From:
To:
Cc:

Subject: RE: Draft BPSOU Public Health Study Report Deliverable
Date: Thursday, February 27, 2014 8:54:19 AM

I think it's really nice and useful to the public, so thanks. A few small suggestions"

- After the first three bullets, consider a concluding statement like, "The understanding gained is applied toward making recommendations for improving the RMAP program."
- Your second header, "Blood lead levels provide..." is not addressed by the text. That is, you don't explain why blood lead is a good indicator of exposure. Also, too, the goals and standards are brought in rather late in the summary, and could be brought into a new paragraph here that addresses the header. I would add that there is no known beneficial effect of exposure, that the goal is no exposure but that there are standards (5 for CDC, 10 for EPA). The text is good, but maybe needs a different header.
- Third header, revise to: "...Levels in Butte Have Declined..."
- Page iii, second full paragraph, last sentence. Edit to: "...cannot be ~~identified~~ conclusively proven based on this analysis...reductions in other lead exposures achieved through other government programs."
- Header on page iv, revise to: "The RMAP ~~has been~~ continues to be and important..."

I expect the reasons for the changes are self-explanatory, but I am available if there are questions. I grant liberty to respond to these suggestions as you deem best. Thanks.

-----Original Message-----
From:
Sent: Tuesday, April 08, 2014 4:37 PM
To:
Subject: Fwd: Failure Notice

>
> Hello,
> I am a part-time resident of Butte and interested in the quality of
> life in t= he area. I have downloaded and scanned parts of the Draft
> Report to be discu= ssed tomorrow. I commend your studies and
> actions.=20
>
> 1) Newspaper said there was a 9am meeting. True?
> 2) I could not look at all of the references, so excuse me if this was
> answe= red. What are the other concerns that will degrade (have
> degraded) the healt= h of citizens? Lead seems to be the focus of the
> report. What about arsenic= , mercury and other metals in the
> environment? Is asbestos an issue? Specif= ically, lead paint is
> unrelated to mining. What are mining related issues an= d how well do we understand them? And
attempt to control them?
> 3) Were I to reside here for 30 years, living a healthy lifestyle, am
> I at i= ncreased risk to certain diseases that are environmentally
> related? COPD? C= ancer? Mercury poisoning? ??? If the answer is
> unknown, what measures are un= derway to learn it?
> 4) What approaches and attitudes are present among the business
> leaders, tec= hnologists and citizens that would tend to prevent the
> polution and cleanup t= hat the area faces from a history of, what I
> must assume, was irresponsible m= ining practices? Note, I am aware
> that much particulate polution of the air= is caused by coal and wood
> burning in homes during winter, and forest fires= in the summer.
> Please feel free to criticize my causal assumption. Hind sig= ht is
> always clearer.=20
>
> Thank you
>

-----Original Message-----
From:
Sent: Thursday, April 10, 2014 3:59 PM
To:
Subject: BSOU Public Health Study - Phase 1 Review

BSOU Public Health Study - Phase 1 Review

Having attended the two meetings and spoken with participants, I submit these comments and questions:

1) has the level of lead decreased in the environment over the same time period as measured in public and private spaces. Clearly the blood levels show a decrease, but do they indicate its decrease in the environment? Blood levels are one measure, but let's add other measures. True, the presence of Pb in blood indicates its presence in the environment of those individuals. I suggest that all city parks and playgrounds be tested for metals at least annually, if not twice a year. If these tests have been done, please report them. Is there a test that can be applied to biological samples. For example, tree rings should contain a history of both water and air contaminants. Old and young trees are cut down exery year. It would seem that tests by area of the city might be informative. I suggest that vegetables and fruits that are grown for consumption should be tested as well. If nothing else, a sample of produce from the public gardens adjacent to the Hummingbird restaurant should be tested annually. I am unfamiliar whether other potential test sites of this nature exist. It is conceivable that a controlled test garden(s) within the area could be created and maintained by some entity. Another testing location would be the soil on selected trails, abandoned and converted railroad beds and otherwise in all directions of Butte.

2) Is there no way of attributing the presence of Pb (and other metals) to mining operations as opposed to the other cited Pb sources? The results of the above paragraph's testing may provide a hint to this.

Having submitted these suggestions, I still commend all who worked on the existing study for a job well done. As always, studies beget studies.

To a better Butte,

Why isn't the public more involved with the Citizens Technical Env. Committee CTEC should involve the public. (For the people?!?)

Sent: Saturday, February 15, 2014 10:58 AM

Subject: Comments--Butte Health Study Draft

Attached please find comments that I am submitting preceding the impending release of Phase I of the Health Study. I feel that the time is now ripe for my comments, prior to the official start of the public comment period, in that it has been made clear to the public through numerous venues, such as public meetings, what will be in the draft. It has also been made clear that the EPA and MDEQ are reneging on their promise of an independent peer review of the study that would actually impact the process before any final decisions are made. It is also clear that the EPA has failed to live up to its environmental justice mandate.
Perhaps, although I am so to speak "not holding my breath," these comments will have some impact.
Specifically, I ask EPA and MDEQ to honor their commitment to provide an independent peer review of the Health Study. I ask EPA to live up to its mandage to promote environmental justice in all of its activities. I ask EPA and MDEQ to provide for meaningful public involvement in this process.
Again, please see my **attachment** to this email.

If men were angels, no government would be necessary. If angels were to govern men, neither external nor internal controls on government would be necessary. In framing a government which is to be administered by men over men, the great difficulty lies in this: you must first enable the government to control the governed; and in the next place oblige it to control itself. A dependence on the people is, no doubt, the primary control on government.

James Madison—Federalist # 51

In our representative democracy, we delegate our sovereign authority to government officials, both elected and appointed, who are supposed to act on our behalf. Holding such officials accountable is no easy task: How do we know they are acting in our interest? How do we know that our interests are being protected?

Nowhere is this difficulty more apparent than regards the Superfund cleanup in Butte. Citizens see an agency impervious to public influence. Most recently, this callous disregard for meaningful public involvement in Superfund decision-making is seen in the development of a so-called "health study" which is supposed to evaluate Superfund's effectiveness in Butte. The public has a right to know if the Superfund cleanup is protecting public health. The public has a right to an independent, valid health study process.

Yet, what we have is another instance of the EPA evaluating the EPA's work or of one of the liable parties for the cleanup, ARCO, hiring a contractor to evaluate its work. Could bias be operating in such a situation? How likely is it that the EPA will find that its performance over the past several decades has been poor? Is there a proclivity on EPA's part toward finding its own work satisfactory? How can the public have any confidence in an agency evaluating its own work? Under such conditions, how can the public have any confidence in the results of this so called "health study"? Look at the hatchet job that EPA performed on Dr. Stacie Barry's health study. Her study came up with the wrong conclusions from EPA's perspective and the agency pulled out all the stops to discredit her and her report. (As an aside, no wonder citizens are loathe to get involved in the Superfund process. EPA officials have stormed out of presentations, yelling that

the speaker was a liar and, on other occasions, stating they would delete any communications from citizens that were critical before reading, or criticizing citizens simply for providing input.)

Brazenly, the EPA, in an exercise of wanton hubris, has been "informally" announcing the results of the Health Study before it is conducted. Surprise: the EPA finds that all is well—don't worry. It is bad science indeed to announce ahead of time the results of a supposedly independent study.

The EPA had promised when the health study process got started that the study would be subjected to independent, peer review by a qualified expert or experts prior to the study being completed. Now EPA is retreating from this promise and speaks only of submitting the study (obviously in a condensed form) for possible publication in a peer reviewed journal at some distant time in the future.

This recent retreat on EPA's part is unacceptable for the following reasons:

1. What at best will be reviewed by the journal is a condensed, article length version of the study. We were promised that the whole study would be peer reviewed by independent, qualified experts.
2. Contrary to EPA assurances, this journal article peer review will not impact the process. The study, according to EPA, is going forward no matter what the result of the peer review.
3. It may take a year or two for a journal article to be accepted. Again, we have further proof that EPA is reneging on its promise that the independent peer review would actually impact the process. The peer review journal article process will come out too late to impact the process.
4. We have no assurances what will be considered in the peer review journal article process. Will it be the questions that need to be asked? Will it be the questions that the public wants answered? How do we know that the journal to which the article is submitted will conduct a thorough, independent review?
5. In another instance of wanton hubris, the EPA, contrary to earlier promises, wants a local citizens group to pay for the peer review. EPA could design no better way of excluding the pubic than to say the public that it has to pay.

6. The whole process of the health study has ignored environmental justice concerns. The EPA has conducted no outreach to the poor. Although uptown Butte has a disparate number of low-income citizens, the EPA has included no representatives of low-income citizens to be involved in the process. This is contrary to the national EPA mandate to promote environmental justice in ALL of its actions.

In short, why is EPA afraid to have its work subjected to independent peer review? Is EPA hiding something?

In Libby, Montana, the EPA officials there, under public pressure, have created an independent scientific advisory board to oversee the cleanup. Why can't we have such a board in Butte? All of the so-called health study work should be subject to independent peer review by a group of distinguished scientists. If the EPA is so confident in its work, why not have such an independent peer review? We need an end to the situation of the EPA evaluating its own work. Other EPA regions subject their work to independent peer review. Why is the Montana office refusing to do so?

The EPA also needs to reevaluate its commitment to public involvement in Superfund decision-making. Democratic theory as well as the EPA's own policies demands meaningful public involvement whereby the public is a major player in agency decision-making. In Butte, the EPA confines its public involvement activities to PR by informing that public about the great job the agency is doing. Yet, time and again, the public's input, when it is contrary to what the agency wants to do, is ignored. This low regard for public input on the part of Montana's EPA office is demonstrated by that office largely eliminating site specific community relations officers and assigning community involvement tasks to their project engineers whose primary task is implementing cleanup technologies and who have no training, background or interest in community relations. Recently, one project engineer said that the only value of public input was to provide "emotional" data.

Maybe, the EPA needs to assign "fresh blood" to Butte. Some of the EPA officials here have been working on local sites for several decades. Perhaps, they have

become so “invested” in their work that they can’t see any difficulties in the cleanup. When Cromwell dismissed the “Long-Parliament” he said: “You have sat here too long for all the good you are doing. In the name of God, go.”

Local government needs to be more proactive in overseeing the cleanup. Promisingly, the new administration has a solid background in Superfund and is committed to public participation. The Council of Commissioners needs to be more involved. It cannot defer to staff the task of overseeing the cleanup. Remember, it was the staff that sold out Butte with the settlement agreement with ARCO.

EPA should keep its promise and fund an independent, blind, and qualified peer review of the health study prior to any final decisions being made.

EPA should adhere to its environmental justice mandate and reach out to the low-income community in Butte.

From:
Sent: Sunday, April 06, 2014 6:40 AM
To:
Subject: Questions I would like addressed at the Public Meetings on the Butte Superfund Health Study

Follow Up Flag: Follow up
Flag Status: Completed

I would like the following questions addressed at the Public Meetings on the Health Study.

1. Butte was promised an independent peer review of the study. This independent peer review was supposed to be part of the process of developing and conducting the health study, It was not supposed to be an after the fact endeavor that would have no impact on the design and conduct of the study. EPA appears to be reneging on that promise. Now all the agency promises us is that at some time after the process is finished some condensed version of the study will be submitted for possible publication. It was also stated by EPA that this review would not change the study. Such a review will have no impact on the design and conduct of the study as EPA originally promised. What good is it? Why is EPA afraid to have its work independently reviewed? Having a condensed article published is not the kind of independent peer review EPA promised. What the pubic is left with is that the EPA and its associates will be reviewing their own work. What assurances can the public have that this report was done in an unbiased manner and done correctly? Without an independent peer review, the public can have NO such assurance. Why has EPA reneged on its promise? What is EPA afraid of discovering?

2. The purpose of the study is to demonstrate that the Residential Metals Abatement Program is working. I support the program but the methodology the study uses is faulty. It is an example of the "post hoc, ergo propter hoc" fallacy. On the one hand the study says the Residential Metals Abatement Program exists. On the other hand the study says that lead levels are dropping in Butte. The unproved assumption is that the first is the cause of the second. Yet, no methodology is utilized in the study to demonstrate this causal link.
How was this causality established?
Also, just because lead levels in Butte are approaching the national average, is the national average protective of human health? No data to warrant this conclusion is provided by the study.

3. By looking only at lead levels, the study does not give a big picture view of the entire toxics problem in Butte. We are told that the studies will be going on for some 30 plus years. By the time the studies are completed the point of the effectiveness of Superfund in Butte will be largely mute. We need some assurance for the residents of Butte currently alive that Superfund is working. This is just another example of the EPA dragging things out to the point that people either die or are no longer interested.

4. The study ignores environmental justice concerns. How is environmental justice incorporated into the design and execution of the health study?

5. Stacie Barry's peer reviewed study reached the conclusion that Superfund overall in Butte was not working and that public health was not being protected. We now have an EPA funded study that reaches the opposite conclusion. Why should we believe this EPA produced study? How is the EPA study better than the work that Stacie did? Is this EPA study simply a PR effort by EPA to refute Stacie's conclusions?

6. Why has EPA refused to change its action levels on lead to be congruent with the CDC recommendations? Is this a one size fits all approach?

7. What assurances can the public have that the toxics of concern have been properly characterized?

I will be raising other questions during the comment period but I think the above are a good place to start. Please address these at your public meetings.

From:
Sent: Monday, April 07, 2014 11:55 AM
To:
Subject: Input--Butte Health Study Public Comment Period

The following expands on my views regarding the environmental justice issue in regard to the Butte Health Study mandated by EPA under a unilateral order. Please consider this as public comment and I would like this issue addressed at the public meeting to be held this week on environmental justice.

