In re: Oil Spill by the Oil Rig "Deepwater Horizon" in the Gulf of Mexico, on April 20, 2010

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA
MDL NO. 2179, SECTION J
JUDGE BARBIER; MAGISTRATE JUDGE SHUSHAN

Round 3 Expert Report of
Robert Cox, M.D., Ph.D.

September 26, 2014

Prepared on Behalf of BP Exploration & Production Inc.

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1. Purpose of Report and Qualifications

On August 15, 2014, I submitted an expert report in this matter, which states my opinions regarding the potential[1] health risks to individuals who were engaged in clean-up activities, remediation efforts, or other responsive actions in connection with the *Deepwater Horizon* ("DWH") oil spill (collectively "Clean-Up Workers"), and to residents of the Gulf Coast communities of Alabama, Florida, Louisiana, and Mississippi (collectively "Gulf Coast Residents") resulting from potential inhalation, dermal, and oral exposures to the components of MC252 crude oil, dispersants, and other compounds associated with the DWH oil spill.[2]

On September 12, 2014, Dr. Richard Clapp submitted a report on behalf of the United States in response to my August 15 Report. The purpose of this report is to rebut points raised by Dr. Clapp in his September 12 Report.[3]

My full qualifications and resume are included as appendices to my August 15 Report.

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[1] Throughout this report, when I refer to potential health risks or potential exposures, I am not referring to actual, realized health effects or actual exposures. I do not consider potential health risks or potential exposures to be probative of any actual impact of the DWH oil spill on human health.

[2] The scope of my August 15, 2014 work did not include any assessment of the human health impact resulting from the explosion and fire on the DWH oil rig on April 20, 2010, and the resulting rig worker deaths and injuries. Nor did it include assessment of the deaths of four men not involved in response activity tasks at the times of their deaths.

[3] The initial report of Dr. Clapp was submitted on August 15, 2014. I responded to that report in my Round 2 report submitted on September 12, 2014.

2. Opinions and Conclusions

The report prepared by Dr. Clapp in response to my initial report does not change the opinions I reached in my August 15 Report or in my September 12 Report. Dr. Clapp's September 12 Report is deficient because Dr. Clapp:

- is not a toxicologist and does not seem to understand the science of toxicology;
- failed to review and consider the extensive exposure data pertaining to the DWH incident;
- failed to consider the chemical changes that occurred in weathered oil;
- failed to review the surveillance of potential health effects by the CDC and state health departments;
- failed to perform any type of risk assessment;
- misinterprets and misquotes the scientific literature;
- lacks any experience evaluating the utility of personal protective equipment ("PPE"); and
- completely ignores the analyses and conclusions of numerous federal agencies and entities.

Therefore, Dr. Clapp cannot offer scientifically valid opinions on the issue of any potential human health effects resulting from the DWH incident.[4]

[4] I addressed the issue of potential mental health impact of the DWH incident in my August 15 Report. Additionally, on September 12, 2014, Dr. George Bonanno submitted a report regarding mental health concerns pertaining to the DWH incident. It is not necessary for me to further address these issues in this report.

3. Discussion

3.1 Dr. Clapp is not a toxicologist and is incorrect that reliance on toxicological benchmarks for assessment of potential DWH-related exposures is inappropriate and outdated.

Dr. Clapp suggests that the standard, four-step approach to risk assessment outlined in my August 15 Report is outdated because I relied on *Risk Assessment in the Federal Government: Managing the Process* (the "Red Book") instead of the National Academy of Sciences ("NAS") 2009 Book, *Sciences and Decisions: Advancing Risk Assessment* ("2009 NAS Book"). Dr. Clapp is not a toxicologist and does not seem to understand how a risk assessment is properly conducted. Furthermore, Dr. Clapp apparently failed to read the 2009 NAS Book because, if he had, he would have learned that the NAS does not attempt to displace the Red Book's approach to risk assessment. In fact, the NAS recognizes the Red Book approach as widely used and accepted by experts in the field:

> The committee concluded that [the U.S. Environmental Protection Agency's ("EPA")] overall concept of risk assessment, which is generally based on the National Research Council's Risk Assessment in the Federal Government: Managing the Process (1983), also known as the Red Book, should be retained. The four steps of risk assessment (hazard identification, dose-response assessment, exposure assessment, and risk characterization) have been adopted by numerous expert committees, regulatory agencies, public-health institutions, and others.[5]

In framing the EPA's risk management process, the 2009 NAS Book retains the four-step risk assessment, but suggests added planning and risk management steps for certain situations.[6] These risk management steps are not applicable to my evaluation of the DWH oil spill.

