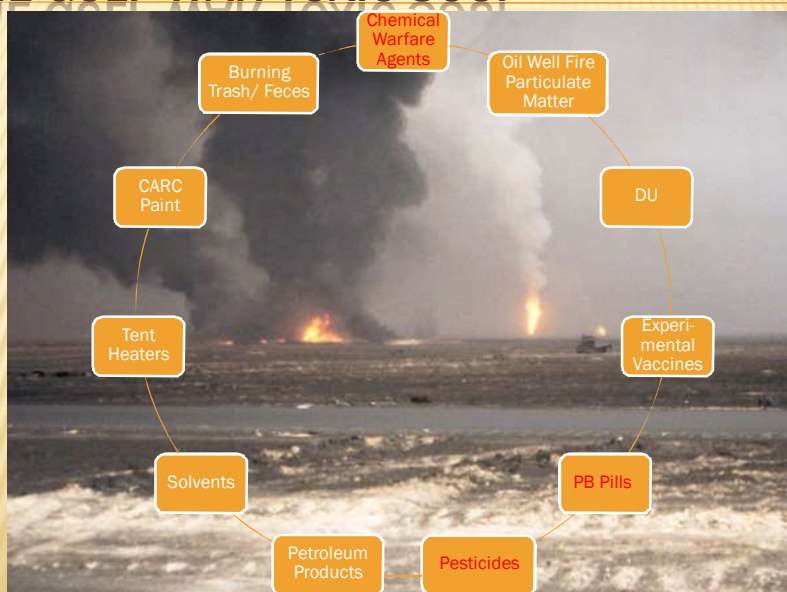


## 697,000 GULF WAR (1990-91) VETERANS

AGE		GENDER		
27 (mean age in 1991)		Male: 93%		Female: 7%
RACE				
White: 70%		African-American: 23%	Hispanic: 5%	Other: 2%
BRANCH OF SERVICE				
Army: 50%		USMC: 15%	Navy: 23%	Air Force: 12%
MILITARY STATUS				
Active: 83%	Reserve/Guard: 17%	Officer: 10%		Enlisted: 90%

Source: Joseph, 1997, cited in Institute of Medicine, "Gulf War and Health, Vol. 1," p. 41.

## THE GULF WAR TOXIC SOUP



## GULF WAR ILLNESS: GULF WAR'S SIGNATURE HEALTH OUTCOME

***“Gulf War illness continues to be the signature health concern of veterans who served in the Persian Gulf region in 1990-91.”***

-National Academy of Sciences, Institute of Medicine, “*Gulf War and Health, Volume 10: Update of Health Effects of Serving in the Gulf War, 2016*” (p.87)



## IOM GULF WAR & HEALTH, VOL. 8 (2010)

- ✦ “[C]urrent estimates [are] that more than 250,000 US Gulf War veterans have persistent unexplained medical symptoms.” (p. 262)
- ✦ “The excess of unexplained medical symptoms reported by deployed Gulf war veterans cannot be reliably ascribed to any known psychiatric disorder.” (p. 109)
- ✦ “[I]t is likely that Gulf War illness results from an interplay of genetic and environmental factors.” (p. 261)
- ✦ “The committee believes that the path forward for veterans has two branches. The first is continued surveillance of Gulf War veterans. ... [The] second branch of inquiry . . . consists of a renewed research effort with substantial commitment to well-organized efforts to better identify and treat multisymptom illness in Gulf War veterans.” (pp. 260-261)

SOURCE: Institute of Medicine, “*Gulf War and Health, Volume 8: Health Effects of Serving in the Gulf War*,” (2010). [http://books.nap.edu/openbook.php?record\\_id=12835](http://books.nap.edu/openbook.php?record_id=12835)



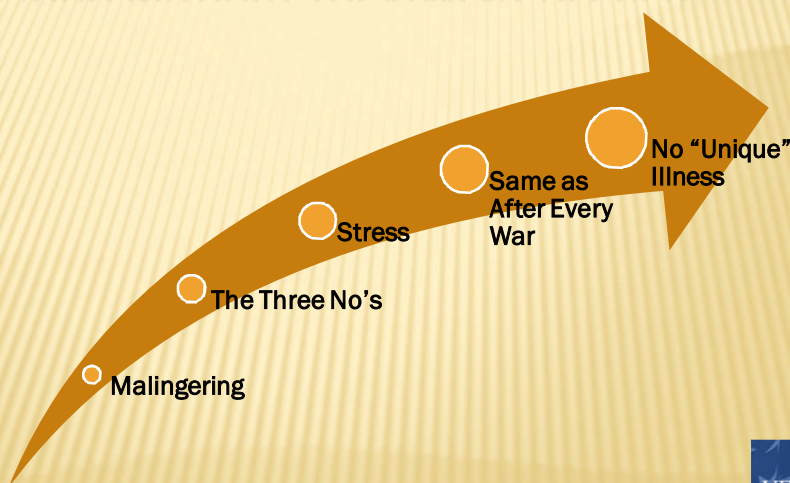
## IOM GW&H V.10 (2016): GULF WAR ILLNESS