Butte Superfund Health Study Ignores Environmental Justice

I have written several times about my concerns regarding the Butte, Montana Superfund Health Study which is being conducted under the auspices of the Montana Office of EPA to demonstrate Superfund's effectiveness in Butte, Montana. Currently, particular emphasis is being directed to the issue of lead contamination in Butte.

One of my complaints has been that the EPA Montana Office has ignored environmental justice concerns in the conduct of the first phase of the health study. The first draft of the health study has been completed and released for public comment. Although it notes that in central Butte, the area encompassed by the Butte

Priority Soils Superfund Operable Unit, blood lead levels in children living in that area are higher than those found in the rest of Butte and that lead levels were particularly elevated in low-income families who disproportionately live within the Priority Soils area, ***no particular outreach to or involvement of or consideration for the low-income community is planned or seen as necessary by the Montana EPA office with regard to the development and implementation of the health study protocol.*** *Low income citizens have been excluded from meaningful participation in the development, conduct and implementation of the health study*

Clearly this is an environmental justice issue. Yet, no representatives of the poor are participants in the planning and execution of the health study. No effort is made to assess the health effects of exposure to the toxics of concern in the Priority Soils site—lead, arsenic and mercury—specifically on low income residents who are particularly susceptible because of their poverty to the detrimental effects of toxics exposure. Given that the low-income community in Butte is being ignored, the results of the health study will be to perpetuate the disparate toxics burden that low-income citizens have had to endure in Butte. We will see a perpetuation of "environmental injustice." The Montana Office continues its "one size fits all" approach to dealing with environmental justice. In reality, environmental justice concerns are being ignored by the Montana Office of EPA.

It is not sufficient to just recognize that low income citizens in Butte are disparately and unequally affected by toxics exposure. The EPA needs to act and do something to remove this disparate, disproportionate toxics burden. How is Montana EPA addressing this problem? Why has it been ignored?

From the inception of the health study, the Montana EPA office sa**w** this study as a means to justify the efficacy of the Butte Superfund cleanup. (After all, it was announced when the health study was announced, before the study was conducted, that the study would confirm Superfund's efficacy. Is this "good science, to announce what you expect to find before the study is completed? That is why citizens demanded an independent peer review of the study. EPA originally agreed to an independent peer review during the process of developing and conducting the health study. Now, the Montana Office of EPA is apparently reneging on that promise.) In their attempt to prove Superfund has worked, the Montana Office has ignored environmental justice concerns which should give the Montana EPA office pause when considering the efficacy of the Superfund cleanup.

One study, conducted a couple of years ago, indicated that there were significant problems regarding the efficacy of the Butte Superfund cleanup, particularly in terms of low-income citizens. Other past studies reached similar conclusions. As I mentioned earlier, this current, Montana EPA office sponsored health study was formulated to counteract the conclusions of the original study by Stacie Barry. Stacie's study was independently peer reviewed while it was being developed. Why does the Montana Office of EPA refuse that same level of independent scrutiny? Such action on EPA's

part might lead some to conclude that EPA is NOT confident about its study or that EPA has something to hide. If all is ok, let us have an independent peer review prior to the completion of the health study.

Certainly, the folks conducting the Residential Metals Abatement program (RMAP), which is part of the Superfund remedy, in Butte are doing an exemplary job. (My concern is with the development and conduct of the health study.)The RMAP folks work long hours and are easily accessible. They are doing all that they can, given the restrictions placed on them by EPA. In fact, they need more support from EPA. Problems are often beyond their control such as some landlords who refuse to grant them access to their properties. Butte needs more protective action levels and EPA needs to remove artificial restrictions on when the RMAP program can cleanup a property. EPA, which has the power, needs to do more to get reluctant landlords "off the dime" and to allow RMAP access to clean up their properties.

The issue is EPA's overall approach to the cleanup on the Butte Hill that has largely ignored environmental justice issues. No special consideration is offered to low income citizens in contradiction to EPA's stated policy. EPA still supports action levels for cleanup that are based on old and what the CDC (Centers for Disease Control) considers non-protective blood lead levels. Why hasn't the EPA changed its cleanup action levels, which are very permissive, to reflect the new CDC findings and offer maximum protection to low-income citizens?

Certainly, Butte citizens want Superfund to be effective. After all, we live here. But desire for a favorable outcome should not blind us from asking tough questions of EPA. Conflicting studies with conflicting results leads to citizen confusion. Why won't EPA subject its study to independent peer review? Low-income citizens need special consideration as part of the EPA's commitment to environmental justice, which is really an extension of equal protection of the laws. Why won't EPA give them special consideration? I really believe that the Montana Office of EPA doesn't have a clue as to what is mandated by environmental justice.

One additional point. The Montana Office of EPA dismisses any recent concerns about their failure to actively pursue environmental justice concerns on the Butte Hill by pointing to a decision a few years back that EPA made about itself that environmental justice concerns were being properly addressed. Leaving aside the fact that this is another instance of the EPA evaluating itself and finding all is well, even if environmental justice concerns were being addressed a few years back, that does not mean that they are being addressed now. The EPA's position is analogous to a thief saying that I was acquitted on the charge of robbery a few years back so I can never we charged with robbery again. How ludicrous but that is the position that the Montana EPA office takes.

From:
Sent: Tuesday, April 08, 2014 5:40 AM
To:
Subject: More on Environmental Justice Concern/Issue and Butte Health Study Phase I

The following is additional information that I would like to be part of the public comment on the EPA mandated Butte Health Study. It adds to the information that I provided in another recent email.

For purposes of my concern regarding the lack of environmental justice consideration in the development and conduct of the Butte Health Study mandated by an EPA unilateral order, my focus is on the development and conduct of the study. Contrary to the EPA's environmental justice mandate, low-income citizens in Central Butte, the focus area of the health study, have been excluded. I am **not** focusing on the implementation of the Residential Metals Abatement Program.

An earlier email detailed how and the extent to which low-income citizens in Central Butte, the area of the Butte Priority Soils Superfund Operable Unit--the focus area of the health study, have had no representation regarding the development and conduct of the health study nor has any attention been given by EPA to the differential, negative effects of the toxics of concern on low-income citizens.

As I mentioned earler, the EPA in Montana dismisses all current environmental justice concerns/complaints because a few years back the EPA found that it was meeting its environemtnal justice mandate. I cannot stress enough that I am raising a ***new issue*** regarding environmental justice. Just because the EPA found a few years back that it was meeting its environmental justice mandate, a finding I dispute, does not mean that the EPA is meeting its environmental justice mandate today in regard to the health study. As I mentioned in an earlier email, this would be analogous to saying that someone was acquitted of robbery a few years back, so they can never be found guilty of robbery in the future.

The EPA needs to take this concern seriously and answer it directly. The EPA in Montana should not be allowed to have a perpetual "get out of jail" card on this issue.

From:
Sent: Tuesday, April 08, 2014 12:18 PM
To:
Subject: Why is the Health Study limited to considering exposure levels only? Other questions that need to be answered.

The Health Study conducted pursuant to the EPA's unilateral order has been unjustifiably limited to, not a health study, but an exposure study. Doing so is a disservice to the Butte community and is an unjustified and unwarranted limitation of the Health Study. The argument that there are many potential causes of diseases that are related to the toxics found in Butte is not persuasive. It repeats the old and tried argument that industry constantly uses that we can never know whether or not a particular toxic directly causes a specific disease.

We know that the toxics found in Butte such as lead, arsenic, mercury, zinc, cadmium, etc. cause disease. As a member of the public, I want to know whether or not the incidences of diseases related to the toxics found in Butte are decreasing. I am more interested in incidences of diseases related to the toxics of concern on the Butte Hill than I am in exposure studies.

I ask that the Precautionary Principle inform and guide the Butte Health study. This principle is part of both federal as well as Montana law.

The essence of the precautionary principle is that government should act before harm to human health and the environment occurs from the releases of toxic substances. The precautionary principle "dictates that indication of harm, rather than proof of harm, should be the trigger for action." (Sandra Steingraber, *Living Down Stream: An Ecologist Looks at Cancer and the Environment*, p. 270.) If there is a reasonable suspicion that harm to human health and the environment could occur from the release or presence of a toxic substance, government should step in and fix the problem before its hurts people and the environment. The 1998 Wingspread Statement on the

Precautionary Principle states: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." Former EPA director Christine Todd Whitman stated: "policymakers need to take a precautionary approach to environmental protection. . . . We must acknowledge that uncertainty is inherent in managing natural resources, recognize it is usually easier to prevent environmental damage than to repair it later, and shift the burden of proof away from those advocating protection toward those proposing an action that may be harmful." If there is a strong suspicion that something bad is going to happen, government has an obligation to stop it prior to its occurring. The precautionary principle is really grounded in old common sense sayings: "An ounce of prevention is worth a pound of cure." "Better safe than sorry." "A stitch in time saves nine." "Look before you leap."

The President's Council on Sustainable Development supports the precautionary principle. The Council declared: "Even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health or the environment is thought to be serious or irreparable." The American Public Health Association has passed a similar resolution concerning chemical exposure. (Resolution 9606)

The U.S. Court of Appeals for the District of Columbia Circuit upheld the EPA's use of the precautionary principle in *Ethyl Corp. v. U.S. Environmental Protection Agency* (541 F. 2d 1, 6 ELR 20267 (D.C. Cir.), cert denied, 426 U.S. 941 (1967) This was the case which supported the banning of leaded gasoline by the EPA. The banning of lead additives to gasoline was an example of the precautionary principle in action. "The U. S. Court of Appeals for the D.C. Circuit upheld the U.S. Environmental Protection Agency's decision to take a precautionary approach and ban lead anyway, even in the absence of scientific evidence adequate to demonstrate exactly what the risks from the lead were or what the benefits of removing it would be. As it turned out, banning leaded gasoline was the single most important contributor to the virtual elimination of lead from air and from most children's blood." (Charnley and Elliott, *Risk Versus Precaution: Environmental Law and Public Health Protection*, Environmental Law Institute, March 2002)

There is ample support for the precautionary principle from international organizations and treaties, to many of which the United States is a signatory. For example, the Rio Declaration from the 1992 United Nations Conference on Environment and Development, also known as Agenda 21, stated: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The United States signed and ratified the Rio Declaration.

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The precautionary principle is also part of the following: Ozone Layer Protocol, Second North Sea Declaration, United Nations Environment Programme, Nordic Council's Conference Declaration of October 18, 1989, PARCOM Recommendation 89/1, Third North Sea Conference, Bergen Declaration on Sustainable Development, Second World Climate Conference, Bamako Convention on Transboundary Hazardous Waste into Africa, OECD Council Recommendation of January 1991, Maastricht Treaty on the European Union, Climate Change Conference, UNCED Text on Ocean Protection, and the Energy Charter Treaty.

My point is that it is a specious argument that we cannot look at incidences of disease because the specific cause of a disease cannot be traced to a specific toxic.What are the incidences of diseases related to lead exposure? What are the incidences of diseases related to exposure to arsenic? What are the incidences of diseases related to mercury exposure? What are the incidences of diseases related to cadmium exposure?

This is an urgent question the answer to which should not be delayed for 30 years.

In time to make any difference for the citizens of Butte, will we ever look at the synergistic and cumulative effects of exposure to the toxics of concern?

In time to make any difference for the citizens of Butte, will the action levels for the toxics of concern on the Butte Hill ever be changed to reflect new reality?

Will the citizens ever have access to the raw data upon with the Health Study is based so that we can see for ourselves whether or not the conclusions of the Health Study are warranted?

Will the Health Study ever be subjected to an independent peer review as the EPA promised?

If the incidence of diseases associated with toxics found in Butte is not decreasing or actually increasing, something is wrong. If disease rates for diseases associated with the toxics found in Butte are steady or increasing, as the Barry report found, the ROD for Priority Soils should be reopened to deal with the diseases associated with the toxics found in Butte. We can of course only ascertain the above if we expand the scope of the Health Study to looks at mortality rates and disease rates, not just exposure data. To confine the study to exposure data is unwarranted.

Could it be that the design of the study was selected more with a view to reinforcing the existing ROD for Butte Priority Soils than to really find out whether or not Superfund was working to protect public health? Inquiring minds would like to know. I would like this question addressed at the public meeting. Why does EPA not want to look at incidences of disease? Why does EPA only want to focus on exposure data? Is

EPA really committed to investigating whether or not Superfund is really protecting public health?

From:
Sent: Wednesday, April 09, 2014 6:35 AM
To:

Subject: Additional Issues and Questions I would like to see addressed at today's health study meetings

The following are additional questions/issues I would like to see addressed at today's health study meetings. Please also consider these as questions I would like to pose AND comments I would like to make as part of the official public comment period:

1. What exactly, in as succinct a statement as possible, is the purpose of Phase 1 of the Health Study?

2. Given the limited scope of the current health study, what will be the scope of future health studies in Butte? Does the current study give an adequate picture of what is going on in Butte?

3. Will future health studies in Butte include medical monitoring of **chronic** exposure to the toxics of concern in Butte and will this medial monitoring include ALL toxics of concern? I still am not convinced that the study is doing anything more than just measuring acute exposure, yet the concern is with chronic exposure.

4. Will the results of all these tests and the raw data be made available to the public? If so, under what format? If not, why?

5. Why did the current health study fail to consider the cumulative and synergistic effects of the toxics of concern on public health? The failure to do so is to me a serious shortcoming of the current study.

6. Why was no protocol established as part of the current health study to medically monitor disease incidence related to exposure to the toxics of concern? This again seems to be a serious shortcoming of the current study.

7. Why were mortality rates ignored in the current study? Could it not be that, if exposure rates are dropping, diseases related to exposure are increasing and mortaility from these diseases is also increasing. Should not the study have looked at this? There appears from the data to be such a disparity. Why did the study ignore this disparity?

