Greetings,

It is my pleasure to answer the technical questions you have asked in your comparison of the Ahern et al. (2011) and Lamm et al. (2015) papers on mountaintop-mining (MTM) counties and birth defects.

1. Why did our study look only at the West Virginia data and not the four-state data that Ahern looked at?

This was answered in our paper (page 77) in the last three paragraphs of the introduction. Because of the lack of balance of MTM mining counties across the four states, the Ahern comparison was of MTM-mining counties in WV and KY and the non-mining counties of TN and VA. Only WV had a significant proportion of its live births occurring to residents of MTM counties – 34% compared to 9%, 2%, and 1%. WV had a balanced distribution of counties with about 1/3 having MTM-mining activity (18/55 = 33%), 1/3 non-MTM mining activity (14/55 = 25%), and 1/3 no mining activity (23/55 = 42%).

2. Why did you exclude hospitals with fewer than 1,000 live births in your more detailed analyses?

The answer to this question is demonstrated in Table 1. The last paragraph of the introduction states the purpose of this paper: We hypothesize that hospital of birth may bias the estimation and comparison of prevalence rates for birth defects by mining groups. We shall assess whether the prevalence rates for birth defects are explained by county of maternal residency (MTM or non-mining) or by hospital of birth. This gives us an opportunity to demonstrate how data quality issues, such as unbalanced distributions of live births
among hospitals and observer bias, may be handled to bring clarity to findings and conclusions.

Table 1 demonstrates that the crude prevalence rate ratio [PRR] (birth defect rate for residents of MTM-mining counties versus for residents on non-mining counties) was 1.43 (95% CI, 1.36-1.52) when all 319 birth sites were included. However, the analysis for the hospital-adjusted PRR could not converge. The model did converge when the analysis was restricted to the 44 hospitals that had greater than 1,000 resident live births in MTM-mining and non-mining counties during the 20-year study period.

This reduced data set still contained 98% of the live births to residents of the MTM-mining counties (152,540/155,382 = 98%) and 95% of the live births to residents of the non-mining counties (132,732/139,603 = 95%). Further, there was no loss of information as the crude prevalence rate ratio was still 1.43 (95% CI, 1.35-1.51). With this data set, the analytic model for the hospital-adjusted prevalence rate ratio converged with Hospital-adjust PRR = 1.08 (95% CI, 0.97-1.20; p = 0.16).

3. Why did you not adjust for maternal age, education, or smoking status, as Ahern et al. (2011) did?

Table 3 in Ahern (2011) report both “unadjusted” and “adjusted” prevalence rate ratios (with 95% confidence limits) for birth defect rates for residents of MTM-mining counties and of non-mining counties.

The “unadjusted” PRR was 1.63 (95% CI, 1.54-1.72), which is statistically significantly elevated [the lower confidence limit is greater than 1.0]. The “adjusted” PRR was 1.26 (95% CI, 1.21-1.32), also statistically significantly elevated, but much less so than the “unadjusted” PRR. The purpose of performing the “adjusted” PRR calculation was determine whether the statistically significant elevated “unadjusted” PRR could be entirely explained by known co-variates. This procedure showed that the co-variates could explain most of the increased risk. The “unadjusted” PRR showed an excess PRR of 0.63, and the “adjusted” PRR showed an excess PRR of 0.26. Therefore, the examined co-variates explained 59% of the statistically significant excess PRR in the “unadjusted” PRR [(0.63-0.26)/0.63 = 0.37/0.63 = 59%]. There still remained a statistically significant residual excess PRR of 0.26 that was not explained by the examined co-variates.

In contrast, our unadjusted PRR showed an excess PRR of 0.43, and our hospital-adjusted PRR showed an excess ERR of 0.08. Therefore, the one examined co-variate (hospital of birth) explained 81% of the statistically significant excess PRR in the unadjusted
PRR $[(0.43-0.08)/(0.43) = 0.35/0.43 = 81\%]$. As there was no statistically significant residual excess PRR after adjusting for hospital of birth, there was no need to seek other explanatory co-variates, such as maternal age, education, or smoking.

In addition to the technical questions, you asked about the role of ARIES and its member companies in the development of this paper. The statement of the non-role of ARIES applies also to the member companies of ARIES. Our only contacts were with the staff of Virginia Polytechnical Institute. CEOH closed its offices in 2016, and I do not recall the financial value of this contract.

You also asked what other work we have done for ARIES – that would have been the work on small for gestational age infants in Appalachia and analyses related to epidemiologic studies on arsenic.