Likewise, Dr. Clapp's statement regarding NAS's "warning" against the "uncritical use of 'bright line' characterizations such as reference dose or reference concentration values"[7] is a complete mischaracterization of the actual discussion found in the 2009 NAS Book. The NAS admits that what it calls "bright line" approaches are valuable in public health decision-making contexts, but lack utility in other contexts.[8] The NAS discusses that the reference dose, as it is currently used, does not quantify risks for different magnitudes of exposure and fails to provide guidance for risk managers where an exposure *exceeds* the references dose. This discussion of risks associated with reference dose exceedances is completely irrelevant in the context of the DWH oil spill because 1) specific EPA references doses were not used and 2) toxicology benchmarks were not exceeded.[9]

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5 Science and Decisions - Advancing Risk Assessment (National Academy of Sciences, 2009), at 4.

6 *Id.* at 11, 31.

7 Richard W. Clapp, Expert Report, September 12, 2014, at 6.

8 Science and Decisions - Advancing Risk Assessment, at 40.

9 The discussion is further irrelevant because the 2009 NAS Book specifically addresses suggestions to improving *EPA's* risk analysis approaches. The book does not address risk analysis by any other agency, such as the U.S. Occupational Safety and Health Administration ("OSHA"), National Institute for Occupational Safety and

As mentioned by the NAS, the four-step approach of risk assessment is used by multiple government agencies. Toxicology benchmarks are used by not only EPA, but OSHA, NIOSH, ACGIH, the U.S. Food and Drug Administration ("FDA"), the Centers for Disease Control and Prevention ("CDC"), the National Oceanic and Atmospheric Administration ("NOAA"), the Agency for Toxic Substances and Disease Registry ("ATSDR"), and state health and environmental agencies.[10] Furthermore, toxicology benchmarks were widely used during the DWH oil spill. EPA scientists compared air sampling results to health-based screening levels to evaluate volatile organic compounds ("VOCs") in the Gulf region.[11] The Florida Department of Health ("FDOH") stated, "To determine if contaminant levels in environmental samples collected from Florida coastal waters and beach sediments pose a human health risk, screening levels must be adopted."[12] The FDOH developed screening levels derived with the same formulas used by the EPA to determine whether coastal water and sediment samples pose a human health risk. Dr. Clapp's suggestion that the toxicology approach used by all of these agencies is outdated demonstrates his complete lack of understanding of the science of toxicology.

3.2 Contrary to Dr. Clapp's assertions, biomonitoring would not have yielded actionable, useful information and could have produced confusing information for Clean-Up Workers.

3.2.1 Federal agencies acknowledge the difficulty in obtaining useful, actionable information from biomonitoring.

Federal agencies and scientific organizations recognize the problems associated with biomonitoring testing. I am not aware of any federal agency that recommended biomonitoring as part of the DWH response. NIOSH discussed biomonitoring in the context of the DWH incident within the agency, but the agency did not conclude that it should perform biomonitoring on workers, nor did it recommend biomonitoring to the Unified Area Command ("UAC").[13] The CDC noted, "CDC and ATSDR guidelines issued during the Deepwater Horizon Oil Spill did not recommend the use of laboratory testing for specific chemicals to either determine exposure or guide delivery of clinical care."[14] In its final assessment of its response to the DWH oil spill response, NIOSH stated: "Determining when biological monitoring should be conducted can be difficult in part because it may not be clear as to whether a

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Health ("NIOSH"), or American Conference of Governmental Industrial Hygienists ("ACGIH"), who developed all of the Occupational Exposure Limits ("OELs") that I used.

10 *See* OSHA. Deepwater Horizon Oil Spill: OSHA's Role in the Response. May 2011, at 9. Available at: https://www.osha.gov/oilspills/dwh_osha_response_0511a.pdf.

11 EPA, EPA Response to the BP Spill in the Gulf of Mexico: Volatile Organic Compounds (VOCs) on the Gulf Coastline, available at http://epa.gov/bpspill/vocs.html.

12 Florida Department of Environmental Protection, Human Health-Based Screening Levels for Petroleum Products Impacting Gulf Coastal Waters and beach Sediments, available at http://www.dep.state.fl.us/deepwaterhorizon/files2/FLScreeningLevels.pdf.