8. Given that EPA no longer wants to have an independent peer review of the Health Study process other than at some time in the future as an after the fact journal article submission, what assurances does the public have that this is an independent, unbiased Health Study? Most of the people involved are agency personnel. It appears that we have another case of the agencies evaluating their own work. How can the public have confidence in such a process?

9.Bioavailablity is an important issue. Would it not have been better to include in the current Health Study hair and nail analysis in order to determine the bioavailability of the toxics of concern? Why was this not done? Why has bioavailabilty data never been correlated with attic and yard toxics measurements? Again, this appears to be a significant shortcoming.

10. How and to what extent has the "precautionary principle," which is part of federal law, been incorporated into the current Health Study? It seems to be absent.

11. **A FUNDAMENTAL QUESTION IGNORED BY THE STUDY: HOW HAVE THE CONTAMINANTS OF CONCERN AFFECTED THE HEALTH OF BUTTE RESIDENTS? WHAT IS THE RELATIONSHIP IN BUTTE BETWEEN EXPOSURE TO THE TOXICS OF CONCERN AND DISEASES SUCH AS CANCER, DIABETES, ALS, MULTIPLE SCLEROSIS, ETC.?**

12. Is Butte safer today than before Superfund commenced its cleanup activities? If so, in what ways?

13. ENVIRONMENTAL JUSTICE QUESTION: HOW DOES EXPOSURE TO THE TOXICS OF CONCERN AFFECT SPECIFICALLY LOW-INCOME RESIDENTS OF BUTTE? THIS ENVIRONMENTAL JUSTICE ISSUE HAS BEEN IGNORED IN THE CURRENT HEALTH STUDY.

Plesae consider this as part of the public comment period.

MORE IMPORTANTLY, I WOULD LIKE THESE ADDRESSED THIS EVENING.

From:
Sent: Thursday, April 10, 2014 8:17 AM
To:
Subject: Additiona Public Comment--Butte Health Study Phase I

I would like to submit the attached as public comment on Phase I of the Health Study,

Public participation is an integral part, or at least should be, of the Health Study. The attached presents concrete suggestions for improving public participation.

The attachment gives my suggestions for improving public participation. The bottom line is that the public will participate if they feel that their participation matters and that it can actually impact decisions. In the responsiveness summary to the Health Study Phase I, I would ask that the EPA clearly indicate how public participation and community involvement actually impacted the Health Study, i.e. indicate the efficacy of public input.

Public Participation and Superfund Decision-Making in Butte—Some Suggestions for Improvement

> If men were angels, no government would be necessary. If angels were to govern men, neither external nor internal controls on government would be necessary. In framing a government which is to be administered by men over men, the great difficulty lies in this: you must first enable the government to control the governed; and in the next place oblige it to control itself. A dependence on the people is, no doubt, the primary control on the government; but experience has taught mankind the necessity of auxiliary precautions. (James Madison, *Federalist 51*)
>
> Who will guard us from the guardians? (Juvenal)

The Superfund decision-making process mandates public involvement and numerous institutional mechanisms are provided for public comment. The EPA has a policy mandate that holds that it is: "imperative that EPA pay close attention" to citizen input and that citizens need to be "involved in the decision-making process." (OSWER 9230.0-18-"Incorporating Citizen Concerns into Superfund Decision-making.") The Introduction of the EPA's *Superfund Community Involvement Handbook* (April 2002) notes that the EPA is committed to "early and meaningful community participation during Superfund cleanup." The agency goes on to say that community involvement and participation in decision-making is a "foundation" of the Superfund program. The *Handbook* talks about citizens "shaping" Superfund decisions. The *Handbook* further notes: "Superfund community involvement is not a public relations effort to sell the Agency or its plans to the community, nor is it just the communication of information. Community involvement is the vehicle EPA uses to get community concerns and interests to the decision-making table." EPA endorses the core values of the International Association for Public Participation that in part include "the promise that the public's contribution will influence the decision." Community concerns should be reflected in agency decisions. (OSWER 9230.0-99, "Early and Meaningful Community Involvement") In its description of the Superfund process in the January 2000 booklet *This is Superfund,* the statement is made that there is community involvement throughout the Superfund process. (p. 8) The above comments present a rather strong commitment on EPA's part to the efficacy of public participation.

Certainly, the EPA provides numerous institutionalized vehicles of public participation—public meetings, public hearings, comment periods, etc. But the question is whether or not public participation is efficacious or do these venues of participation simply provide environmental theatre and stylized ritual. Does public comment matter? Are the forms of participation at best giving citizens the feeling that they participate in decision making without giving citizens the power to influence decisions? Is there participatory form

without substance? Should citizens bother to participate in the process? This issue came to the fore recently with regards to the BSB Health Study mandated by an EPA unilateral order, the Five-Year Review of Butte Superfund sites and the ongoing discussion surrounding the Butte Priority Soils Operable Unit. People raise the legitimate question whether or not they are wasting their time in commenting when their comments seem to have no effect.

Although the EPA has a strong mandate to involve that public regarding the development and implementation of environmental rules and regulations, this mandate does not guarantee the efficacy of public participation in Superfund decision making in Butte. Often agency personnel express exasperation at low levels of public participation in agency functions. The question often gets asked: How can we increase public participation and get more citizens involved?

My answer is that citizens will be involved if three conditions are met:

1. Citizens must know the issue, i.e. are aware of the issue.
2. Citizens must see why the issue is important to them
3. Citizens must feel that their participation will have some efficacy.

If citizens don't' participate, are least one of the above conditions are missing. If citizens are not participating, the EPA should not blame citizens but should evaluate the effective of the agency's public involvement activities.

This paper will examine three issues: (1) What **should be** the role of public participation in Superfund decision making, (2) What **is** the role of public participation in Superfund decision making, and (3) **How can** public participation in Superfund decision making **be enhanced**. *The focus of this discussion will be the Superfund process in Butte.*

What should be the Role of Public Participation in Superfund Decision Making

While it is indisputably the case that the EPA and MDEQ are necessary for the administration of environmental policy and the implementation of environmental programs, it is also the case that the authority of these agencies springs from the governed. The bureaucracy exists to provide services to the public and to promote the general welfare. Authority is transferred to the bureaucracy in order to achieve some public purpose and accrue some public benefit. Any exercise of bureaucratic power necessarily diminishes individual liberty. Any rule or regulation necessarily prescribes or proscribes or prohibits certain individual action. Under what conditions is this justifiable? Justification can only come if the public impacts agency decisions and forms agency decisions.

It is a basic tenet of democratic decision making that: "on all matters where social action is substituted for individual action, liberty exists only through participation either in decision making or in control of leaders who make the decisions." (Emmette Redford- *Democracy in the Administrative State*.) It is not just the ethics of democracy that mandates citizen participation, but the quality of public decisions is enhanced by public participation. The more people who are substantively involved in making a decision, the

more information and the more perspectives that are brought to that decision. Public participation means that more alternative solutions are considered and the resulting decision will have greater credibility and legitimacy. Meaningful public participation promotes public civic education and increases trust in government institutions. Efficiency is also enhanced by public participation in that public acceptance of an agency decision decreases the likelihood of prolonged challenges to that decision. The law also mandates that most public agencies take into account public comments in rendering their decisions.

Yet, research has indicated that only about one-third of public comments are accepted by decision-making agencies. There are a number of reasons, whether valid or not, for this limited public role: (1) The public does not speak with one voice-segments of the public support a decision, segments oppose it. (2) Not all public comment is of equal discernment and environmental decision-making is not a popularity contest. (3) Agencies have invested their prestige in preferred decisions. (4) There is a view that it is government that is supposed to aggregate all of the articulated interests into sound public policy. (5) Government decision-makers are influenced by their own interests, values and perceptions. (6) Agency personnel see themselves as professional scientists and/or engineers who possess the technical expertise to make the right environmental decisions. Their view is that the ordinary public does not possess this technical discernment. (7) There is a distrust of the public and a view that public participation is often too time consuming, wastes money, and allows for too much obstructionism. There are government officials who would prefer to leave the decisions to the government experts and not needlessly complicate matters by involving the public. I recall the comment of one EPA official, I believe in Ohio, who remarked that they had a pretty good decision until the public got involved and messed it up.

There are also structural limits to the extent of public participation.

1. It is a basic principle of government, particularly democratic government, that government agencies, such as EPA, have to aggregate all of the articulated public interests into some decision. Governing means to choose and deciding means choosing between alternatives and those whose alternatives are not selected will be disgruntled. No decision can totally include all perspectives on an issue.
2. The right to participate does not guarantee the right to succeed.
3. Agency rule making is not totally a democratic process.

On the other hand, there are valuable contributions that the public can make to the Superfund decision-making process.

1. Citizens know best how a decision will affect their interests.
2. Citizens know the local area.
3. Because it is concerned with the making and enforcing of government policy decisions, Superfund decision-making is as much, if not more, a political process than it is a scientific process. Cleanup decisions cannot be determined with the certitude of a mathematic or scientific theorem. Although there are those who would seek to avoid conflict by an appeal to the certainty of science (after all you can't argue with science), an appeal to "good science" cannot eliminate conflict. Correct environmental decisions lie in the realm of the probable and contingent

not the certain and absolute. As an inherently political process, the public must not only be involved but also allowed to be effective in their participation by decision makers. For example, consider Superfund's nine criteria for remedial alternatives evaluation. These criteria do not have scientific or technological certainty or precision. How they apply to perspective decisions, what they mandate and what they do not mandate, how they relate to each other, what they mean, and their significance are the result of political processes, bargaining and decision making. If one takes cost, for instance, how do you determine with scientific and technical certainty whether or not an alternative costs too much? The very standards such as contaminant action levels and the risk assessment process are infused with politics. Often action levels are the result of political bargaining and represent the lowest common denominator of what is acceptable to the various groups fighting about where the levels should be placed. The notion of value neutral decisions in Superfund is unobtainable.

4. Even decisions which are based in science and technology have to be open to public scrutiny and comment. The expert must offer his or her expert opinion to the public in the public realm. The expert's opinion must be tested, analyzed and evaluated in the public realm. We do not, even in environmental decision-making, have a government of experts. To this end, it is important to remember that not all expertise resides in government or the PRPs. Members of the general public often have extensive knowledge, experience, and expertise in the areas under consideration in Superfund. The wanton corporate hubris displayed at a recent meeting on Priority Soils where public input was characterized as the articulation of "feelings" is a disservice and mischaracterization of the value of the public participation process.

The issue of public participation in environmental decision-making is a subset of the larger question of how does one make the bureaucracy accountable and responsive to the public while at the same time ensuring that the bureaucracy will perform its functions with effectiveness and efficiency. The personnel of public agencies such as EPA are not elected. Merit and other current personnel systems can isolate agency personnel from the public. The hiring of agency personnel based on technical and scientific qualification does not ensure that these personnel will be attuned to the public process or will value the public process. There will always be tension between efficiency, effectiveness, public accountability and public responsiveness. No totally satisfactory answer has ever been given to the question: How do you balance the desired independence of decision-makers with accountability to the public? How do you incorporate "good-science" into decisions that are inherently political?

The Current State of Public Participation in Superfund Decision-Making

Are there problems with the public participation process in Superfund decision making in .Butte?

Based on my participation in the Superfund process, I have reached the following conclusions:

1. The EPA seems to be content to provide public forums often more to provide information to the public rather than to involve the pubic in Superfund decision-making
2. The last couple of years have seen overt hostility on the part of some EPA officials to public input and participation, particularly critical public input.
3. Such things as the law, promulgated administrative rules and regulations and the fact that their decisions do have to enjoy some measure of public support limit and define EPA's commitment to public participation.
4. Some project officers see limited utility in public involvement. Their reasoning is that Superfund decisions require technical and scientific expertise that the general public does not possess and that the public's wishes do not contribute to the "good science" required for sound Superfund decisions. Their view is that the Superfund process is basically a technical, scientific process that is aided little by public input which process requires too much time and effort for the results received. I think this is a minority view.
5. More resources need to be devoted to improving the public participation process.
6. Public participation needs to be conducted in a more comprehensive and systematic way. This will require additional resources being committed to public involvement activities.
7. There still is need to sensitize agency personnel to the necessity of clear, non-technical communication with the general public. It is possible to communicate clearly with a general audience while not losing scientific precision or legal accuracy. This necessitates giving people who were hired on the basis of technical competency the additional competency of being effective spokespersons.
8. The public may be laboring under a misapprehension as to exactly what is the role of public participation in Superfund decision-making. They may think that they have a greater role than is mandated by the law.