Cordially,

Steve

Steven H. Lamm, MD, DTPH
Center for Epidemiology and Environmental Health
Washington, DC
HAL QUINN  
President & CEO

September 27, 2018

Mr. Arvind Ganesan  
Director  
Business and Human Rights  
350 Fifth Avenue, 34th Floor  
New York, NY 10118-3299

Dear Mr. Ganesan:

Thank you for reaching out and providing the opportunity for the National Mining Association (NMA) to offer its perspective on the many topics raised in your letter.

**Research.** Your letter mentions Human Rights Watch’s examination of mining-related research. NMA and its members also rely on independent, peer-reviewed research and, in the case of research on mountaintop mining, I would direct you to the research of the National Institute of Environmental and Health Sciences at the National Institutes for Health (NIH), which concluded in July 2017, after examining more than 3,000 available studies, that it is not possible to “reach conclusions on community health effects of MTR mining because of the strong potential for bias in the current body of human literature.” Researchers noted specifically that studies often failed to account for “individual-level contributors to mortality such as poor socioeconomic status or smoking.” (Source: Systematic Review of Community Health Impacts of Mountaintop Removal Mining, Abee L. Boyles*, Robyn B. Blain, Johanna R. Rochester, Raghavendran Avanasi, Susan B. Goldhaber, Sofie McComb, Stephanie D. Holmgren, Scott A. Masten, Kristina A. Thayer)

**Regulatory and Policy Protections.** Regarding your question on “regulatory and policy response,” there are extensive environmental protections currently administered by the Environmental Protection Agency, the Army Corps of Engineers, the Fish and Wildlife Service and the states’ regulatory authorities to ensure environmental protections are in place wherever mining occurs – indeed, the United States has some of the strictest environmental protections in the world.

Even before mining begins, detailed plans are made, and funding is secured to support the restoration of land after mining operations have concluded. Today’s mining...
Mr. Arvind Ganesan  
Page Two  
September 27, 2018

projects begin with extensive environmental and engineering studies, public involvement in major decision-making, and compliance with scores of state and federal laws and regulations governing every facet of the environment, from wildlife habitat protection to water quality monitoring. Projects end with land reclamation that often includes making reclaimed mining sites useful to the community for wildlife enhancement, developed recreation areas and other local community needs.

You specifically asked about the Stream Rule, which was ultimately unsuccessful because it would have duplicated, contradicted and created confusion around established state and federal regulations. As you may know, the Surface Mining Control and Reclamation Act of 1977 expressly prohibits rulemaking that creates regulatory overlap resulting in uncertainty through inconsistent requirements. We were public about our opposition to the Stream Rule for these very reasons – it was unlawful and would have provided no additional protections that weren't already covered by existing state and federal authorities.

The National Academies of Sciences (NAS) Study. Finally, your letter also asks about the NAS study that was cancelled in 2017. We publicly opposed the NAS study, whose committee was charged with a review of existing research to “identify(ing) gaps in the research and consider(ing) options for additional examination.” Our position was and is that, for $1 million, taxpayers should expect more than research to identify new areas to research. Legitimate efforts to improve health and safety in and around mines should be supported and applauded, but this re-review of existing flawed research would have been a very expensive waste of taxpayer dollars.

Nevertheless, we continue to believe that efforts made in good faith and without an agenda to advance health and safety in and around mines deserve support.

Sincerely,

[Signature]

Hal Quinn
Arvind Ganesan  
Director, Business and Human Rights  
Human Rights Watch  
350 Fifth Avenue, 34th Floor  
New York, NY 10118-3299

Dear Mr. Ganesan,

Thank you for your September 17, 2018 correspondence to the U.S. Environmental Protection Agency (EPA) Acting Administrator Andrew Wheeler regarding your interim findings concerning the environmental impacts of mountaintop removal mining in central Appalachia. I want to thank you for your commitment, information, and input in support of efforts to reduce these impacts. Your letter has been referred to me in EPA’s Oceans, Wetlands and Communities Division within the Office of Water. I would like to take this opportunity to respond to the specific questions raised in your letter.

1) In light of studies indicating the health risk posed by mountaintop mining, as well as severe degradation of streams near these mines, has the EPA taken or considered taking any actions to change its process for issuing permits for valley fills or for monitoring, preventing, mitigating or remediating possible Clean Water Act violations due to mountaintop removal mining?

