

August 1, 2019

Rachel Levine, MD
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An open letter to Dr. Rachel Levine, Pennsylvania Secretary of Health

Dear Dr. Levine:

On June 19, you were quoted as saying the following (in a Pittsburgh Post-Gazette article titled “Gov. Wolf wants more data about how gas drilling impacts citizens’ health,” Hopy and Templeton, 2019): “As a pediatrician and a public health advocate, the public can rest assured that if I knew that we were inadequately protecting public health, I would make that case clear to Governor Wolf. But I believe that we do not have enough information to make such a determination in this case.”

As a public health organization focused on the health impacts of exposure to shale gas development, we at the Southwest Pennsylvania Environmental Health Project (EHP) are deeply concerned by this remark. We have reviewed the study you based this comment on, as well as many other studies, and we have performed our own research and heard from enough community members to determine that the Department of Health is indeed failing to protect the health of Pennsylvanians in the face of rampant shale gas development. We know that you, at the Department of Health, have also received hundreds of complaints from residents about their health and the health of their children.

We are especially disappointed in your department’s reliance on a single literature review of 20 studies conducted jointly by the Pennsylvania and Colorado Departments of Health, authored by Bamber et al. (2019). Our disappointment lies in the methodology this review employs, which seemingly leads to your *wait and see approach*. While you wait, health risks and outcomes related to shale gas drilling within your state and others have been well-documented by credible researchers.

In particular, we are troubled by the Bamber review’s inappropriate rating scheme, which gives inadequate weight to observational studies, as well as its lack of recognition of additional pertinent evidence streams in assessing the potential for harm. It begs the question, “What *were* the reviewers looking for?”

OBSERVATIONAL EPIDEMIOLOGIC STUDIES

Bamber and the other authors of the systematic review article point to four review frameworks that helped them assess the strength of the research on ONG (oil and natural gas) operations: GRADE (Guyatt et al., 2008), MOOSE (Stroup et al., 2000), the Navigation Guide (Woodruff & Sutton, 2014), and OHAT (Rooney et al., 2014). Under scrutiny, however, we found those models to be misapplied. In fact, had the authors more thoroughly

understood the papers they cited on evaluation of evidence, their assessment would have been quite different.

While it cited four models, it was the GRADE model that the Bamber review most fundamentally incorporated. GRADE rates observational studies as starting at “low quality” and randomized controlled trials at “high quality.” This is based on the relative merit of the two types of studies when both are applicable, since randomized controlled trials with informed research participants are considered the more controllable and unbiased scientific design.

In environmental exposure scenarios, however, randomized controlled trials are not just difficult; they’re impossible. Guyatt et al. (2008) present GRADE as a model used not in environmental public health but in making clinical health care decisions, such as evaluation of hormone replacement therapy safety and other determinations of whether clinicians are making the best possible evidence-based decisions for their patients. In fact, given that the Bamber review cites three other review models specifically designed to evaluate observational environmental health studies, we wonder with great curiosity why the GRADE framework was incorporated at all. The inappropriately applied ranking system of the GRADE model led the authors of the Bamber review to designate the majority of reviewed studies as “low quality,” which largely accounts for the authors’ ultimate conclusion that there is insufficient weight of evidence for most health outcomes related to ONG.

The Bamber review also cited the Navigation Guide as a framework it drew upon to evaluate the studies in question. While this framework would have been entirely useful, as it was designed specifically to systematically review environmental health literature as opposed to research affecting clinical decision making, we can’t find that the Navigation Guide was utilized to any suitable extent here. As discussed by Woodruff and Sutton (2014), the Navigation Guide presents observational studies as the preferred method for evaluating the causes of disease, including environmental causes. This view is backed up by the Institute of Medicine (2008).

Woodruff and Sutton say, “Ethical considerations virtually preclude experimental human data from the environmental health evidence stream. Therefore, relative to the evidence available for decision making in environmental health, human observational studies are the ‘gold standard’ of the evidence base.” As such, the Navigation Guide assigns, *a priori*, a “moderate” rating based on the absolute and relative merit of human observational data in evidence-based decision making in environmental health science. The authors of the Bamber review, however, inexplicably take the limitations of observational studies as their starting point and ultimately as the basis for their conclusion.

WHY NOT INTEGRATE MULTIPLE EVIDENCE STREAMS TO COMPLETE THE PICTURE?

Another major flaw of the Bamber review is the authors’ failure to incorporate evidence from nonhuman data streams, including animal studies and risk assessments. The review authors refer to the framework developed by the National Toxicology Program Office of Health Assessment and Translation (OHAT), which integrates multiple evidence streams in developing hazard identification conclusions and rates confidence in the body of evidence.