Improving Public Participation in Superfund Decision-Making—Some Suggestions

1. There must be an articulated commitment on the part of top management to the principles of public participation. Management must establish an organizational climate that welcomes and invites efficacious public participation in Superfund decision-making. The first step would be to conduct an analysis of the basic ideas, beliefs, and attitudes that guide agency personnel with regard to public participation. After this analysis, the Montana EPA, using a consensus decision-making process, should develop its own philosophy of public participation to which all personnel should agree. Finally, training in facilitating public participation should be provided to all organizational members. One area of investigation of new hires should be their view of public participation. The EPA's *Superfund Community Involvement Handbook* notes: "Integrating community involvement into every phase of cleanup requires the commitment of all members of a Superfund Site Team." (p. 3)

2. Establish an ad-hoc citizen advisory committee to analyze and evaluate community involvement in Superfund decision-making. This committee could have representatives of all the groups which are generally involved in Superfund decision making as well as a couple of representatives of the interested general public. As is the case generally in this country, the most effective public participation is participation through a group. The requirements for effective public participation-awareness of proposed decisions; organizational ability; a knowledge of the opportunities available for participation; the ability to mobilize citizens; access to decision makers; the resources and expertise needed to make effective comments-generally mean that the most effective participation in environmental decision making is done through groups. Groups can mobilize support or opposition to an agency decision, hold agency decisions up to public scrutiny, and, if necessary, appeal agency decisions. Perhaps not surprisingly, research indicates that groups are more effective than individuals in influencing agency decisions on environmental issues. Without groups, public participation would be of limited utility.
3. It would be good for all public meetings to begin with a discussion of the role of public comment and participation in the decision-making process: what is the role and what is not the role. Citizens could then know up front what to expect from their participation. Citizens often think that the cleanup decision should be the result of public input and that the community has a veto over agency decisions. "You should always be clear about the respective roles of the participants to avoid creating unrealistic expectations about how decisions will be made." (OSWER 9230.0-99) Meeting announcements should make clear the purpose of the meeting and how public participation will be used to shape agency decision-making.
4. In terms of meeting attendance, there is often the lament that the public does not attend these meetings. It is important to remember that public attendance at an agency meeting is a function of a cost-benefit analysis: How will I benefit from attending a meeting versus the cost (time, effort to attend, etc.). If citizens feel that attending a meeting is a waste of time, they will stay home. At present, for too many citizens, the "cost" of attending far surpasses the benefit. Case in point: the recent "open house" on the health study. (Only around nine or so citizens attended the "open house." The rest were agency people, local government people, PRP people, MDEQ people, etc. Must effort and money was spent on this "open house." No one could say it was effective. But EPA is repeating the same format in January. Why is there any rational expectation that another "open house" will be effective?
5. The public also will only attend a meeting if they feel that there is some efficacy in attending. If the public feels that they will have little impact, why bother to attend? That is why, it is important that EPA respond, directly, to public input. The EPA needs to clearly and directly indicate its response to public input. More may be needed than just responsiveness summaries. In short, the EPA needs to look at meeting from the public's point of view—What and how will the public gain/benefit from coming to a meeting?
6. Environmental justice concerns must shape EPA's community involvement activities particularly in Butte. Butte has a higher than average poverty rate as

compared to the United States and Montana. Disproportionately, a higher percentage of low income citizens live with Butte Superfund sites. The EPA needs to be more **proactive** in reaching out to these citizens. I will discuss this at greater length in another "paper" that I am preparing.

7. Make clear the extent to which local governmental entities' interests are considered to be part of the public participation process and the extent to which local government represents, in the Superfund decision making process, citizen concerns. What per se is the role of local government in Superfund decision-making?
8. Encourage TAG groups to do more than simply disseminate information to the public but encourage them to also be advocates of the public interest.
9. TAG groups could also provide training as to how to make participation in the public participation process more productive for citizens.
10. Greater use needs to be made of non-ritualized venues for public participation. For example, public hearings and 30-Day Comment Periods, while important, do not effectively reach large segments of the public.
11. Agencies should provide public reports or assessments of how well they are implementing their public participation programs.
12. **Process**. In general, citizens will be more accepting of a decision if they feel that the decision makers have genuinely listened to them. They may not agree with the outcome but at least they will respect the process. "The measure of success should not be whether the community applauds the remedy because EPA did what the community asked, but whether or not EPA honestly listened to people who participated and genuinely responded to their concerns." (*Superfund Community Involvement Handbook*, p. 6) Agencies need to demonstrate that they have listened to citizen concerns even if they have not agreed with them. For example, the agency could regularly have public meetings after a decision has been reached in order to explain the rationale for the decision and why citizen comments were rejected or accepted. (Not all citizen comments could be addressed at one meeting but if certain comments tended to have widespread support, those could be addressed.) Relying on a responsiveness summary is insufficient. It would also be useful to follow the recommendation of the International Association for Public Participation, which is endorsed by EPA, of allowing citizens to define for themselves how they will participate. (*Superfund Community Involvement Handbook*, p. 7)
13. Agencies should be more pro-active in dealing with the media. Rather then waiting for the media to contact an agency spokesperson, agencies should seek out media contacts and make appearances on informational media programs. Perhaps having a regular, periodic column in local papers updating the community on cleanup activities could be utilized. In short, there needs to be more media outreach to the affected communities beyond those who are regular participants in the Superfund process.
14. Agencies could also be more proactive in reaching out to the communities. For example, service clubs are always looking for speakers. Agency personnel could reach active citizens by speaking at such groups.

15. Greater attention needs to be paid to making reports, proposals, etc. user friendly. To that end, the EPA "Summary of the Proposed Plan on the Clark Fork River" was a good example of having a user-friendly document. Documents need to be seen in more than just their legal or technical light but also as documents to inform and include and empower the general public.
16. Citizens also have a responsibility to be informed about the Superfund process, about what Superfund can do and not do and to offer reasoned comments about proposed plans of action.
17. Greater attention needs to be given as to how the different parts of the Superfund public involvement process fit together, particularly from RI/FS to ROD. The BPSOU decision illustrates my point. .
18. *OSWER Directive 9230.0-18* states that: "it is important that we demonstrate to citizens that they are involved in the decision-making process." How will this be demonstrated? It needs to be made clearer how are citizens really involved apart from participation in the formal opportunities for public comment. There needs to be evaluation mechanisms developed for assessing the efficacy of public participation.
19. In addition to the recommendations of #15, terms such as "meaningful participation," "shaping Superfund decisions," "influencing decisions" and other similar terms used by EPA need to be defined with some precision. Currently, they are too imprecise and amorphous. What for example, constitutes "meaningful participation"?
20. It would be beneficial to engage in a community visioning process wherever possible.
21. The agency needs to make a clear distinction between "community acceptance" as a modifying criterion in the remedy evaluation process and public participation throughout the process. To me "community acceptance" is a quantitative expression of community preference and a function of whether or not a majority of interested parties in the community support or oppose a proposed remedy. Community acceptance is a function of counting heads or hands. On the other hand, public participation is different in that it is qualitative. Public participation in a qualitative sense should impact the whole Superfund decision-making process. If one member of the public has a comment with merit, the agency should listen to that comment. The public participation element means that the public has the right and duty to understand, analyze, evaluate and recommend modifications, additions, or deletions to proposed plans of action. For example, the public can provide valuable insight as to the meaning of permanence or the relation of cost to the other criteria, etc.
22. The use of jargon must be minimized. All professions such as law and medicine have their jargon that mystifies those who do not belong to the profession. By limiting public comprehension, this mystification stands in the way of effective public participation.

Although they are inherently political decisions, Superfund decisions cannot and should not be the result of plebiscite. Government is entrusted with promoting the public interest in environmental protection. As a practical matter, the public cannot substitute its agency

for that of the government. When a proposed plan of action is submitted for public comment, we assume that that plan is the outcome of due deliberation within the agency and represents what agency personnel think is the most effective and efficient way of attacking a problem.

The above should however not be used as an excuse to limit public participation in Superfund decision-making. "While EPA retains the final responsibility and authority to decide what will happen at a Superfund site, the Agency values and seriously considers community input." (*Superfund Community Involvement Handbook*, p. 1) For reasons already articulated, the public has a right to participate in Superfund decision-making. For reasons already articulated, public participation produces sound environmental decisions.

From:
Sent: Friday, April 11, 2014 6:59 AM
To:
Subject: Public Comment--Butte Health Study and Environmental Justice Issue requiring Immediate Attention

Attached is a document detailing my concerns regarding what I see as a failure to address environmental justice concerns in the current Butte Health Study, which is being conducted pursuant to a unilateral order of the Montana Office of EPA.

In addition to considering this as public input, I would like the issue addressed as a separate issue requiring immediate action.

The standard response from that Montana Office is that since it was determined by EPA many years back that there was no environmental justice issue regarding the Superfund cleanup in Butte, Montana, any future concerns have therefore already been addressed.

This is specious reasoning on the face of it. Let us say for that sake of argument that just because in the past there was no environmental justice issues in Butte, this does not a priori mean that there is no current environmental justice issue in Butte. This reasoning would be analogous to saying that because a person was acquitted of robbery several years ago, that person can never be charged again for robbery. I ask that the EPA take seriously this environmental justice issue.

Pursuant to the U.S. Environmental Protection Agency (EPA) Unilateral Administrative Order (UAO) for "Partial Remedial Design/Remedial Action Implementation and Certain Operation and Maintenance at the Butte Priority Soils Operable Unit/Butte Site" (EPA Docket No. CERCLA-08-2011-0011), the Montana Office of EPA has mandated that a Health Study be conducted in Butte, Montana in order to ascertain health issues and problems associated with the Superfund toxics of concern in Butte, particularly in the Butte Priority Soils Operable Unit, and the degree of effectiveness of the Superfund cleanup and the Residential Metals Abatement Program.

The first draft report is ready to be released for public comment.

My complaint/concern is that, contrary to the EPA mandate to promote environmental justice in all of its activities, the Montana Office of EPA has failed to address environmental justice issues as part of their mandated health study.

Discussion

I. The area of Butte Priority Soils has a disproportionate number of low income citizens.

In Butte-Silver Bow, the poverty rate is at 15.8%, which is higher than both the national and state rates, and has risen almost a full percentage point since 2000. (U.S. Census Bureau) According to the U.S. Census Bureau, over 25% of Butte families with children under the age of five years have incomes below the official poverty line. 21% of Butte children live below the poverty line. (Butte Silver Bow Health Department, *Community Needs Assessment.*)

Most of Butte's poor live in uptown Butte, the area encompassed by the Superfund site—Butte Priority Soils. Within Butte/Silver Bow, there are pockets of deep poverty which tend to occur in uptown Butte. Forty percent of Butte-Silver Bow's Census Block Groups (17 out of 43) had poverty rates higher than the overall county rate in 2000 that ranged from 15% to 61%.

The poor in Butte's central district do have to endure a disproportionate toxics burden. Consider the fact that of the 1200 houses in Butte that have a high risk of lead exposure, the vast majority are in the Butte Priority Soils site. The poor in Butte have a greater risk of cancer from exposure to heavy metals than do the non-poor. The poor in Butte, who live predominately within uptown Butte, are more threatened by the release of toxic, heavy metals associated with past mining than are the non-poor. (Source: Environmental Defense Fund, *Summary Report: Silver Bow County*)

Much of the housing stock in uptown/central Butte is in a state of decay. Homes in uptown/central Butte often have contaminated attic and indoor dust, contaminated yards and lead based paint in the home.

Therefore, the area of Butte encompassed by Butte Priority Soils is an environmental justice area.

II. The EPA has a strong environmental justice mandate to reach out to low income citizens.

Consider the definition of environmental justice: On February 11, 1994, through Executive Order 12898, President Clinton declared that: "each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States." According to the EPA, the President's concern was that: "minority and low-income populations bear a disproportionate amount of adverse health and environmental effects." Today, the EPA further defines environmental justice as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, ***implementation, and enforcement*** of environmental laws, regulations, and policies. Fair treatment means that no group of people, including a racial, ethnic, or a socioeconomic group, should bear a disproportionate share of the negative environmental consequences resulting from industrial, municipal and commercial operations ***or the execution of federal, state, local, and tribal programs and policies***." (Emphasis supplied.) EPA administrator Whitman in August 2001 stated that environmental justice would be an integral part of all EPA programs, policies, and activities. According to Whitman, the goal of the EPA's Environmental Justice program is that no segment of the population, including low-income citizens, suffers disproportionately from the EPA's policies, programs and activities. Furthermore, EPA has a mandate to provide for the equitable distribution of the burden of cleaning up sites. (The Office of Solid Waste and Emergency Response [OSWER] in their *Integration of Environmental Justice into OSWER Policy, Guidance, and Regulatory Development* mandates that "Environmental Justice issues should be considered at all stages of policy guidance and regulation development, beginning with preliminary efforts" and that environmental justice should be integrated into all agency actions. (OSWER Directive 9200.3-18FS, EPA540/F-95/023) OSWER Directive No. 9200.3-17 entitled *Integration of Environmental Justice into OSWER Policy, Guidance, and Regulatory Development* states: "Where environmental justice concerns or the potential for concerns are identified, staff

should conduct an appropriate analysis of the issues(s). To the extent practicable, staff should evaluate the ecological, human health (taking into account subsistence patterns and sensitive populations) and socio-economic impacts of the proposed decision document on minority and low-income communities. Examples include how a policy on future land use would impact minority or low-income communities versus non-minority, affluent communities. The analysis should be documented and retained for public availability." The Region 8 of EPA also equates environmental justice with the legal concept of equal protection under the law. In April of 2003, Region 8 issued its *Environmental Justice Action Plan* which mandates that the agency will work with stakeholders to "correct and prevent inequitable environmental and public health impacts to any groups." In short, environmental justice mandates a particular concern with populations, such as low-income populations, that bear a disproportionate burden of environmental degradation and environmental regulations. "Fair treatment means that no group of people, including a racial, ethnic, or social economic group should bear a disproportionate share of the negative . . .consequences resulting from . . .the execution of federal, state, local and tribal programs and policies." (Headquarters Press Release, EPA, *Administrator Whitman Reaffirms Commitment to Environmental Justice*, August 21, 2003) This issue is important because a false definition of environmental justice will ensure, from the start, that community involvement activities will miss the environmental justice mark.

III. The Montana Office of EPA has failed to include environmental justice considerations in the process of developing the required health study.

1. No low income citizens have been part of the process. For example, no low income citizens serve on the health study advisory board. No attempt has been made by EPA to survey or assess the needs or wants of low income citizens in terms of the health study. No meetings have been held in venues conducive to participation by low income citizens. In short, low income citizens have been ignored.
2. No special outreach has been conducted to involve low income citizens in the process.
3. The study has failed to consider the differential impacts of the toxics of concern on low-income citizens who are particularly susceptible to the harmful health effects of exposure to the toxics of concern in the Butte Priority Soils Operable Unit.