- ✘ “A variety of studies in U.S. veterans and coalition force veterans who served during and even after the conflict continue to show that veterans who were deployed to the Gulf War experience more symptoms, signs, and ill-defined conditions, and that their symptoms are more severe than their nondeployed counterparts; furthermore, these symptoms have persisted for more than 25 years after the war.” (p.87)
- ✘ “Therefore, the Volume 10 committee concludes that there is sufficient evidence of an association between deployment to the Gulf War and the constellation of chronic symptoms (including fatigue, musculoskeletal pain, sleep disturbance, cognitive dysfunction, alterations of mood) known as Gulf War illness.” (p.88)

SOURCE: -National Academy of Sciences, Institute of Medicine, “*Gulf War and Health, Volume 10: Update of Health Effects of Serving in the Gulf War, 2016*”



## THE PROBLEM: YEARS SQUANDERED BY VA/DOD WITHOUT TREATMENT RESULTS



## THE PROBLEMS COMPOUNDED

- ✘ Systemic problems with VA's process of epidemiological research → NAS "Gulf War and Health" reviews of that research → VA disability claims presumptive determinations (lack thereof)
- ✘ Systemic problems with VA healthcare provision for ill GWV's
- ✘ Systemic problem with VA minimization of Gulf War Illness – the signature adverse health outcome of the 1990-91 Gulf War.



## THE PROBLEMS: SYSTEMIC FLAWS IN NAS "GULF WAR & HEALTH" REVIEWS

- ✘ 1998 laws required VA contract with NAS to evaluate health risks of 33 Gulf War toxic exposures
- ✘ Laws required consideration of animal studies, because most studies of toxic effects are necessarily done in animals.
- ✘ But VA did not contract for consideration of animal studies in standards of evidence
- ✘ "As a result, these studies – the basic studies that show these toxic substances are toxic -- have never been considered in any IOM report, and no IOM report has ever found sufficient evidence that any of the 33 toxic agents are associated with health problems."

- ✘ SOURCE: Congressional testimony of James H. Binns, former Chairman, RAC, Feb. 23, 2016



## THE RESULT: INADEQUATE HEALTHCARE, BENEFITS FOR GULF WAR VETERANS

- ✘ VA still has no evidence-based treatments to offer for GWI
  - + Promising treatments still in early research stages (4 to date from GWIRP-CDMRP)
  - + VA's current clinical guideline instead focuses on somatization/psych. causes and treatments
  - + Documented deleterious effects of clinical VA minimization of physical health effects of GWI & excessive VA referrals to mental health
- ✘ VA still denies Gulf War disability claims at >80% rates (!!!!)



### VA Research Advisory Committee (RAC) on Gulf War Veterans' Illnesses

- Limited VA GWI research portfolio
- VA Research Advisory Committee (RAC) on Gulf War Veterans' Illnesses

### DOD Congressionally Directed Medical Research Program (GWIRP, DoD CDMRP)

- FY06-FY16: Gulf War Veterans' Illness Research Program ( <http://cdmrp.army.mil/GWIRP> )
- FY17: Related Congressionally Directed Medical Research Program (CDMRP) and War Related Illness and Injury Study Centers (WRIISC's): Referral centers for veterans within VA healthcare system for hard-to-diagnose health conditions
- Most veterans say its very helpful, BUT: Too few centers, hard to get into, too limited in scope

More information: [www.warrelatedillness.va.gov](http://www.warrelatedillness.va.gov)



## POTENTIAL IMPACT OF GULF WAR RESEARCH

- ✘ Exposures animal research – may illuminate causes, biological pathways (biomarkers; pathobiology), prevention
- ✘ Biomarker/pathophysiology research in veterans – may illuminate current disease processes/progression, improve diagnosis/definition
- ✘ Treatment research – may find evidence-based treatments
- ✘ Translational research – may take research from the realm of research to that of clinical care
- ✘ Epidemiological research – may identify excess symptoms/conditions; may impact service-connected disability claims (“presumptives”)



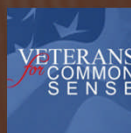
## VA VS. GWI CMDRP AWARDS, FUNDING

During this FY	VA		GWIRP-CDMRP		
	VA Funding Expended this FY	# of New Proposal Funded this FY	# of New Proposals Funded with this FY's appropriated funding	Amount of the Appropriation made for this FY	New Appropriation Made during this FY (for future year)
2011	\$5.54 m	3	8 (CY2012)	\$8 m	\$10m (for FY12)
2012	\$6.72 m	7	6 (CY2013)	\$10 m	\$20m (for FY13)
2013	\$7.94 m	7	16 (CY2014)	\$10 m	\$20m (for FY14)
2014	\$9.73 m	5	21 (CY2015)	\$20 m	\$20m (for FY15)
2015	\$11.63 m	8	TBA (CY2016)	\$20 m	\$20m (for FY16)
2016	TBD	TBD	TBD (CY2017)	\$20 m	TBD (for FY17)