The EPA works with our regulatory partners to help ensure that Clean Water Act (CWA) Section 404 permit decisions for surface coal mining projects are environmentally protective and legally defensible. Although the EPA does not render a decision as to whether or not to issue the required permits, the U.S. Army Corps of Engineers (Corps) makes that determination. We have an important role in this process. The EPA, in coordination with the Corps, the environmental criteria used in evaluating CWA Section 404 permit applications for the proposed discharge of dredged or fill material into the nation’s waters. These criteria are known as the CWA Section 404(b)(1) Guidelines (Guidelines). Importantly, the Guidelines require a demonstration that the proposed discharge will not result in significant degradation of the aquatic environment, that there are no less environmentally damaging alternatives to the discharge, and that all appropriate and practicable steps have been taken to avoid and minimize impacts and to compensate for any unavoidable impacts to the aquatic environment. The EPA continues to affirm these key tenets of the Guidelines in our coordination with the Corps and in our careful review of surface coal mining proposals under CWA Section 404. Through this review, the EPA has recommended the incorporation of cost-effective best management practices (BMP) for...
associated with surface coal mining and reclamation operations that have been authorized or are being processed by States with approved programs under the Surface Mining Control and Reclamation Act. The Corps’ reissuance of NWPs in 2012 included significant revisions to NWP 21 to provide greater assurance that this general permit will authorize only those discharges of dredged or fill material into waters that have minimal individual and cumulative adverse effects on the aquatic environment. Environmental thresholds limiting stream loss were added to NWP 21 for consistency with many of the other NWPs. The revised NWP 21 also included a new condition prohibiting its use to authorize valley fills. These provisions were retained in the current version of NWP 21 that was reissued by the Corps in 2017.

4) Several peer-reviewed studies conducted by West Virginia University scientists measured concentrations of toxic particulate matter in residential areas near mountaintop removal sites that dramatically exceeded legal limits under the Clean Air Act. What steps, if any, has the EPA taken to ensure that areas near surface mining sites comply with particulate matter limits?

The Clean Air Act requires the EPA to set national air quality standards for particulate matter, as one of the six criteria pollutants considered harmful to public health and the environment. The law also requires the EPA to periodically review the standards to ensure that they provide adequate health and environmental protection, and to update those standards as necessary. The EPA is committed to helping state and local governments meet the Agency’s national air quality standards for particulate matter.

Thank you again for your letter and raising these important concerns. I hope this information is helpful. If you have any further questions or concerns, please contact me at Frazer.Brian@epa.gov.

Sincerely,

[Signature]

Brian Frazer, Acting Director
Oceans, Wetlands and Communities Division
October 29, 2018

Arvind Ganesan  
Director Business and Human Rights  
Human Rights Watch  
350 Fifth Avenue, 34th Floor  
New York, NY 10118-3299

Dear Mr. Ganesan:

Thank you for contacting us regarding the Appalachian Research Initiative for Environmental Science (ARIES) program and policies. I am happy to share the following information with you.

The Virginia Center for Coal and Energy Research (VCCER) administers the ARIES program. The VCCER was created by an Act of the Virginia General Assembly on March 30, 1977, as an interdisciplinary study, research, information and resource facility for the Commonwealth of Virginia, located at Virginia Tech. Derived from its legislative mandate and years of experience, the mission of the VCCER involves five primary functions:

- Research in interdisciplinary energy and coal-related issues of interest to the Commonwealth
- Coordination of coal and energy research at Virginia Tech and in the Commonwealth of Virginia
- Dissemination of coal and energy research information and data to users in the Commonwealth
- Examination of socio-economic implications related to energy and coal development and associated environmental impacts
- Assistance to the Commonwealth of Virginia in implementing the Commonwealth’s energy plan

The Virginia Center for Coal and Energy Research and Appalachian Research Initiative for Environmental Science has no affiliation with the U.S. Department of Interior.

ARIES is an Industrial Affiliates Program and functions under Virginia Tech’s policies for such programs, information about which can be found here: https://osp.vt.edu/industry/industrial-affiliates-program.html. Simply stated, Virginia Tech’s industrial affiliates program allow companies to become members, to pay membership fees, and for the fees to be expended in support of the specific purpose(s) of the individual industrial affiliates program. As with all Industrial Affiliates Programs at Virginia Tech, ARIES members would not have a role in selecting specific projects to receive contracts for sponsored research.
Furthermore, it has been ARIES policy since its inception that the focus of individual research projects is not dictated by ARIES IAP members and that researchers must adhere to the integrity policies of their respective organizations. Virginia Tech policy, precludes members from dictating research methodology. Per the Industrial Affiliates Program FAQs (at https://esp.vt.edu/resources/faq/industrial-affiliates-faq.html), “An industrial affiliate is not entitled to specify the protocol to be used in the conduct of a specific research effort.”