OHAT integrates observational human studies, experimental animal toxicology, and other relevant data in developing hazard identification conclusions or state-of-the-science evaluations regarding health effects from environmental exposures. If other data provide strong support for, as an example, biological plausibility of the relationship, the conclusion could be upgraded. Similarly, the Navigation Guide recommends reviewing both

observational human studies and pertinent nonhuman studies separately and then ultimately taking both conclusions into account to arrive at a more complete picture of the available evidence.

ANOTHER PERSPECTIVE

Interestingly, another recent epidemiologic literature review of the same group of studies (Gorski and Schwartz, 2019) out of Johns Hopkins Bloomberg School of Public Health came to a completely different conclusion than the Bamber review. Gorski and Schwartz write:

The body of research to date on UNGD and health would allow several conclusions. UNGD activity metrics have been found to be associated with preterm birth, high-risk pregnancy, and possibly low birth weight; three types of asthma exacerbations; and nasal and sinus, migraine headache, fatigue, dermatologic, and other symptoms. In these studies, associations were robust to increasing covariate control; the associations were robust in several sensitivity analyses, in which researchers evaluated whether observed associations decline or disappear under certain varying assumptions; and the associations were biologically plausible.... This emerging evidence is of concern, and it is somewhat surprising that any health impacts have been reported given the relatively limited funding, to date, that has been devoted to finding them.... Finally, given that this article was written less than a decade after the expansion of UNGD, the studies in these sections have been limited to investigation of short-latency health outcomes in the context of UNGD.... In the history of public health, industrial development has always gotten ahead of public health protections. The UNGD industry has developed particularly rapidly. When is there enough evidence to regulate UNGD on the basis of health?.... Given the limited resources devoted to these investigations along with the difficulty of obtaining information on the industry early on, and that in environmental epidemiology there are often many biases that result in difficulty uncovering evidence (called bias toward the null), *what has been reported to date offers no reassurance that UNGD is likely to be safe for public health.*

WHEN SHOULD THOSE CHARGED WITH THE PROTECTION OF PUBLIC HEALTH ACT?

At EHP, we acknowledge, to our dismay, that our state's public health system employs a reactionary approach instead of a precautionary one. Instead of tasking industry with supplying evidence of safety before exposure, you task scientists with supplying evidence of disease afterwards. But even when presented with scientific evidence that points toward the possibility of harm, the Department of Health is choosing to take no definitive action in the interest of the public's health, citing a lack of credible evidence. As Woodruff and Sutton put it, "Failing or delaying to take action to prevent exposure to harmful environmental chemicals is not an inconsequential or neutral policy choice."

With regards to shale gas development, the fact that you have made the determination that Pennsylvanians' health is adequately protected, based on one flawed review of 20 epidemiologic studies – many of which *have* found evidence of significant harmful health impacts – while ignoring the hundreds of other pertinent studies from other data streams that lay out the potential for harm is, in our opinion, negligent.

The Bamber review you rely on refers to Bradford Hill's (1965) criteria for causation as undergirding their assessment tool. However, the scientist who aimed to distinguish causation from association concluded an address saying, "In asking for very strong evidence I would, however, repeat emphatically that this does not imply crossing every 't', and

swords with every critic, before we act. All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. *That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.*”

Have we learned nothing from the historic examples of asbestos, tobacco, and perfluorinated chemicals? In each case, an abundance of early evidence pointed toward harm, but policymakers, under pressure from industry, waited decades for overwhelming, irrefutable, epidemiologic evidence to accumulate before taking action. Pennsylvania allows the gas industry to pollute the air, the water, and the soil with toxic contaminants. Paradoxically, the state then depends upon and simultaneously mistrusts observational science to tease out this exposure and show, in statistically significant numbers, that the public has been harmed. But the residents of the Marcellus Shale region, essentially the guinea pigs in this experiment, shouldn't need to idly wait for the particular proof you are demanding.

Instead of putting on blinders and focusing solely on one problematic literature review, EHP asks you, Dr. Levine, to provide specific comments on the contents of the *Compendium of Scientific, Medical, and Media Findings Demonstrating Risks and Harms of Fracking (Unconventional Gas and Oil Extraction)* now in its sixth edition (Concerned Health Professionals of NY and Physicians for Social Responsibility, 2019). To fully understand the weight of this problem, you must understand not only the epidemiologic literature, but the toxicology, animal, and risk studies, as well as the regulatory loopholes the Commonwealth of Pennsylvania has afforded the gas industry. If you still feel that the Department of Health is adequately protecting Pennsylvanians from the health impacts of shale gas development, we ask you to specifically outline how much more evidence of the contrary you need before you make the case to Governor Wolf that now is the time to act.

Sincerely,

Sarah Rankin, MPH, BSN, OCN

Beth Weinberger, PhD, MPH

cc: Governor Tom Wolf

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