4. The EPA's community involvement plan activities vis a vis the health study fail to articulate any strategy, tactics or actions directed at involving low-income citizens in EPA decision-making regarding the health study.
5. The Montana Office of EPA has consistently ignored environmental justice considerations.

I ask that the EPA mandate to include environmental justice considerations in all of its activities be enforced in terms of the EPA mandated health study in Butte.

I ask that the Montana Office of EPA develop a specific community involvement plan regarding Superfund decision-making for low-income citizens in Butte.

I ask that the Montana Office of EPA undergo training in the EPA's environmental justice requirements as the office often seems oblivious to these requirements.

From:
Sent: Sunday, April 13, 2014 2:11 PM
To:

Cc:
Subject: CORRECTED VERSION--METHODOLOGY ISSUES--BUTTE HEALTH STUDY PHASE I--PUBLIC COMMENT PERIOD SUBMISSION
Attachments: Questions on Methodology.docx

Importance: Low

Please see **attached *CORRECTED*** document and email which contains my public comments regarding methodology issues submitted pursuant to the public comment period on the Butte Health Study.

I would like the following potential problems/concerns/issues that I see as possibly occurring in the methodology of Phase I of the Butte/Silver Bow Health Study addressed in the responsiveness summary to public comments. Please consider these as submitted as part of the public comment period. (These issues/concerns/questions focus on Sections 3, 4 and 5 of the Draft Phase I Health Study.) If the methodology of the study is questionable or inadequate, any conclusions resulting from the use of that methodology also become highly suspect. I would appreciate detailed not perfunctory answers to my questions regarding methodology. These questions were developed with some care and after extensive research and deserve to be taken seriously. (EPA "says" that the responsiveness summary is an important vehicle for demonstrating that the agency is sensitive to public input. Yet, recent responsiveness summaries have been brief, cursory and superficial. If EPA really values public input as

EPA claims, public comments should receive due attention.) If these problems which I discuss do not adhere to this study, I would like some explanation as to how the study assures us that these problems are in fact mute and non-existent. I would like an answer to the question What has the study done to avoid the occurrence of these significant methodology problems?

EPA has, it appears, back-tracked on its promise of an independent peer review of the Health Study. The answers to the above questions are therefore vitally needed if the Health Study Methodology is to have any reliability and validity. As I said before, I hope these comments are taken seriously.

Issues/Concerns/Questions on Methodology—Phase I—Butte Health Study Public Comment Period

I would like the following potential problems/concerns/issues that I see as possibly occurring in the methodology of Phase I of the Butte/Silver Bow Health Study addressed in the responsiveness summary to public comments. Please consider these as submitted as part of the public comment period. (These issues/concerns/questions focus on Sections 3, 4 and 5 of the Draft Phase I Health Study.) If the methodology of the study is questionable or inadequate, any conclusions resulting from the use of that methodology also become highly suspect. I would appreciate detailed not perfunctory answers to my questions regarding methodology. These questions were developed with some care and after extensive research and deserve to be taken seriously. (EPA "says" that the responsiveness summary is an important vehicle for demonstrating that the agency is sensitive to public input. Yet, recent responsiveness summaries have been brief, cursory and superficial. If EPA really values public input as EPA claims,

public comments should receive due attention.) If these problems which I discuss do not adhere to this study, I would like some explanation as to how the study assures that these problems are in fact mute and non-existent. What has the study done to avoid the occurrence of these significant problems**?**

Methodology Issues that Need and Answer

1. Model misspecification. The model is poorly characterized and specified.
2. Unusual observations and lack of standardization. The Study appears to confuse grapefruit and perception.
3. Wrong sign of regression. It is unclear to me how the contradiction between intuition or theory and the sign of the estimated regression coefficient is solved. EPA has had this problem before in terms of setting action levels for Butte Priority Soils. Supposedly, good science dominates EPA decision making but we will see.
4. Misinterpretation of the coefficient of determination.
5. Using confidence intervals when prediction intervals are warranted.
6. Overfitting *With four parameters I can fit an elephant and with five I can make him wiggle his trunk.* John von Neumann
7. Problems with regression on residuals.
8. Lack of standardized comparisons.

9. Failure to show the representative nature of the population sampled in Butte.
10. Failure to quantify causality. There are several ways of doing this but the study doesn't do any. Why? If there are multiple reasons for the alleged drop in blood lead levels, why aren't these causal factors quantified?
11. Assuming linearity is preserved when variables are dropped. One common mistake in using "variable selection" methods is to assume that if one or more variables are dropped, then the appropriate model using the remaining variables can be obtained simply by deleting the dropped variables from the "full model" (i.e., the model with all the explanatory variables). *This assumption is in general false*. Cook and Weisberg (1999) Applied Regression Including Computing and Graphics, Wiley.
12. Confusion of dichotomous variables.
13. Succumbing to the illusion of predictability.
14. Using a regression model without knowing the subject.
15. Problems with Stepwise Model Selection Procedures

"*... perhaps the most serious source of error lies in letting statistical procedures make decisions for you.*"

"*Don't be too quick to turn on the computer. Bypassing the brain to compute by reflex is a sure recipe for disaster.*"

Good and Hardin, *Common Errors in Statistics (and How to Avoid Them)*, p. 3, p. 152

Further resources concerning cautions in regression (I relied on these as well as other sources for this paper):

- R. A. Berk (2004), *Regression Analysis: A Constructive Critique*, Sage
- R. D. Cook and S. Weisberg (1999), Applied Regression Including Computing and Graphics, Wiley
- D. A. Freedman (2010), edited by D. Collier, J. S. Sekhon, and P. B. Stark, *Statistical Models and Causal Inference: A Dialogue with the Social Sciences*, Cambridge University Press.
- P. Good and J. Hardin (2006), *Common Errors in Statistics (and How to Avoid Them)*, Wiley; Chapters 10 - 13 and Appendix A
- T. Ryan (2009), *Modern Regression Methods*, Wiley

I would ask that the following be specifically addressed in the Responsiveness Summary that EPA is preparing:

- How were these Common Mistakes in Multiple Regression Avoided in the Health Study?

1. The response variable, Y, doesn't need to be normal as this is not an assumption of multiple regression. In fact, *Y* will rarely be normal. What must be true is that the errors around a prediction Y^ must be normal which one can check with a normal plot of the residuals. The errors must also have a constant variance which you can check with a predicted by residual plot. This plot should have not pattern. One should what for a fanning out in this plot which would indicate that a log transformation is needed. Doing a normal plot of *Y* will cost one points.
2. Regression does not assume that the regressors have any distribution. So checking to see if they have a normal distribution with normal plots is not required and will cost one points. One should, however, use box plots to check for outliers in the regressors. (Just don't do a normal plot.) One probably leaves these points in the data and once the multiple regression is done check for influential observations

3. It is a waste to do bivariate regressions with least square fits. The fits give no useful information so one should not do them if one doesn't want to lose points. It is good, however, to look at the scatter plots of each regressor versus the response. They may give one insights to whether transformations are needed.
4. It is a mistake to relay on stepwise regression exclusively to identify the model. The model that stepwise regression comes up should be taken as a suggestion that you have to check using the tools taught in the class, such as, the Effects Table and residual analysis. When one has a small number of regressors one can select "all models" from the triangle menu on the stepwise output. The model selected this way will be better in term of the highest R-Square for a given number of regressors. However, this is not the only criteria for a model being good. One must check it as one must do with the model selected by stepwise regression.
5. Confusing the errors with the residuals

Source: University of Tennessee--Knoxville—Department of Statistics

Common Conceptual mistakes that could have, based on my reading, compromised the quality and validity of the Butte Health Study.

•

1. Saying that a confidence interval contains an statistic, such as the sample mean, $\bar{x}$, with a given confidence instead of a parameter such as the population mean, μ.
2. Confusing the terms: predictor variable, regressor, independent variable, dependent variable and response
3. Confusing the concept of outlier and influential observation
4. Confusing "estimating" with "predicting"

University of Tennessee--Knoxville—Department of Statistics

How was the uncertainty graphed into the relationships between exposure incidence and the other variables considered in the study? Was the uncertainty graphed?

How were prior studies used to determine which variables to include in the modes and study?

What role did prior studies of exposure, disease rates and mortality rates play on the development of the first phase of the Butte Health Study?

What was superior about the methodology used in Phase I of the Butte Health Study as compared to the methodology used in other studies of exposure, disease rates/incidences and mortality? Why should we have more confidence in the methodology used in this study as compared to the methodology used in previous studies related to the health effects of the toxics of concern in Butte?

On what bases were the confidence and prediction intervals determined?

EPA has, it appears, back-tracked on its promise of an independent peer review of the Health Study. The answers to the above questions are therefore vitally needed if the Health Study Methodology is to have any reliability and validity. As I said before, I hope these comments are taken seriously.

From:
Sent: Monday, April 14, 2014 11:59 AM
To:

Cc:
Subject: Question--How Clean is Clean? After remediation under RMAP are there still use restrictions for occupants?

I would like the following questions to be considered in two ways:
1. As questions from a citizen regarding the results of cleanup under the Residential Metals Abatement Program. What is any use restrictions remain after remediation under RMAP?
2. Public comment relative to Phase I of the Health Study.
I would appreciate any responses you may be able to provide.

Please see questions below.

Questions:
After a property is cleaned under the Residential Metals Abatement Program, are there any health related restrictions on the occupant's or occupant's family's use of the "cleaned" or remediated property?

By that I mean:
After a yard has been remediated, what if any are the restrictions on the use of that yard? For example, is it safe to grow vegetables for human consumption? Is it safe for children to play on it? It is safe for recreational activities? If there are any restrictions, what are they?

After an attic has been remediated, is it safe to use the attic as a living space, storage space, crawl space, etc.? If there are any restrictions, what are they?

After the indoor portion of a home or apartment is "cleaned," are there any remaining health concerns about which to be concerned? If so what are they?

I realize that there are certain criteria, i.e. action levels, which must be met in order to have a home and yard remediated under the RMAP program. The assumption is, I assume, that if the action levels are met for a home/yard/attic than the exposure levels will be below the levels of concern. Is this correct? In other words, remediation under the rubric of the action levels will produce "safe" levels of exposure to the toxics of concern. Is that correct? Therefore, disease related to exposure to unsafe levels of the

toxics of concern will not occur? Is there any risk to a child, for example, if he or she plays in a remediated yard? Is there any chance that the child could develop lead poisoning from playing in that soil?

The assumption is of course is that after remediation any exposure level by adults and children to the toxics of concern will be below those detrimental or harmful to health? Is that a correct assumption? If not, why not? Also, how will we know that this is the case? Is there empirical evidence to support the efficacy of the action levels in Butte for the toxics of concern?

I would appreciate having these issues addressed during the responsiveness summary for Phase I of the Health Study. I would also appreciate having these addressed as soon as possible.

Also, what steps are being taken to prevent recontamination of a cleaned site?

To me the issue is that the toxics of concern are a threat to human health at certain concentration levels and at certain exposure levels. If the toxics of concern are remediated to levels below the level at which they pose a threat to human health and if they are remediated to a level below the level of exposure that threatens human health and if they are remediated to levels below the action levels, then, if such is the case, residents need have no fear of any adverse health effects from the toxics of concern. Is that a correct assumption?

In part, what I am asking is whether or not the action levels are the levels of protection of human health.

From:
Sent: Tuesday, April 15, 2014 7:07 AM
To:

Cc:
Subject: MORE ON HOW CLEAN IS CLEAN EMAIL OF 4/14/2014

Importance: Low

Yesterday, I sent an email entitled *How Clean is Clean*? (April 14, 2014)

The following are additional questions/issues I would like addressed in the responsiveness summary for Phase I of the Butte Health Study.

Given the current action levels for dusts and soils, if a yard, for example, is below those action levels is the assumption that these yards are "safe" for use by children? Is the assumption that yards, for example, that test below the action levels for lead, mercury and arsenic are safe to use for growing vegetables and eating them? If for example, a yard comes in at 800 mg/kg, which is below the action level and which will not be remediated under the current remediation rubric, is that yard safe for use by children? If children play in such a yard can they expect to be free, all things being equal(for example they don't chew on a battery), from diseases associated with the toxics of concern--lead, arsenic and mercury? Nationally, the average acceptable level for lead is much lower than the current action levels in Butte, what assurance can the public have that remediation based on the current action levels will be protective of human health, particularly children's health?

If yards and homes with dusts and soils below the action levels are not "safe" something is seriously amiss with the Butte Superfund cleanup which is supposed to remove threats to human health caused by the toxics of concern. Any real health study should have addressed this. Unfortunately, the current health study is pretty much silent on this issue.

Also, since, for example, acceptable blood lead levels in children are continually becoming less permissive and more restrictive, what assurances can the public have that current remediation levels are really protective of human health? Will RMAP in a few years, when standards of permissive blood and exposure levels for lead will probably be tighter and less permissive, have to go back and redo yards that are currently below the lead action levels? Assuming that there is some degree of functional correlation between action levels and acceptable blood and exposure levels, won't these action levels have to be reduced in the near future and a new round of cleanups begun?

This also raises the question of the level of bioavailability for toxics such as lead. It is my understanding that bioavailability was tested on tailings dust not dust that is found in attics, homes and yards which in large part was not from tailings at all but from smelter dust, etc. What assurance can the public have that current bioavailability data and levels are accurate? It would appear that the lead and arsenic found in Butte homes and yards are much more bioavailable than assumed. Again, the issue of protectiveness of current standards comes to the forefront.

Also, I find it a serious short coming that the study focuses on very young children only. While that is certainly important, shouldn't a real health study consider the effects of the toxics of concern on people above the age considered?