ARIES was a 5-year program, with membership beginning in 2011 and ending in 2015. Research funded by ARIES continued beyond 2015 and all contracted research projects were completed by 2017. As stated in the ARIES membership agreements,

The purpose of this membership program is to conduct research on potential upstream (mining, drilling and processing) and downstream (water, land, air) environmental impacts of the mining, gas and energy sectors in Appalachia. To accomplish its mission, ARIES will conduct scientific inquiry and research, foster publication and contribute to the relevant literature, and engage in outreach efforts to share and disseminate research results.

At this time a portion, but not all, of the research results have been published.

Thank you for your interest in our research.

Sincerely,

\[ Signature \]

Edmund Jong, Ph.D.
Research Assistant Professor and
ARIES Project Director
Mr. Arvind Ganesan  
Director, Business and Human Rights  
Human Rights Watch  
350 Fifth Avenue, 34th Floor  
New York, New York 10118-3299

Dear Mr. Ganesan:

Thank you for your September 17, 2018, letter regarding concerns about the health risks of mountaintop removal mining in central Appalachia. I am responding to your letter on behalf of Lieutenant General Todd Semonite.

A complex statutory framework governs the regulation of coal mining activities such as the construction of valley fills and associated sediment ponds. Congress passed the Surface Mining Control and Reclamation Act of 1977 (SMCRA) to establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations. While the federal Office of Surface Mining (OSM) has the responsibility for SMCRA implementation, all states in the Appalachian Region (with the exception of Tennessee) have been granted primacy by OSM and those states currently regulate and permit surface coal mining and reclamation operations in their states. The U.S. Army Corps of Engineers (Corps) regulatory authority under Section 404 of the Clean Water Act (CWA) applies to the discharge of dredged or fill material into waters of the United States. The Section 404(b)(1) Guidelines developed by the Environmental Protection Agency (EPA) in conjunction with the Corps are the substantive environmental criteria used by the Corps in evaluating activities regulated under Section 404. The Corps' review is limited to effects caused by the discharge of fill material into jurisdictional waters, while broader effects from the overall mining operations are appropriately regulated under SMCRA. See Ohio Valley Environmental Coalition v. Aracoma Coal Company, 558 F.3d 177 (4th Cir. 2009).

In your letter, you raised three specific questions about the Corps of Engineers permitting of valley fills associated with surface coal mining. I will respond to them in the order in which they were presented.

1. In the May 9, 2002, "Definition of Fill" Rule, EPA and the Corps clarified that overburden from mining is appropriately classified as fill material (33 CFR Part 323.2(e)(2)). In this regard, the discharge of this overburden material into waters of the United States must be authorized by a permit issued by the Corps pursuant to Section 404 of the CWA.
2. As noted above, the Corps evaluates a proposed discharge to determine compliance with the Section 404(b)(1) Guidelines. If a proposal would cause or contribute to significant degradation of waters of the United States, it would not comply with the Guidelines and a Section 404 permit would not be issued. Conversely, if a Section 404 permit is issued for a proposed discharge of fill material, a determination has been made by the Corps that the proposal will not cause significant degradation. Additionally, before the Corps can issue a Section 404 permit, the state must issue a water quality certification pursuant to Section 401 of the CWA that the proposal will not violate state water quality standards.

3. For many years, Nationwide Permit (NWP) 21 was the primary type of general permit that was used to authorize surface coal mining activities. When the NWPs were reissued in 2012 (effective date March 19, 2012), a restriction was added to NWP21 to prevent it from being used to authorize the construction of valley fills. While a similar restriction was not added to NWP49 (Coal Remining Activities) or NWP50 (Underground Coal Mining Activities), historically those NWPs have not routinely been used to authorize construction of valley fills. In the event that a Corps district proposes to use either NWP49 or NWP50 to authorize a project that involves construction of a valley fill, that NWP verification could only be issued if the district determines that the discharge will result in no more than minimal adverse effects.

If you have any additional questions or wish to further discuss these issues, please feel free to contact Mr. William L. James, the Corps National Mining Expert at (615) 389-7508 or by email at william.l.james@usace.army.mil.

Sincerely,

[Signature]

James C. Dalton, P.E.
Director of Civil Works