*"Services and Benefits for Gulf War Veterans"*

## **BACKGROUND: RAC MISSION & SCOPE OF ACTIVITY**



## **CURRENT (2015) RAC CHARTER GUIDANCE**

### **RAC OBJECTIVES:**

- ✘ The RAC “provides advice and makes recommendations” to SecVA
- ✘ “on proposed research studies, plans, and strategies”
- ✘ “related to understanding and treating the health consequences” of 1990-91 Gulf War service.





## CURRENT (2015) RAC CHARTER GUIDANCE

**RAC SCOPE OF ACTIVITY** – “Shall...review and advise [SecVA} about:

- ✘ “VA funded research relevant to understanding and treating all health consequences of [1990-91 Gulf War military service];
- ✘ “Processes conducted to solicit, review, and select such VA-funded research; and
- ✘ “The methods, results and implications of the research.”



## CURRENT (2015) RAC CHARTER GUIDANCE

**RAC SCOPE OF ACTIVITY** – RAC “may also....

- ✘ “[R]eview publicly available research plans, initiatives, strategies, and activities from other agencies supporting health research about the health consequences of military service in the [1990-91 Gulf War].”
- ✘ “...[A]dvice [SecVA] about the relationship between VA-funded research and research supported by other agencies.”

SOURCE: RAC Charter, May 12, 2015



## NEW CONGRESSIONAL GUIDANCE, FY17 VA APPROPRIATIONS ACT (S. RPT. 114-237)

- ✦ **RAC ROLE:** “The role of the Research Advisory Committee on Gulf War Veterans’ Illnesses (RAC) – was intended to provide a meaningful consultative role in helping shape the Persian Gulf War research agenda, strengthen the process by which the government sets its Persian Gulf War research agenda, and lend credibility to future research activities. However, concern has been raised that this role has been degraded and compromised.



## NEW CONGRESSIONAL GUIDANCE, FY17 VA APPROPRIATIONS ACT (S. RPT. 114-237), CT'D

- ✦ **RAC CHARTER:** “The RAC charter no longer requires it to assess the effectiveness of Federal Gulf War research, no longer contains a requirement for its own staff, and its purview is presently limited solely to research conducted by the Department.
- ✦ **RAC MEMBERSHIP:** “Determinations by the RAC and the IOM that Gulf War illness is physiological and not psychological or psychiatric in nature should be the basis in determining the type of medical practitioners and scientific researchers needed to create a well-qualified membership.



## NEW CONGRESSIONAL GUIDANCE, FY17 VA APPROPRIATIONS ACT (S. RPT. 114-237), CT'D

- ✘ **RAC ACTIVITY:** “The Committee notes the RAC has provided no new recommendations since September 2014 and encourages the RAC renew its efforts in studying **Gulf War Illness.**” (p.58) [*emphasis added*]

SOURCE: [S. Rpt. 114-237](#), “Military Construction, Veterans Affairs, and Related Agencies Appropriation Bill, 2017” (April 18, 2016), accompanying [S. 2806](#) (114<sup>th</sup> Congress), the Military Construction, Veterans Affairs, and Related Agencies Act, 2017.



“Gulf War Research Recommendations”

## RECOMMENDATIONS FOR FUTURE RAC ACTIVITY



## RECOMMENDATION: FULFILL GWI RESEARCH STRATEGIC PLAN (!)

- ✘ Review the various versions of the “Gulf War Research Strategic Plan 2012-2016” (January 2012 consensus version; VA 2012 version; VA updates). Key provisions (Ch. 5):
  - + Symptomatic/specific treatments
  - + Databases/Continued medical surveillance – disease-specific morbidity/mortality; incidence/prevalence
  - + Develop consensus GWI Case Definition
  - + Genetics/Genomics/Systems Biology
  - + Biomarkers
  - + Animal Models (!)
  - + Communication & Coordination
  - + Translation to Clinical Care
- ✘ Hold VA accountable; Note that designating ongoing research with plan codes doesn't necessarily equate to fulfilling the plan



## RECOMMENDATION: TRACKING, REPORTING STATUS OF PREVIOUS RAC RECOMMENDATIONS

- ✘ Recommend RAC develop a perpetual tracking system for all RAC recommendations, past and future
  - + Including recommendations from RAC 2004, 2008, 2016 major reports, *and*
  - + all minor reports and committee documents, *and*
  - + possibly meeting minutes
- ✘ Recommend RAC make the tracking system public, on RAC website
- ✘ Recommend RAC identify current status of all RAC recommendations
- ✘ Recommend RAC seek VA update at each RAC meeting of all pending RAC recommendations
- ✘ Recommend RAC review recommendations not implemented