These issues need to be addressed in any real health study. Of course, we really don't have a "health study." At best, we have a reanalysis of existing data. The issues I have presented above and in other messages should be addressed in Phase I. The failure to do so is a serious shortcoming of the report. The report should be corrected immediately. Again, I look forward to seeing how "responsive" the responsiveness summary will be. The EPA says constantly that it wants public input and public involvement. The degree of responsiveness of the responsiveness summary is a good test of EPA's sincerity.

From:
Sent: Sunday, April 20, 2014 10:12 AM
To:

Cc:
Subject: Additional, new Public Comment on Methodology Problems and Issues--Phase I of Butte Health Study
Attachments: Additional Methodological Concerns.docx

I have **attached** a document that discusses further/additional/new problems/issues/concerns that I have regarding the methodology of Phase I of the Butte Health Study.

I would like to submit these as Public Comment and I request a complete and comprehensive addressing of these issues and concerns in the responsiveness summary to public comment--Phase I--Butte Health Study..

Additional Methodological Concerns/Issues/Problems—Phase I—Butte Health Study

I would like for the following to be considered as public comment on Phase I of the Butte Health Study. The following are my additional methodological concerns/issues/problems that I would like to be addressed in the responsiveness summary regarding Phase I of the Butte Health Study.

BERKSON'S BIAS

Given the missing data in the data set used for Phase I of the so-called Health Study and the selection bias which is also present, Berkson's Bias would seem to be operating. In what ways, specifically, did the methodology of the so-called Health Study control for and/or eliminate Berkson's Bias? ("While Berkson's bias is widely recognized in the epidemiologic literature, it remains underappreciated as a model of both selection bias and bias due to missing data." (Reference: Daniel Westreich, "Berkson's bias, selection bias and missing data," *National Institutes of Health*.)

COLLIDER BIAS

The study also seems to have fallen prey to the larger problem of collider bias. How does the methodology of Phase I of the Health Study control for and/or eliminate collider bias? In what ways does Phase I avoid potential collider bias? How does Phase I avoid collider bias? There appear to be collider bias problems with the Phase I methodology. Consider: "If neither E nor De affects C, the situation is equivalent to simple random sampling. If E, but not D causes C, then contrasts in risks remain unbiased in expectation. If both E and D cause C, then all contrast may be biased. The above comments apply whether data are missing at

random or missing not at random." (Reference: Daniel Westreich, "Berkson's bias, selection bias and missing data," *National Institutes of Health*.)

CONFOUNDING

"Cases must be characterized for potential confounders if aetiology is to be correctly interpreted." (Peter Greenwald and Gladys Block, "Methodological Issues in Epidemiological Studies of Disease Clusters and environmental Contamination," *Methods for Assessing the Effects of Mixtures of Chemicals*, Edited by V. B. Vouk, G. C. Butler, et. al., 1987) How does the methodology of the Health Study eliminate confounding problems? It does not appear to do so. How does Phase I address confounding? How does Phase I avoid confounding?

ACTUAL EXPOSURE MEASURING PROBLEMS

"When the disease under study is related to environmental contamination, actual exposure in the cases is difficult to establish and expected disease outcome may be uncertain. A fundamental problem in conducting a sound epidemiological study is the need to identify who is exposed, to what they are exposed, who develops the disease and who are in the population from which the cases arose. Failure to identify all cases could result in underestimating the incidence rate." (Peter Greenwald and Gladys Block, "Methodological Issues in Epidemiological Studies of Disease Clusters and environmental Contamination," *Methods for Assessing the Effects of Mixtures of Chemicals*, Edited by V. B. Vouk, G. C. Butler, et. al., 1987) Actual exposure measuring problems abound in the Health Study. How will these be addressed? How will these be eliminated? If there are actual exposure measuring problems, how can the public have any confidence in the remainder of the Health Study?

FALSE NEGATIVE SAMPLING ERRORS

False-negative rates with capillary sampling can be as high as 8%. 20% to 10% of clinical laboratories participating in proficiency testing programs did not meet performance criteria for blood lead. Some labs have higher false negative rates. ("Screening for Elevated Lead Levels in Childhood and Pregnancy," *U.S. Preventive*

Services Task Force.) What assurance does the public have that labs that do the sampling and analysis are certified and reliable?

FAILURE TO QUANTIFY THE DEGREE OF PRECISION OR IMPRECISION--- CONFIDENCE INTERVALS

How are these problems addressed or avoided in Phase I of the Health Study?

FAILURE TO REDUCE RANDOM VARIATION

How are these problems addressed or avoided in Phase I of the Health Study?

FAILURE TO ESTABLISH INTERNAL AND EXTERNAL VALIDITY

What assurances do we have of internal and external validity? How does the study address these validity issues?

FAILURE TO ESTABLISH MEASUREMENT VALIDITY

How are these problems addressed or avoided in Phase I of the Health Study?

FAILURE TO ADEQUATELY DEAL WITH BIAS (Reference: Schoenback, 2001, "Sources of Error.")

1. Neyman Bias
2. Berkson Bias
3. Direction Signal Bias
4. Non-respondent Bias
5. Membership Bias
6. Diagnostic Suspicion Bias
7. Exposure Suspicion and Identification Bias
8. Recall Bias
9. Family Information Bias
10. Selection Bias
11. Information Bias
12. Confounding Bias
13. Medical Surveillance Bias (See: Sackett.)
14. Response Bias

15. Incidence Bias
16. Prevalence Bias
17. Temporal Bias and Unknown Temporal Sequence
18. Screening Bias
    a. Selection bias
    b. Incidence-Prevalence Bias
    c. Length Bias
    d. Lead Time Bias

How are these biases, which appear to be present in Phase I of the Health Study, going to be addressed and remedied in the final version of Phase I of the Butte Health Study? If these biases are not addressed and remedied, how can the public have any confidence in the Health Study? With biases such as these apparently present, what is the value of the Health Study?

CONCEPTUAL FRAMEWORK PROBLEMS

1. Failure to adequately characterize the external population
2. Failure to adequately characterize the target population
3. Failure to adequately characterize the study population.
4. Failure to adequately define the alpha, beta, gamma and delta selection probabilities.

My reading of Phase I is that these failures are present. How will they be corrected in the final version of the Health Study? If the conceptual framework is faulty, the study based on this faulty conceptual framework will also be faulty and have little utility.

OVERMATCHING AND THE SELECTION OF CONTOLS

"If the characteristics are related to the exposure and are not risk factors for the disease, then forcing the controls to be more like the cases will distort both the exposure prevalence in controls (making it more like that in the cases and less like that in the study base) and odds ration relating exposure and disease. This scenario is termed overmatching." (Reference: Schoenback, 2001, "Sources of

Error.") The apparent control problems in Phase I of the Health Study must be addressed. How will they be addressed and rectified?

ASSESSMENT OF RELIABILITY PROBLEMS

How are these problems addressed or avoided in Phase I of the Health Study?

ASSESSMENT OF VALIDITY PROBLEMS—PARTICULARLY SENSITIVITY AND SPECIFICITY PROBLEMS

How are these problems addressed or avoided in Phase I of the Health Study?

Sensitivity—ability to detect a case.

Specificity—ability to detect a noncase. (Reference: Schoenback, 2001, "Sources of Error.")

MISCLASSIFICATION PROBLEMS—such as misclassification of exposure or differential exposure misclassification.

How are these problems addressed or avoided in Phase I of the Health Study?

Misclassification can distort rates, proportions and measure of effect. (Reference: Schoenback, 2001, "Sources of Error.")

Summary

A simple, cursory reading of Phases I of the Health Study shows clearly that these issues must be addressed in the responsiveness summary. Failure to do so can only increase the public's concern about the methodology of Phase I of the Health Study.

I have omitted discussion of each of these points because I assume that the preparers of the study are familiar with these issues. I don't want to spend hours preparing something that will be dismissed out of hand by EPA. I have provided some citations to indicate that the issues that I have raised are significant and deserve a full and complete answer.

Again, I call, as a citizen, for a complete discussion of these issues in the responsiveness summary. Recent responsiveness summaries have been very cursory with statements such as "This issue was fully considered by EPA and found to be without merit." The public deserves, if responsiveness summaries are to mean anything significant, serious answers to serious questions. If the EPA doesn't treat public comment seriously, why should the public bother to take the time and make the effort to submit comments?

Of course, these issues could be answered if EPA adhered to its promise of an independent, peer review of the methodology and results of Phase I of the Health Study. Again, I raise the point: Why is EPA so loathe having the methodology and results of the Health Study subjected to an independent, peer review? We were promised that an independent peer review would be conducted before any final decisions on Phase I were made. I again ask EPA to adhere to its promise of an independent peer review prior to any final decisions on Phase I. Other regions have done so? Why not the Montana Office of EPA?

From:
Sent: Tuesday, April 22, 2014 5:23 AM
To:

Cc:
Subject: Additional Public Comment Submitted during the Public Comment Period on Phase I of the Butte Health Study--Responsiveness Summaries.

Additional Public Comment Submitted during the Public Comment Period on Phase I of the Butte Health Study.

I would like to submit the following as additional public comment on Phase I of the Butte Health Study.

In an advertisement in the *Montana Standard* announcing the release of the Draft Final Superfund Health Study, the statement is made that the final study report will include a responsiveness summary prepared by members of the Health Study Working Group.

While the Health Study Working Group should be involved in preparing the responsiveness summary, this responsiveness summary is the responsibility of the EPA and must be developed in accordance with EPA policy guidances.

Delegatus non potest delgare. ("A delegate cannot delegate; an agent cannot delegate his functions to a subagent without the knowledge and consent of the principal; the person to whom an office or duty is delegated cannot lawfully devolve the duty on another. . . . " *Black's Law Dictionary*, 5th Edition)

This Health Study is being conducted pursuant to an EPA unilateral order. Ultimate authority for the responsiveness summary, which is part of the Health Study, cannot be delegated by EPA to any other authority. EPA's responsibility is inalienable. The responsibility for the responsiveness summary stays with EPA.

My reason for elaborating the above is that, in terms of the design, development and conduct of the Butte Superfund Health Study, as mandated under the Unilateral Administrative Order under an effective date of September 6, 2011, ultimate supervisory authority for the conduct of all aspects of the Health Study, including the development of the responsiveness summary, remains with the EPA. While the EPA may have delegated

to local government the task of designing, developing and implementing the Health Study, the EPA is still responsible for the outcome of the Health Study, including the responsiveness summary. Not only must EPA retain ultimate authority over the development of the responsiveness summary, that responsiveness summary must conform to EPA policy guidances.

Therefore, I request that the responsiveness summary, in conformity with EPA policy, must be more than just a cursory response to public input. This public input must be taken seriously and be accorded a full and complete response.

The responsiveness summary must conform to the following EPA Guidance:

EPA prepares responsiveness summaries to comments, criticisms, and new data received primarily during Public Comment Periods. . ." The comments include oral or written citizen input submitted at public meetings, public hearings, or during public comment periods, as well as major issues and concerns raised during the various phases of the program. Responsiveness summaries provide a comprehensive response to all major comments and concerns raised by the community, including PRPs. They briefly summarize major community concerns and document EPA's response to the comments. Responsiveness summaries are intended to be concise and complete reports that the public can understand. Responsiveness summaries are used by EPA and the public. Members of the public may use the document to determine how their comments were considered during the decision making process.

At the conclusion of the 30-day public comment period on the Proposed Plan, NCP at 40 CFR § 300.430(f)(3)(F) requires that EPA "[p]repare a written summary of significant comments, criticisms, and new relevant information submitted during the public comment period and the lead agency response to each issue."

As discussed in the ROD guidance and OSWER Directive "Superfund Responsiveness Summaries," responsiveness summaries contain four sections: overview; background on community involvement; summary of comments received and agency responses (topics of comments); and remedial design/remedial action concerns.

Typically, community relations staff has the responsibility of coordinating the development of a responsiveness summary. EPA's technical and legal staff may be needed to respond to some

Whenever possible, the response to a "yes" or "no" question should begin with a "yes" or "no" before providing a detailed explanation; or, if this is not possible, then a statement to that effect should be made at the beginning of that answer. Responses should be clear,
accurate, and written by the RPM and/or the Commu**nity **Relations Coordinator.

Comments should reflect a genuine attempt to address citizen's questions and concerns, and not simply re-assert the correctness of EPA's determination.

Last Updated

September 2002

Reference also:EPA 540-R-96-031; OSWER 9200.1-23P; PB98-963241

My point is that, since EPA has stated that there will be a responsiveness summary prepared in response to public comments on Phase I of the Health Study, that responsiveness summary must be developed in accordance with EPA policy governing the preparation of responsiveness summaries. I call for EPA to prepare a thorough and complete response to public input.

ED_002601_00001420-00056

From:
Sent: Wednesday, April 23, 2014 5:28 AM
To:

Cc:

Subject: Another Environmental Justice Issue--Butte, Montana Superfund Health Study--Public Comment--Methodology and Execution Problems

The following is presented as additional public comment on my part regarding Phase I of the Butte Health Study. I expect a full response in the responsiveness summary but I would hope action would be taken to the correct the environmental justice issue I raise immediately.

This is not just an issue for a future responsiveness summary but EPA needs to deal with the environmental justice problem in Butte, Montana quickly.