13 Tr. of John Howard Dep. at 194:19-197:22.

14 CDC, CDC/ATSDR Guidance on the Interpretation and Use of Blood Laboratory Analyses for Volatile Organic Compounds, available at http://emergency.cdc.gov/gulfoilspill2010/pdf/Clinician_VOC_FactSheet.pdf.

scientific rationale exists for biological monitoring in a given situation, or whether results from the monitoring can be interpreted meaningfully or reliably."[15]

The problems with biomonitoring are well known. In 2006, the NAS noted, "In spite of the potential value of biomonitoring, tremendous challenges surround its use. They include improving our ability to design biomonitoring studies, interpreting what biomonitoring data mean for public health, addressing ethical uses of the data, and communicating results to study participants, policy-makers, and the public."[16] Furthermore, no toxicology standards exist for biomonitoring tests for substances found in oil. As the CDC noted in its National Reports on Human Exposure to Environmental Chemicals, "the presence of a chemical in a blood or urine specimen does not mean that the chemical causes a health risk or disease."[17]

The NAS further discussed the problems associated with interpreting biomonitoring results:

> Considerable controversy often surrounds the interpretation of biomonitoring data. Researchers are generating biomonitoring data whose relevance to human health is unclear in many cases.[18]. . . For most other chemicals, however, there are no epidemiologic data on the relationship between the biomarker and the effect, and the exposure sources and routes are not known[19] . . . . Effective communication of results is among the biggest challenges to the future of biomonitoring.[20]

The NAS acknowledged that "the science (epidemiology, toxicology, pharmacokinetic modeling, and exposure assessment) needed to understand the implications of biomonitoring data for human health is still in its nascent stages."[21]

3.2.2 Dr. Clapp does not seem to understand the complexities of biomonitoring.

Dr. Clapp suggests that biomonitoring—through blood and urine tests—should have been performed along with air monitoring to detect potential exposures to DWH-related chemicals.[22] Dr. Clapp does not appear to be familiar with the science of biomonitoring in the context of environmental exposures. His suggestion demonstrates a lack of understanding of the many issues concerning biomonitoring testing that make biomonitoring impracticable in the context of the DWH oil spill.

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15 NIOSH, Lessons Learned from the Deepwater Horizon Response, at 15, (Dec. 2011), available at www.cdc.gov/niosh/docs/2012-117/pdfs/2012-117.pdf

16 Human Biomonitoring for Environmental Chemicals (The National Academy of Sciences, (2006), at 2.

17 *Id.*

18 *Id.*, at 5

19 *Id.*, at 6.

20 *Id.*, at 10.

21 *Id.*, at 3.

22 Richard W. Clapp, Expert Report, September 12, 2014, at 13-16.

First, there is far too much interindividual variability in biomonitoring to provide useful information regarding potential exposures.[23] Because of interindividual variability, two individuals may experience the same exposure level but have vastly different biomonitoring test results due to differences in genetics, body composition, and ways in which chemicals are metabolized in the body. For example, two individuals exposed to the exact same dose of benzene may metabolize benzene differently and will therefore return different biomonitoring results.

Second, biomonitoring tests for benzene and polycyclic aromatic hydrocarbons ("PAHs") have multiple confounders that have a significant impact when testing at low environmental levels. Given the numerous common sources of benzene exposure, a positive biomonitoring test provides no information as to the source of the benzene. Studies have shown that for PAHs, PAH exposure through food increased biomonitoring results by a factor of 4 to 12.[24] Monitored individuals would therefore need to keep strict dietary logs for biomonitoring of PAHs to have any chance of producing useful results.

Finally, the detection limits of current biomonitoring tests lack the necessary sensitivity to be useful in the context of the DWH oil spill. The detection limits for benzene biomonitoring are at concentrations of 10 – 250 ppb.[25] These limits are 53 to 1,300 times higher than the median concentration of benzene found along the Gulf Coast following the DWH oil spill.[26]

3.2.3 Biomonitoring attempts in previous oil spills did not yield useful results.

Biomonitoring was attempted during previous oil spills that had much higher hydrocarbon concentrations than occurred during the DWH oil spill and was not found to yield useful, meaningful results. During the *MV Braer* oil spill, urine samples were analyzed for biomarkers for xylenes and toluene. The xylenes biomarker was not detected and, as to the toluene biomarker, there were no significant differences in the test results of the exposed and control groups. Hydrocarbon concentrations in the air following the *Braer* spill were 95 to 1,400 times higher than the concentrations measured along the Gulf Coast during the DWH oil spill.[27] During the *Nakhodka* oil spill, the urine of ninety-seven clean-up workers was tested for biomarkers of xylenes, toluene, and benzene after a day of work. Of all workers tested, only three individuals showed a slightly positive test for the toluene biomarker, hippuric acid. In these workers, hippuric acid was not present in a follow-up urine examination. The authors of the study noted that hippuric acid also comes from foods containing benzoic acid or benzoates, which are common preservatives. The average concentrations of benzene and toluene during the *Nakhodka* oil spill were 4 to 6 times higher than those during the DWH oil spill.

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23 *See* Frédéric Dor, et al., Validity of Biomarkers in Environmental Health Studies: The Case of PAHs and Benzene, Critical Reviews in Toxicology, 29(2):129-168 (1999).

24 *Id.*, at 147.