## RECOMMENDATION: REVIEW PROPOSED NAS STUDIES, STRATEGIES

- ✘ Recommend RAC seek to review all NAS contracts before they are finalized
- ✘ Recommend RAC seek new reviews that include animal study toxic exposure research fully considered as basis for human health outcomes
- ✘ Recommend RAC seek for VA to make these contracts public before they are executed
- ✘ Recommend RAC call for greater transparency, accountability with VA-NAS



## BACKGROUND: TRANSLATIONAL RESEARCH STRATEGIES – FROM BENCH TO BEDSIDE

- ✘ Since 2014, VA has had a joint DOD-VA *Clinical Practice Guideline (CPG) for Chronic Multisymptom Illness (CMI)* (incl. GWI)
- ✘ The CMI CPG has come under heavy criticism from VSO's, advocates, and Congress, including for its focus on psychosomatic illness rather than evidence-based treatments specific to Gulf War Illness



## BACKGROUND: TRANSLATIONAL RESEARCH STRATEGIES – FROM BENCH TO BEDSIDE, CT'D

- ✘ In April 2016, the Senate Appropriations Committee included in Report language accompanying FY17 VA appropriations: (S.Rpt. 114-237, p.58)
  - + “The Committee urges the Secretary to consider revising and updating the Clinical Practice Guideline for Chronic Multisymptom Illness [CMI] consistent with the July 2011 Veterans Health Initiative, ‘Caring for Gulf War Veterans,’ that it, ‘cannot be reliably ascribed to any known psychiatric disorder,’ and to focus on recent Gulf War illness treatment research findings and ongoing Gulf War illness treatment research direction.”
  - + “The Committee encourages VA to strengthen the training of primary, specialty, and mental healthcare providers on the Gulf War illness case definitions recommended by the IOM.”



## RECOMMENDATION: TRANSLATIONAL RESEARCH STRATEGIES – FROM BENCH TO BEDSIDE

- ✘ **RECOMMENDATIONS:** The RAC should develop recommendations to VA for a translational research strategy, beyond the Strategic Plan, for what’s known and viable “now”:
  - + 1) Supporting VA revision of the “CMI” CPG as suggested, including to avoid recommending psychiatric interventions that are not specifically evidence-based for treating GWI; and
  - + 2) Supporting VA clinician incorporation, in VHA clinical care provided to GWI patients, of state-of-the-science GWI research knowledge (including currently recommended case definitions) and ongoing GWI treatment-research direction.



## RECOMMENDATION: AIRBORNE HAZARD & OBP REGISTRY

- ✘ Veterans who are eligible for the Gulf War Registry may also join the **Airborne Hazards and Open Burn Pit Registry (AH&OBPR)**, which includes additional data related to airborne hazards, including burning oil well fires and burn pits.
- ✘ **RECOMMENDATION:** RAC recommends VA should mandate that distinct deployments (e.g., Gulf War; OIF/OND; OEF) be kept distinct in data gathering, exposure assessment, analysis, and reporting



## RECOMMENDATION; REPORT GW SPOUSES & CHILDREN REGISTRY

- ✘ VA has publicly reported that the statutorily-mandated Gulf War Spouses & Children Registry has been lost
- ✘ It remains unclear whether VA has made all (or any) attempt to find or reconstitute this data
- ✘ **RECOMMENDATION:** RAC calls for VA to relocate or reconstitute this important Registry data, and upon its relocation or reconstitution, for VA to make a final report of its data and an analysis of its findings.



## RECOMMENDATIONS: CORE RAC MISSION MEASURES

In order to enhance public access, including by impacted Gulf War veterans, **recommend that RAC:**

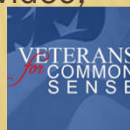
- ✘ Continue to issue regular major reports on Gulf War Illness and Gulf War health research, including updating the state-of-the-science and making future research recommendations.
- ✘ Continue to host state-of-the-science GWI researchers to enhance VA and public understanding, including of the implications of this research.



## RECOMMENDATIONS: RAC ADMINISTRATIVE MEASURES

In order to enhance public access, including by impacted Gulf War veterans, **recommend the RAC ensure that:**

- ✘ Presenters' materials (PowerPoints, etc.) be uploaded to the RAC website immediately following each RAC meeting
- ✘ Meeting minutes and reports be uploaded in a truly expeditious manner
- ✘ Public comment opportunities be fully maintained
- ✘ Distance meeting monitoring (streaming online video, teleconferencing) be maintained and enhanced.





# Thank You. Questions?