The methodology as well as the conduct of developing the Butte Health Study has ignored the environmental justice concerns of low-income citizens in Butte.
So far the EPA has failed, as part of the Health Study, to assess the risks specifically to low-income citizens posed by lead in Butte. The differential effects on low-income citizens of exposure to lead has been ignored. "In epidemiological studies, the term confounding is used to describe the situation where an association between the factor of interest and the disease outcome is explained by the association of both these factors with another variable, the confounder, which itself is either a cause or closely related to the cause of the disease. Age and social class, for example, are commonly regarded as confounders as they are strongly related to disease occurrence and are also related to a wide range of environmental exposures." [Lesley Rushton and Paul Elliott, Institute for Environment and Health, "Evaluating evidence on environmental health risks," *British Medical Bulletin* {2003} 68 {1}]

Any health study that fails, as this Health Study does, to consider the health effects of lead exposure specifically on low-income citizens is seriously incomplete as well as violating the requirements of environmental justice. Butte's low income citizens are as special risk in terms of the effects of exposure to lead and other toxic of concern and that risk must be fully assessed and mitigated. The studies that the Health Study relies on were not specifically designed to assess lead exposure on low-income citizens in Butte. "Assessment of the impact of a potential adverse health effect from an environmental pollutant is dependent on an understanding of several issues, including: the variability and susceptibility of the potentially exposed population, for example, regarding sub-groups of the population that might be at special risk due either to the pattern and distribution of exposures in the population, or to non-environmental factors that might influence the risk of disease." [Lesley Rushton and Paul Elliott, Institute for Environment and Health, "Evaluating evidence on environmental health risks," *British Medical Bulletin* {2003} 68 {1}] Different areas in Butte have different levels of toxics exposure and exposure to lead. Butte's areas of greatest toxic concentration correspond to areas that are home, disproportionately to the rest of Butte and Montana as a whole, to low-income citizens. Therefore, environmental justice concerns must be at the forefront of the health study. So far no particular, specific attention has been given to the effects of toxics, such as lead, specifically on low-income citizens.

Not only has the methodology of the study ignored environmental justice issues but no special outreach to low-income citizens, as required by the environmental justice rubric, has been conducted by EPA-Montana regarding the development of the Health Study. For example, the poor are not represented on the Health Study Working Group.
I call upon the Montana Office of EPA to live up to its environmental justice mandate. Low-income citizens need to be part of the process of developing the Butte Health Study.Low-income citizens need to be focus of the Health Study in Butte. The Montana Office of EPA's "one size fits all" approach ignores and excludes the special situation of Butte's low-income citizens who live disproportionately within the Superfund area in Butte.

The methodology and process of developing the EPA mandated Health Study in Butte needs to pay full attention to environmental justice concerns.

ED_002601_00001420-00058

From:
Sent: Thursday, April 24, 2014 6:05 AM
To:

Cc:
Subject: Causality Methodology Problems--Phase I--Butte Health Study--Public Comment

The following are additional comments about the methodology used in the Phase I of the Health Study, particularly pertaining to the issue of causality. This discussion presents serious causality methodology problems that are visible in the Study. It appeals that the Health Study methodology is weak. **I ask that the following problems be addressed, comprehensively, in the responsiveness summary to Phase I of the Butte Health Study.** Please consider this additional public comment on my part.

1. How does the current Health Study unite physical mechanisms and probabilistic dependencies in order to establish causality? Both need to be done, neither seems to have been done. Does the current Health Study use, as it should, an epistemic model of causality? (Reference: Federica Russo and John Williamson, "Interpreting Causality in the Health Sciences," *International Studies in the Philosophy of Science* , Vol 21, No.2, July 2007, pp. 157-170). A**ny study that does evaluation, as this study claims to do, must have a strong and solid methodological approach to causality. My earlier submissions of public comment have called this into question. I do so again. The causality discussion in the Health Study is weak and almost non-existent**. With respect to number 1, I would like the responsiveness summary to show clearly how the Study specifically addresses the following critical causality issues that must be completely and comprehensively addressed if a sound causality argument is made (Hill's Criteria):

Strength of Association
Temporality
Consistency
Theoretical plausibility
Coherence
Specificity in the Causes
Exposure-response relationship
Experimental Evidence
Analogy

My reading of the Health Study indicates that these issues are not comprehensively addressed and so the discussion in the Health Study of causality is weak..

(Reference: Federica Russo and John Williamson, "Interpreting Causality in the Health Sciences," ***International Studies in the Philosophy of Science*** *, Vol 21, No.2, July 2007, pp. 157-170)*

2. The study is also weak in terms of the following causality issues and requirements:

a. Lack of discussion of sufficient and necessary causality.
b. Lack of discussion of multicausality.
d. Lack of discussion of interaction among causes.
e. Poor causal inference making.
f. Lack of testing of causal conclusions..

(Reference: Kenneth Rothman, Causation and Causal Inference in Epidemiology, ***Public Health Matters, American Journal of Public Health,*** *Supplement 1, 2005, Vol 95, No. 51)*

The responsiveness summary needs to address the causality issues and problems that I have addressed in Number 2 above.

The study needs to be redone in order to address these and other methodology issues I have presented.

The study needs to be redone to address the issue of environmental justice.
The study needs to be redone and to include the public in the process.

From:
Sent: Saturday, April 26, 2014 5:57 AM
To:

Cc:
Subject: Public Comment--Need for Independent Peer Review of Phase I of Health Study

The following is public comment I am submitting as part of the public comment period.

The EPA had promised back when the Butte Health Study was first announced and when the process got started that the study would be subjected to ***independent*, peer review** by a qualified expert or experts prior to the study being completed and finalized.

Given the problems that have been identified with the methodology of the Health Study, an independent peer review is vitally necessary.

Now EPA is retreating from this promise and speaks only of submitting the study (obviously in a condensed form) for possible publication in a peer reviewed journal at some distant time in the future.

This recent retreat on EPA's part is unacceptable for the following reasons:

1. What at best will be reviewed by the journal is a condensed, article length version of the study. We were promised that the whole study would be peer reviewed by independent, qualified experts. At some point, we need to get away from the EPA or EPA contractors evaluating the EPA. How can the public have any confidence in such a process? Isn't there a tendency for an agency, when it evaluates its own work, to find that it is doing a good job? Isn't there a tendency for an agency, when it evaluates its own work, to be biased in its own favor?
2. Contrary to EPA assurances, this journal article peer review will not impact the process. The study, according to EPA, is going forward no matter what the result of the peer review. The promise of a journal article submission is an attempt by EPA to beguile the public into thinking that there will be an independent review. The public is not fooled by this ruse.
3. It may take a year or two for a journal article to be accepted. Again, we have further proof that EPA is reneging on its promise that the independent peer review would actually impact the process. The peer review journal article process will come out too late to impact the process. Is the EPA simply hoping that the public will forget about the Health Study?

4. We have no assurances what will be considered in the peer review journal article process. Will it be the questions that need to be asked? Will it be the questions that the public wants answered? How do we know that the journal to which the article is submitted will conduct a thorough, independent review?
5. In another instance of wanton hubris, the EPA, contrary to earlier promises, wants a local citizens group to pay for the peer review. EPA could design no better way of excluding the pubic than to say the public that it has to pay.
6. The whole process of the health study has ignored environmental justice concerns. The EPA has conducted no outreach to the poor. Although uptown Butte has a disparate number of low-income citizens, the EPA has included no representatives of low-income citizens to be involved in the process. This is contrary to the national EPA mandate to promote environmental justice in ALL of its actions.

In short, why is EPA afraid to have its work subjected to independent peer review? Having the Health Study reviewed by other government agency folks is not an INDEPENDENT peer review. (To be independent, the reviewer must not be related to EPA or have been paid by EPA in the past.) Is EPA hiding something? Other EPA regions regularly include independent peer review as part of the Superfund process. Why won't the Montana EPA office do what is routinely done in other EPA regions? Does EPA have any good reason for not having an independent peer review of Phase I of the Health Study?

I ask that EPA keep its promise. Before Phase I of the Butte Health Study is finalized, EPA should submit it to an independent peer reviewer. EPA should pay for the study. If the public is to have any confidence in the Health Study, the public must be assured that it was conducted in a valid and reliable manner. Why won't EPA subject the Health Study to an independent peer review? The public deserves an answer.

From:
Sent: Monday, April 28, 2014 9:30 AM
To:

Cc:
Subject: Additional Public Comment--Phase I of the Butte Health Study

I would like to submit the following as additional public comment, submitted pursuant to the public comment period, on Phase I of the Butte Health Study.

Additional Comments—Health Study Phase I

1. This study is misnamed a health study. It is not a health study. As it has evolved it is, at best, a uncritical revisiting of past exposure studies. It does not look at the health effects of lead in the population. It does not look at the health effects of the toxics of concern. It does not look at the health effects of other toxics such as cadmium. It should if it is going to be called a Health Study. The "Health Study" should consider rates of diseases associated with the toxics on the Butte Hill, mortality rates of the kind associated with diseases associated with toxics on the Butte Hill—both cancer and non-cancer. The toxics on the Butte Hill are linked to diseases other than cancer.So at best what we have is a limited study of previously published blood lead data. That is a far cry from a "health study." There is certainly not critical evaluation. The Health Study uncritically repeats the confusions of previous government studies. Calling it a health study misleads the public. Call it what it is: a blood lead level study, with serious methodological problems, of some of the population which no assurances that the population considered is representative of the general population or of low income citizens based on previous work. Focusing on disease rates and mortality rates, assuming the use of proper methodology, would give us a better answer to the question as to whether or not Superfund is protecting public health in Butte. After all wasn't the health study supposed to answer this question as to the efficacy of the Superfund cleanup?
2. Focusing on disease rates, mortality rates etc. would help compensate for the uneven distribution/spread of the contamination all over the Butte Hill.

Looking only at blood lead levels does not compensate for the uneven distribution/spread of the contamination on the Butte Hill.

3. The population that is considered/examined/studied is not a representative sample of the Butte Hill population.The methodology used never established this.
4. The study only looks at lead blood levels. It doesn't even look at all of the so called toxics of concern. Also, there are other toxics, such as cadmium, etc., that are present on the Butte Hill and should be evaluated. It gives a very incomplete, limited picture. The health study cannot be considered credible unless it deals with these other toxics on the Butte Hill.Why was the study limited only to blood lead levels when the public was promised at the start of the Health Study process that all toxics would be considered in order to evaluate whether or not Superfund was accomplishing its goal of protecting public health. Why the retreat? Why the limitation? It is alarming that an answer to the question as to the efficacy of the Superfund cleanup is thirty years away. Why this piecemeal approach? This Health Study has been marked by the EPA retreating from promises it made at the start of the study. Why?
5. Arsenic exposure and the health effects of arsenic exposure needed to be a major focus of concern in the study. <u>The EPA needs to release, publically, the urinary arsenic data that it claims to possess</u>.Why hasn't this data been released to the public? The data used in this study needs to be released to the public in a fashion that does not compromise an individual's right to privacy. Why can't the public see the data? We have to depend on what we are told by EPA? We need independent verification.
6. The issue of whether or not the instrumentation/detection level used in analyzing the blood lead data is adequate needs to be addressed. Is the current detection level set at too high a bar? Do the current detection limits used in Butte adequately address whether or not adverse health effects are occurring in Butte children? These questions need a direct answer. The blood lead action levels need to be changed to be congruent with the recent CDC recommendations.What assurances does the public have regarding the accuracy of the collection? What protocols are in place to assure collection accuracy? What are the qualifications of the lab doing the collection and analysis? What controls are in place to assure a lack of bias and accuracy?
7. Is the subset of the Butte Hill population that is tested/studied representative of the whole Butte Hill population? There are serious

questions that the subset of the Butte Hill population that is tested in not representative of the whole Butte Hill population, nor is it representative of the low-income citizens on the Butte Hill. So any conclusions based on a non-representative sample will be flawed.

8. Is the data used in the study biased toward showing lower concentrations of blood lead? Are we confident in the quality of the data?
9. As designed, the "Health Study" does not consider the cumulative and synergistic effects of exposure to lead or the toxics of concern. It should.
10. Numbers 1-9 above demonstrate the need for an independent peer review of the Health Study.

From:
Sent: Monday, April 28, 2014 12:08 PM
To:

Cc:
Subject: Poor Past Health Risk Assessments and the current Butte Health Study--Phase I--Additional Public Comment
Attachments: BPSOU Health Risk Assessment Failure.doc

In evaluating the efficacy of the Superfund cleanup in Butte, the Health Study (Phase I) should have given consideration to adequacy and protectiveness of the health risk assessments that have driven the Superfund cleanup. A consideration of the health protectiveness of the Superfund remedy is impossible unless consideration is given to the health risk assessments that are the basis of that cleanup. The health risk assessments for Butte Priority Soils, that area that is the primary focus of the Health Study, were seriously flawed in that they failed to consider issues related to environmental justice. The **attached** document, which I am submitting as part of the public comment period on Phase I of the Health Study, develops and substantiates my argument. Not only did the risk assessments fail to fulfill the EPA environemntal justice mandate but they failed to adequately evaluate the risks to Butte citizens posed by the toxics of concern including lead.

Ultimately, the Record of Decision for Butte Priority Soils should be reopened in order to re-evaluate the effects of the contaminants of concern on low-income citizens who disproportionately live within the Butte Priority Soils area.

More immediately, the Health Study, if it is to be a real health study, needs to examine the basis and justifications given for the original risk assessments done in Butte. At some point, if we are to really examine the efficacy of Butte's Superfund cleanup, the basis of that cleanup, the health risk assessments, need to be re-evaluated and the first phase of the health study is the place to do so. Environmental justice consideration needs to be given to low-income citizens in evaluating the health risk assessments. This was not done originally. The Health Study needs to address that failure.

Not only were low-income citizens ignored in the design of the Health Study, they are also ignored in terms of the development of the risk assessments for uptown Butte. It is these risk assessments that form the basis for the Superfund cleanup the efficacy of which the current Health Study is supposed to evaluate. If the risk assessments were flawed then the action levels based upon those risk assessments are flawed and, consequently, the cleanup under Superfund is flawed. The Health Study is flawed

because it has failed to evaluate the health risk assessments that are the basis of the Superfund cleanup in uptown Butte. The action levels are not protective that cleanup based on these action levels will not be protective.