25 *Id.*, at 152.

26 Robert Cox, Expert Report, August 15, 2014, at 40.

27 D. Campbell, et al., Initial effects of the grounding of the tanker *Braer* on health in Shetland. *BMJ* 1993; 13:1251-1255.

3.3 Dr. Clapp ignores documentation establishing the prevalence of appropriate PPE use.

Dr. Clapp relies on "anecdotal" evidence for the proposition that appropriate PPE was not always provided, used properly, or used at all, thereby increasing the potential for dermal exposure to DWH-related compounds among Clean-Up Workers.[28] This statement ignores the presence of federal agency personnel at DWH worker sites throughout the response. OSHA had 140 professionals involved in worker protection and staff in all 17 staging areas. OSHA made over 4,200 site visits covering multiple stages of the cleanup process.[29] In addition, NIOSH deployed 106 staff into the field and involved 250 staff in total.[30]

NIOSH interim and final Health Hazard Evaluations ("HHE") reported on PPE use in a variety of cleanup activities. Although instances of inappropriate use of PPE were occasionally seen, PPE was appropriately used in the vast majority of cases. Specifically, NIOSH found:

- As to vessel dispersant application, "The one contract employee who remained on deck wore disposable coveralls, nitrile gloves, steel toe boots, safety goggles, a hardhat, a personal flotation device, and a half mask air purifying respirator with organic vapor cartridges."[31]

- As to skimming operations, "NIOSH personnel observed the potential for dermal contact with oil while placing and removing the skimmer and boom from the water and during cleaning activities on deck. However, contract and [U.S. Coast Guard] personnel wore protective equipment during tasks where there was an increased potential for dermal exposure to oil."[32]

- As to beach and shore clean-up activities, "Even at worksites where oil residue was judged to be heavy, worker exposure to oil residue typically was judged to be limited because of the nature of the oil residue (oil-soaked sand or solid to semi-solid tar-balls) and the use of . . . PPE."[33]

- As to boom maintenance, workers wore no gloves during bladder replacement operations that lasted up to one hour, but cleaned their arms with a citrus hand cleaner after finishing the operations.[34]

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28 Dr. Clapp's anecdotal evidence consists of some boom repair workers who wore medical latex gloves while applying and handling adhesive and photographs of some workers involved in bird rehabilitation who worked with little or no PPE.

29 OSHA. Deepwater Horizon Oil Spill: OSHA's Role in the Response. May 2011, at 5.

30 NIOSH, Lessons Learned from the Deepwater Horizon Response, at 1.

31 CDC. National Institute for Occupational Safety and Health. Health Hazard Evaluation of Deepwater Horizon Response Workers. Interim Report 1, at 1B-1

32 CDC. National Institute for Occupational Safety and Health. Health Hazard Evaluation of Deepwater Horizon Response Workers. Interim Report 3, at 3A-4

33 CDC. National Institute for Occupational Safety and Health. Health Hazard Evaluation of Deepwater Horizon Response Workers. Interim Report 7, at 7-2 - 7-3.

34 CDC. National Institute for Occupational Safety and Health. Health Hazard Evaluation of Deepwater Horizon Response Workers. Interim Report 2, at 2B-8.

- As to decontamination workers, "The PPE used by the decontamination workers (eye protection, coveralls, rubber chemical boots, hardhats, and nitrile gloves) minimized the potential for dermal contact with oil and cleaning agents while decontaminating vessels, boom, and pipe."[35]

Dr. Clapp assumes that a brief dermal exposure to oil would have some significant health risk without providing any justification for this assumption. The CDC recognized, "Although a variety of hydrocarbon products produced from petroleum have specific toxic effects, the toxicity of crude light petroleum itself to humans is relatively low."[36] Dr. Clapp did not consider the chemical composition of the oil from the DWH oil spill, nor did he attempt to do any toxicity risk calculations to support the statements made in his report.

3.4 Dr. Clapp does not appear to understand mixture toxicity.

Dr. Clapp seems to have read the beginning of the ATSDR document discussing the different approaches to mixture toxicity by various organizations, and then concluded that I used the wrong approach and should have used an additive approach. In considering mixture toxicity, I used several approaches recommended by various agencies. For the breathing zone analytical results, I used the additive approach recommended by OSHA, NIOSH, and ACGIH. The results are presented on page 31 of my August 15 Report. For the community data, I used the additive approach recommended by ATSDR on page 32 of its mixture document.[37] ATSDR recommends a different approach for multiple carcinogens if the estimated risks are $\geq 1 \times 10^{-6}$ for at least two of the components. As to the DWH oil spill, there were not two components in the monitoring data that had estimated cancer risks greater than this value. Thus, I used the additive approach recommended by OSHA, NIOSH, and ACGIH for the worker exposures and did not use the alternate ATSDR approach for community exposures because there is no cancer additive toxicity to consider.[38]

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[35] CDC. National Institute for Occupational Safety and Health. Health Hazard Evaluation of Deepwater Horizon Response Workers. Interim Report 8, at A-5. Dr. Clapp selectively quotes from a sentence in HHE #8, "the possibility of dermal exposures to oil and cleaning chemicals was observed to be considerable." He failed to include the remainder of that sentence, "necessitating the use of this PPE." (HHE #8, at A5.)

[36] CDC, Gulf Oil Spill 2010: Deep Water Horizon Oil Spill Human Health Interim Clinical Guidance, available at http://www.bt.cdc.gov/gulfoilspill2010/oilspill_clinical.asp.

[37] ATSDR, Guidance Manual for the Assessment of Joint Toxic Action of Chemical Mixtures, 2007, at 32, available at http://www.atsdr.cdc.gov/interactionprofiles/IP-ga/ipga.pdf.

[38] Some components of crude oil, such as benzene and certain PAHs, are considered carcinogens. However, the International Agency for Research on Cancer ("IARC") has evaluated crude oil and has not classified it as a carcinogen. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 1989, vol 45 Crude Oil, available at: http://monographs.iarc.fr/ENG/Monographs/vol45/index.php. Studies of petroleum workers (with much greater exposures than the potential exposures to Clean-Up Workers or Gulf Coast Residents) have not shown an increase in cancer. *See* Otto Wong & Gerhard K. Raabe, A Critical Review of Cancer Epidemiology in the Petroleum Industry, with a Meta-analysis of a Combined Database of More Than 350,000 Workers, Regulatory Toxicology and Pharmacology, 32, 78-98 (2000); *see also* Otto Wong & Gerhard K. Raabe, Cell-Type-Specific Leukemia Analyses in a Combined Cohort of More Than 208.000 Petroleum Workers in the United States and the United Kingdom, 1937-1989, Regulatory Toxicology and Pharmacology, 21, 307-321 (1995). Thus, even though oil contains low amounts of carcinogens, the mixture known as crude oil is not considered a carcinogen.

3.5 Dr. Clapp's mischaracterizations of exposure risks ignore the fundamental concept of dose.

3.5.1 Dr. Clapp grossly overstates the risk associated with "mundane" exposures.

Dr. Clapp makes unsupported statements regarding the risk associated with "mundane" exposures and suggests potential toxic effects from these everyday exposures that are inconsistent with both the scientific data and literature. These "mundane exposures" have been determined to be safe in doses typical of daily use. For example, dioctyl sodium sulfosuccinate ("DOSS"), one of the chemicals in dispersants, has been used for years as a stool softener following surgeries at a common dose of 100 mg twice daily.[39] It is an extremely safe medication. The highest concentration of DOSS found in seafood was 0.013 µg/g. An individual would have to eat 17,000 lbs of shrimp to get the quantity of DOSS equivalent to that found in one tablet used as a stool softener. In my August 15 Report, I gave a number of examples of everyday household goods that contain the chemicals used in dispersants, to demonstrate that these are substances the general population is exposed to on a daily basis at exposure doses that are ten to hundreds of thousands times greater than those detected during the DWH response without significant adverse human health impacts.

3.5.2 Dose, and therefore exposure risk, is not determined by whether an exposure is voluntary or involuntary.

Dr. Clapp's comments concerning voluntary and involuntary exposures again reflect a lack of understanding of the concept of dose. Dr. Clapp attempts to distinguish between the effects of voluntary and involuntary exposures. However, the effect of an exposure is determined by the dose, not whether an individual was voluntarily or involuntarily exposed. Consequently, where a voluntary exposure is safe in food or cosmetics at a given dose, an involuntary exposure at a dose 10,000 to 100,000 times lower is also safe.

3.5.3 Additional exposure to very small doses of common household chemicals does not increase potential human health risks.

Contrary to Dr. Clapp's assertion, any potential DWH-related exposures that may have occurred in addition to common daily exposures would not create a greater health risk. As mentioned above, any involuntary exposure related to the DWH oil spill would have been significantly lower than common voluntary doses of the same chemicals that the general public is exposed to every day. Since doses of these chemicals in food and common household items are safe when used by individuals on a daily basis, the addition of a minute fraction has no additive effect.

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[39] Colace Stool Softener 100 mg Capsules, http://www.walgreens.com/store/c/colace-stool-softener-100-mg-capsules/ID=prod364511-product.

3.6 Dr. Clapp's statements regarding low-dose health effects are unsupported.

3.6.1 Coal tar is commonly used in FDA-approved products at doses much greater than any PAHs potentially derived from the DWH incident.

Dr. Clapp suggests—without identifying any supporting literature—that low doses of chemicals increase the risk of cancer and that any dose above zero is a risk. The FDA permits coal tars to be used in shampoos and treatments for psoriasis because these have not been shown to cause cancer, even though they are applied for prolonged periods and sometimes to large surface areas.[40] The concentration of PAHs in the weathered oil from the DWH oil spill was very low, 16 to 600 times lower than the concentrations in FDA-approved shampoos and psoriasis gels.[41] It is inconceivable how large doses of PAHs and coal tar applied voluntarily in shampoos or medications do not cause cancer but much lower doses potentially from the DWH oil spill would increase the cancer risk.

3.6.2 Dr. Clapp's statements regarding low-dose effects of dioxins and furans are based on animal studies that involve dioxins unassociated with controlled in-situ burning and are not relevant to assessment of any DWH-related impact to human health.

Dr. Clapp states that "some substances, including endocrine-disrupting substances such as the dioxins and furans created in the DWH oil spill burns, are exquisitely toxic at low doses."[42] Dr. Clapp describes dioxin as "the most potent endocrine disruptor that . . . altered male reproductive development and sperm production . . . in multiple laboratory experiments."[43] Those laboratory experiments involved animals, not humans. Toxicologists are very aware of the differing sensitivities of animals when drawing comparisons to humans. While dioxins and furans are very toxic at very low doses to hypersensitive animals such as guinea pigs, other animal species such as hamsters are quite resistant to the effects of dioxins and furans.[44] Furthermore, the animal experiments Dr. Clapp references were done on a single dioxin congener, 2,3,7,8-TCDD. Had Dr. Clapp reviewed any of the analytical data from the DWH oil spill, he would know that 2,3,7,8-TCDD was not detected during the controlled in-situ oil burns.[45] The NAS reviewed the issue of dioxins for EPA in 2006 and stated: "The potential adverse effects of TCDD, other

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[40] Even though oil contains low amounts of carcinogens, the mixture known as crude oil is not considered a carcinogen. Neither EPA nor the National Toxicology Program has concluded that in humans, dermal exposures to PAHs cause cancer.

[41] Robert Cox, Expert Report, August 15, 2014, at 52.

[42] Richard Clapp, Expert Report, September 12, 2014, at 6.

[43] *Id.* at 7.

[44] L.N. Vandenberg, et al., Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses, Endocrine Reviews 33:1-78, 2012, at 22.

[45] Dr. Clapp also fails to mention—or perhaps does not realize—that components of oil and dispersants are not known to be endocrine disruptors and are not discussed in either of the articles he cites.

dioxins, and dioxin-like chemicals ('DLCs') from long-term, low-level exposures to the general public are not directly observable and remain controversial."[46]

3.7 Dr. Clapp is not a medical doctor and does not seem to appreciate the difference between short-term, nonspecific symptoms and more serious long-term health effects.

Dr. Clapp states that I downplayed some symptoms of exposed workers. Dr. Clapp is not a physician or a medical toxicologist and apparently fails to comprehend the difference between short-term, nonspecific symptoms and symptoms that might suggest more serious long-term effects. He also failed to review the surveillance of potential health effects by the CDC and state health departments during the DWH oil spill. Dr. Clapp fails to appreciate that these short-term, nonspecific symptoms have numerous causes and therefore may be unrelated to the DWH oil spill.[47] The CDC noted, "For several months CDC and state health departments tracked potential short-term health effects related to the oil spill in the affected communities. No trends in illnesses were identified by the multiple surveillance systems used. CDC surveillance did detect some complaints of non-specific symptoms such as throat irritation, eye irritation, nausea, headache, and cough."[48]

Irritant symptoms documented during previous oil spills are generally considered short-term effects.[49] The CDC stated, "Some of the pollutants suspected of being in the crude oil could have caused *temporary* eye, nose, or throat irritation; nausea; or headaches."[50] The effects of upper respiratory and airway irritants are usually transient and related to the period of exposure; the irritant effects usually resolve promptly on removal from exposure.[51] The CDC stated, "Limited studies from previous oil spill disasters showed that common reported acute symptoms were due to irritant effects on mucus membranes, upper airway, and the skin. . . . This is consistent with what is being reported for this spill as described under 'Health Surveillance' later in this document."[52]

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46 *See* Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment (The National Academies Press (2006).

47 CDC. National Institute for Occupational Safety and Health. Health Hazard Evaluation of Deepwater Horizon Response Workers. Interim Report 6, at 6A-2.

48 CDC, CDC/ATSDR Guidance on the Interpretation and Use of Blood Laboratory Analyses for Volatile Organic Compounds, available at http://emergency.cdc.gov/gulfoilspill2010/pdf/Clinician_VOC_FactSheet.pdf.

49 McCoy, M. A. & Salerno, J.A. McCoy, M. A. & Salerno, J.A. Assessing The Effects Of The Gulf Of Mexico Oil Spill On Human Health: A Summary Of The June 2010 Workshop, Institute of Medicine, Nat'l Academies. June 2010, at 47.

50 CDC, CDC Response to the Gulf of Mexico Oil Spill, available at http://emergency.cdc.gov/gulfoilspill2010/cdcresponds.asp.

51 A Practical Approach to Occupational and Environmental Medicine (Robert J. McCunney ed. 3rd ed. 2003).

52 CDC, Gulf Oil Spill 2010: Deep Water Horizon Oil Spill Human Health Interim Clinical Guidance, available at http://www.bt.cdc.gov/gulfoilspill2010/oilspill_clinical.asp.

3.8 Contrary to Dr. Clapp's assertions, the Medical Encounters Database, other injury rosters, and the Medical Benefits Class Action Settlement are not evidence of health effects resulting from exposures relating to the DWH incident, or of future adverse health effects.

The Medical Encounters Database does not attempt to diagnose any injuries or illnesses as being related to chemical exposures, nor does it contain numbers of injuries and illnesses that would be unexpected in any occupational environment of the size of the DWH response. There were over 48,000 workers a week, most working outside. The most common illnesses were due to heat effects. The NIOSH Injury and Illness Report indicates that the vast majority of reported injuries were due to sprains, strains, bruises, lacerations and punctures, and bites and stings. NIOSH did not find the number of reported injuries unacceptable.[53] Given the size, duration, and season of the DWH response, the types of injuries and illnesses reported are not unexpected.

Furthermore, neither rostering efforts nor a medical settlement offer evidence of future human health effects. The fact that the National Institute of Environmental Health Sciences ("NIEHS") is establishing a follow-up study provides no evidence of actual exposures or of adverse future health effects. Similarly, the Medical Benefits Class Action Settlement is by no means proof that adverse health effects were caused by the incident. The Medical Settlement Agreement includes a Specified Physical Conditions Matrix (the "Matrix"). The Matrix lists conditions for which there is a medical basis to conclude that contact with oil and/or dispersants *could* cause those conditions *if* there were exposures to sufficient amounts of such substances for a sufficient duration of time. The inclusion of the Matrix in the Medical Settlement Agreement does not constitute evidence that any person suffered any injury listed on the Matrix as a result of potential exposure to oil or dispersant constituents related to the DWH oil spill.

3.9 It is not premature to reach conclusions about potential health effects resulting from potential DWH-related exposures, as the exposure data is sufficient to draw robust, scientifically-defensible conclusions.

There was a tremendous amount of publicly-available exposure data collected during the DWH oil spill. I have thoroughly evaluated this along with information concerning the changes in the oil composition during weathering, the appropriate use of PPE as well as the evaluations of numerous federal agencies or entities. I performed my own risk assessment and also reviewed and relied upon risk assessments by federal agencies. There is no evidence of a significant chemical exposure that would be expected to result in either significant acute or long-term health effects. Accordingly, it is not premature to reach conclusions about health effects – either acute or long term.

3.10 Dr. Clapp misinterprets prior studies.

Contrary to Dr. Clapp's assertions, I did not ignore historical literature on previous oil spills, but determined that previous spills are not informative as to potential human health effects from the DWH oil spill. The *MV Braer* was a surface spill that involved volatile crude oil. Local winds resulted in the oil

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[53] David Michaels & John Howard, Review of the OSHA-NIOSH Response to the Deepwater Horizon Oil Spill: Protecting the Health and Safety of Cleanup Workers, July 18, 2012 Field Report, available at http://currents.plos.org/disasters/article/review-of-the-osha-niosh-response-to-the-deepwater-horizon-oil-spill-protecting-the-health-and-safety-of-cleanup-workers/.

being blown over land. The *Sea Empress* was also a surface oil spill that involved heavy fuel oil—which has a significantly different chemical composition than the crude oil involved in the DWH oil spill. The *Nakhodka* oil tanker spill (referred to by Dr. Clapp as a Japanese oil spill) involved dense, viscous oil that spilled in very cold and stormy conditions. The *Prestige* spill was a surface spill of Bunker C oil, which has a high viscosity, low water solubility, and a high (50%) content of aromatic hydrocarbons. The weather was very cold and would have inhibited oil weathering. Finally, the *Exxon Valdez* spill did not occur near human populations and there were few direct human consequences of the spill to use as a comparison.[54] Had Dr. Clapp read the literature on previous oil spills, he would have learned that PPE was not routinely used and that in previous spills high percentages of clean-up workers had heavy oil adhered to their face, hands, and extremities,[55] a situation that was never seen by OSHA or NIOSH observers during the DWH response. The differences between these spills and the DWH oil spill make it difficult to draw parallels as to potential human health effects.

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[54] Arata C, et al. Coping with technological disaster: An application of the conservation of resource model to the Exxon Valdez oil spill. J Traumat Stress 2000; 13, 23-39.

[55] *See* Lee CH, et al., Acute Health Effects of the Hebei Oil Spill on the Residents of Taean, Korea, Journal of Preventive Medicine and public Health, March 2010, Vol. 43, no. 2, 166-173; Morita A, Kusaka Y, Deguchi Y, et al. Acute Health Problems among the People Engaged in the Cleanup of the Nakhodka Oil Spill. *Environ Res Sect A* 1999; 81:185-194.

4. Conclusion

Dr. Clapp did not review the extensive exposure data; did not review the chemical changes that occurred in weathered oil; did not review the surveillance of potential health effects by the CDC and state health departments; did not perform any type of risk assessment; has misinterpreted and misquoted the literature; does not have any experience evaluating the utility of PPE; and has completely ignored the opinions of numerous federal agencies. He therefore cannot offer any scientifically valid opinions regarding any actual or potential human health effects, either acute or long term. Furthermore, he has no basis upon which to challenge any of my conclusions as premature.

September 26, 2014

Appendix A - Materials Considered

This rebuttal report incorporates the list of materials considered contained in Appendix A of my August 15 and September 12, 2014 Reports. In addition to those documents and my August 15 and September 12, 2014 Reports, the following materials are added to the list of materials that I have considered in forming my opinions in this matter[56]:

1. Frédéric Dor, et al., Validity of Biomarkers in Environmental Health Studies: The Case of PAHs and Benzene, Critical Reviews in Toxicology, 29(2):129-168 (1999).
2. Human Biomonitoring for Environmental Chemicals (The National Academy of Sciences, (2006).
3. Science and Decisions - Advancing Risk Assessment (National Academy of Sciences, 2009).
4. Barbara J. Devine & Christine M. Hartman, Update of a study of crude oil production workers 1946-94, Occup Environ Med 2000; 57:411-417.
5. Gary Michael Kayajanian, Commentary: The J-Shaped Dioxin Dose Response Curve, Ecotoxicology and Environmental Safety 51, 1-4 (2002).
6. Otto Wong & Gerhard K. Raabe, A Critical Review of Cancer Epidemiology in the Petroleum Industry, with a Meta-analysis of a Combined Database of More Than 350,000 Workers, Regulatory Toxicology and Pharmacology, 32, 78-98 (2000).
7. Otto Wong & Gerhard K. Raabe, Cell-Type-Specific Leukemia Analyses in a Combined Cohort of More Than 208.000 Petroleum Workers in the United States and the United Kingdom, 1937-1989, Regulatory Toxicology and Pharmacology, 21, 307-321 (1995).
8. Kang Xia, et al., Polycyclic Aromatic Hydrocarbons (PAHs) in Mississippi Seafood from Areas Affected by the Deepwater Horizon Oil Spill, Environmental Science & Technology, 2012, 46 (10), pp 5310–5318.*
9. Florida Department of Environmental Protection, Human Health-Based Screening Levels for Petroleum Products Impacting Gulf Coastal Waters and Beach Sediments, available at http://www.dep.state.fl.us/deepwaterhorizon/files2/FLScreeningLevels.pdf.
10. NIOSH, Lessons Learned from the Deepwater Horizon Response, at 15, (Dec. 2011), available at www.cdc.gov/niosh/docs/2012-117/pdfs/2012-117.pdf.
11. Vandenberg LN, Colburn T, Hayes TB, et al. Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses. Endocrine Reviews 33:1-78, 2012.
12. A Practical Approach to Occupational and Environmental Medicine (Robert J. McCunney ed. 3rd ed. 2003).
13. Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment (The National Academies Press, (2006),
14. Chemical Conversion Spreadsheet*
15. Medical Encounters Database*
16. CDC, Community Fact Sheet: Volatile Organic Compounds and Your Health, available at http://emergency.cdc.gov/gulfoilspill2010/pdf/Resident_VOC_FactSheet.pdf.
17. ATSDR, Public Health Assessment Guidance Manual (2005 Update), Appendix F: Derivation of Comparison Values, available at http://www.atsdr.cdc.gov/HAC/PHAmanual/appf.html.
18. Colace Stool Softener 100 mg Capsules, available at http://www.walgreens.com/store/c/colace-stool-softener-100-mg-capsules/ID=prod364511-product.

[56] Materials accompanied by an asterisk (*) were also considered and/or relied upon for my August 15, 2014 Report.