For example, in developing the lead action levels which were based on the health risk assessments, the poor, who were ignored during the health risk assessment process, were ignored contrary to the EPA environmental justice mandate. The Health Study needs to revisit that omission and correct the problem.

Priority Soils Health Risk Assessments Violate Environmental Justice

Environmental justice's goal is that low-income citizens should be equally protected from environmental pollution. Low-income citizens should not have to bear a disparate toxic burden. Environmental justice's goal is not that all should be equally polluted. Environmental law should equally **protect** all. Environmental justice becomes an issue when low-income and minority citizens are disparately impacted by the enforcement of environmental laws, rules and regulations and when low-income citizens and minorities experience a disproportionate distribution of environmental hazards and risks of exposure and illness. Environmental justice is intrinsically related to the equal protection of the law.

Summary of the EPA Policy Mandate on Environmental Justice

On February 11, 1994, through Executive Order 12898, President Clinton declared that: "each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States." According to the EPA, the President's concern was that: "minority and low-income populations bear a disproportionate amount of adverse health and environmental effects." Today, the EPA further defines environmental justice as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, ***implementation, and enforcement*** of environmental laws, regulations, and policies. Fair treatment means that no group of people, including a racial, ethnic, or a socioeconomic group, should bear a disproportionate share of the negative environmental consequences resulting from industrial, municipal and commercial operations ***or the execution of federal, state, local, and tribal programs and policies***." (Emphasis supplied.) EPA administrator Whitman in August 2001 stated that environmental justice would be an integral part of all EPA programs, policies, and activities. According to Whitman, the goal of the EPA's Environmental Justice program is that no segment of the population, including low-income citizens, suffers disproportionately from the EPA's policies, programs and activities. Furthermore, EPA has a mandate to provide for the equitable distribution of the burden of cleaning up sites. (The Office of Solid Waste and Emergency Response [OSWER] in their *Integration of Environmental Justice into OSWER Policy, Guidance, and Regulatory Development* mandates that "Environmental Justice issues should be considered at all stages of policy guidance and regulation development, beginning with preliminary efforts" and that environmental justice should be integrated into all agency actions. (OSWER Directive 9200.3-18FS, EPA540/F-95/023)

This above OSWER Directive also mandates that the economic/regulatory impacts of EPA decisions be considered in terms of environmental justice issues. Part of the EPA's environmental justice strategy is to promote a "sustainable economy" in areas affected by EPA rules, policies and programs. For example, OSWER Directive No. 9200.3-17 entitled *Integration of Environmental Justice into OSWER Policy, Guidance, and Regulatory Development* states: "Where environmental justice concerns or the potential for concerns are identified, staff should conduct an appropriate analysis of the issues(s). To the extent practicable, staff should evaluate the ecological, human health (taking into account subsistence patterns and sensitive populations) and socio-economic impacts of the proposed decision document on minority and low-income communities. Examples include how a policy on future land use would impact minority or low-income communities versus non-minority, affluent communities. The analysis should be documented and retained for public availability." (**This has not been done by the Montana Office of EPA for Priority Soils.**) The point is that the Montana Office of EPA has a mandate to consider how its enforcement actions will disproportionately and adversely economically affect low-income areas and has a mandate to mitigate disproportionate adverse economic impacts on low-income citizens. (See: *Incorporating Environmental Justice Principles into the CERCLA Process*, May 1998.) Low-income citizens should not bear a disproportionate or undue regulatory burden when it comes to the development of cleanup activities. (EPA, Region 8, *Environmental Justice Action Plan*, April 2003)

The **Region 8 of EPA** also equates environmental justice with the legal concept of equal protection under the law. In April of 2003, Region 8 issued its *Environmental Justice Action Plan* which mandates that the agency will work with stakeholders to "correct and prevent inequitable environmental and public health impacts to any groups." In short, environmental justice mandates a particular concern with populations, such as low-income populations, that bear a disproportionate burden of environmental degradation and environmental regulations. "Fair treatment means that no group of people, including a racial, ethnic, or social economic group should bear a disproportionate share of the negative . . .consequences resulting from . . .the execution of federal, state, local and tribal programs and policies." (Headquarters Press Release, EPA, *Administrator Whitman Reaffirms Commitment to Environmental Justice*, August 21, 2003)

Complaint Contention:

The Health Risk Assessments actually conducted for the Butte Priority Soils Superfund site violate the EPA mandate to promote environmental justice. These distorted Health Risk Assessments, conducted at the Butte Priority Soils Superfund Site, preclude the possibility that low-income citizens at the Butte Priority Soils Site will receive equal protection from the harms of pollution as a result of the Superfund cleanup of that Site. The Health Risk Assessments conducted at the Butte Priority Soils Site will lead to a remedy that will not rectify the disparate toxics burden that the poor living in the Priority Soils area endure. In fact, the Health Risk Assessments conducted for the Butte Priority Soils Superfund site actually

increase the disparate toxic burden of low-income citizens who live within the Priority Soils OU.

Summary of Complaint Argument:

1. The EPA has a policy mandate to promote environmental justice in **all** of its activities. (Documented above.)
2. There are a disproportionate number of low-income citizens living within the Butte Priority Soils Site. The Butte Priority Soils Superfund site and its residents of low-income are clearly within the purview and scope of the EPA's environmental justice mandate.
3. These low-income citizens within the Priority Soils area are disproportionately exposed to more hazardous waste materials that are the result of past mining activities.
4. The health risks for low-income residents of the Butte Priority Soils site were assessed using a standard EPA health risk assessment process.
5. The resultant Health Risk Assessments evaluation of the degree and severity of health risks for low-income residents of the Butte Priority Soils site was the basis for EPA's determination of the acceptable level of risk for low-income citizens and the fundamental grounding and justification for the EPA's Proposed Plan and Preferred Alternative for Priority Soils.
6. Health Risk Assessment is inherently biased against the poor.
7. The Health Risk Assessment process for and as **actually applied** at the Butte Priority Soils OU failed to account for the disproportionate health risks borne by the low-income citizens who live within the Priority Soils site.
8. The results of and use of the Health Risk Assessments conducted for the Priority Soils Operable Unit, as the fundamental grounding and justification for the EPA's Proposed Plan and Preferred Alternative for Priority Soils, will actually **increase and exacerbate** the disparate toxic burden of low-income citizens who live within the Priority Soils OU.
9. Therefore, given that the Proposed Plan and the Preferred Alternative for Butte Priority Soils are based on and justified by a Butte Priority Soils Risk Assessment process that **actually and really** discriminated against low-income residents living in the Priority Soils OU, the Proposed Plan and Preferred Alternative for Priority Soils OU are based on a process that violated environmental justice and the EPA mandate to promote and foster environmental justice.
10. Therefore, the outcome of that process, i.e. the Priority Soils Proposed Plan and Preferred Remedy violate the EPA mandate to promote environmental justice. Not only do the Proposed Plan and Preferred Remedy not promote environmental justice, they would increase the discriminatory toxic burden of low-income citizens living within the Priority Soils site.
11. Therefore, because of 9 and 10 above, the Proposed Plan and Preferred Remedy for Priority Soils should be declared null and void.

Substantiation of My Complaint:

I. There are a Disproportionate Number of Low-income Citizens Living within the Butte Priority Soils Site.

According to the 2000 Census, 10.7% of Butte families live in poverty, compared to 10.5% across the state. About 15% of the Butte population lives below the poverty line. Also, according to the 2000 Census, close to 25% of Butte families with children under the age of five years have incomes below the official poverty line. Fifty-eight percent of the homes without fathers have incomes below the official poverty line. According to the Montana Department of Public Health and Human Services, in 2002, about 2.4% of Butte's citizens were receiving Temporary Assistance for Needy Families compared to the state average of 1.89%. Over 10% of the Butte population was receiving food stamps compared to 7.56% statewide.

II. These Low-income Citizens are Disproportionately Exposed to more Hazardous Waste Materials that are the Result of Past Mining Activities.

Studies also indicated that the vast majority of the poor live in the area encompassed by Butte Priority Soils. For example, of the 1200 houses in Butte that have had a high risk of lead, the vast majority are in the Butte Priority Soils site. Compared to Butte as a whole, the low-income citizens living in the area encompassed by the Butte Priority Soils Operable Unit bear a disproportionate burden of exposure to toxics compared to the rest of the community. Comparing income levels to quantity of toxics present clearly demonstrates that low-income citizens in Butte bear a disproportionate toxics burden. The poor in Butte have a greater risk of cancer from exposure to heavy metals than do the non-poor. The poor in Butte are more threatened by the release of toxic, heavy metals associated with mining than the non-poor. "Exposure to hazardous wastes is highly correlated to . . .economic criteria." (Brian D. Israel, "An Environmental Justice Critique of Risk," *New York University Environmental Law Journal.*) [See: Environmental Defense Fund, *Summary Report: Silver Bow County*, 11/24/03] {Note: The EPA's *Revised Community Involvement Plan for Butte Priority Soils Operable Unit,* November 2003 notes the extent of poverty in Butte but makes no attempt to assure that low-income Butte citizens are represented in a meaningful way or have meaningful opportunities to participate in the decision making processes surrounding Priority Soils. The plan makes no accommodation for eliciting the views of low-income citizens for the Priority Soils area. This is directly contrary to stated EPA community involvement and environmental justice policy.} In general, evidence indicates that low-income citizens "experience relatively lower health status with respect to those health effects that are thought to be causally related to environmental pollutants." (Brian D. Israel, "An Environmental Justice Critique of Risk," *New York University Environmental Law Journal.*) This conclusion of Israel is evidenced in the Butte Priority Soils area where survey data indicates that approximately 70% of low-income residents report health problems that have a causal link to the toxics found at the Priority Soils site. (*Community Needs Assessment 2004 Butte, Montana: Summary Report on the Community Needs Assessment Survey and Focus Groups, Summer 2004* by the Imagine Butte Collaborative.)

III. The Health Risks for Low-income Residents of the Butte Priority Soils Site were Assessed using a Standard EPA Health Risk Assessment Process.

Page 5 and pages 20-26 of the *Proposed Plan for Butte Priority Soils OU of the Silver Bow Creek/Butte Area Superfund Site* articulate and substantiate the above claim that the health risks for low-income residents of the Butte Priority Soils site were assessed using a standard EPA health risk assessment process.

IV. The Resultant Health Risk Assessments Evaluation of the Degree and Severity of Health Risks for Low-income Residents of the Butte Priority Soils Site was the Basis for EPA's Determination of the Acceptable Level of Health Risk for Low-income Citizens and the Fundamental Grounding and Justification for the EPA's Proposed Plan and Preferred Remedy for the Priority Soils OU.

On page 20 of the *Proposed Plan for Priority Soils* we find: "Site risk assessments quantified current and potential human health and environmental risks from chemical contaminants. . . . The results of these assessments provide risk managers and the public with information about health risks. They help determine the need for cleanup, and provide a basis for determining the acceptable levels of contaminants that can remain onsite."

V. The Butte Priority Soils Health Risk Assessments were Inherently and Structurally Biased against the Poor.

"To the degree that risk assessment is a requisite element for regulatory action, a risk assessment methodology that obscures risks on the basis of class results in less than adequate environmental and health protection for members of that group." (Brian D. Israel, "An Environmental Justice Critique of Risk," *New York University Environmental Law Journal.*) "The argument that distorted risk assessments preclude the possibility of equal protection from pollution rests on the claim that government regulation must result in similar health status across groups, to the extent that health status is affected by substances that are regulated. This is different than the claim that government efforts must be equal across groups, or that government efforts must result in an equal decrease in pollution across groups. The same government effort may be adequate for one group and inadequate for another." *(Ibid.* p. 2. See also: Vicki Been, "What's Fairness Got To Do With It? Environmental Justice and the Siting of Locally Undesirable Land Uses," 78 *Cornell Law Review*, 1001)

Numerous scientists and legal scholars have argued that, as practiced by the EPA, Health Risk Assessment "is itself causally related to disproportionately inadequate environmental protection." (Israel, *op.cit.*, p. 9) See also: "Symposium on Health Research and Needs to Ensure Environmental Justice: Executive Summary & Proceedings and Recommendations"—*National Institute of Environmental Health Sciences*; Robert Bullard and Beverly Wright, Environmental Justice for All: Community

Perspectives on Health and Research Needs, *9 Toxicology and Indus. Health*, 821, 836; Desohn Ferris, "Testimony Before the Subcommittee on Civil and Constitutional Rights of the House Committee on the Judiciary," and Mary H. O'Brien, "Poisoning the Poisoned: Address Before the *National Institute of Environmental Health Sciences and the U.S. EPA.*" All are on file with the *New York University Environmental Law Journal.*)

In short, the Health Risk Assessments actually conducted at Butte Priority Soils inherently and structurally discriminated against low income citizens: (1) The Butte Priority Soils Health Risk assessments depended on methodologies that intrinsically and inherently precluded equal protection for the poor from pollution [This is true because the same pollution exposure standard may protect the non-poor and not protect the poor. See: Breen, *op.cit.*] and (2) The EPA prides itself on contending the Health Risk Assessment is the least susceptible to income based criteria. (See: U.S. EPA, *Environmental Equity: Reducing Risk for All Communities*, Section 5.0)

Another reason that the Health Risk Assessments conducted for Butte Priority Soils inherently and intrinsically discriminate against the poor is that the **generalizations** used as part of the Risk Assessments **discriminated against the poor**. ***The EPA itself has admitted this***: "Demographic categories may be useful markers for identifying population subgroups that have some likelihood of experiencing exposures significantly different from the average exposure and, thereby, possibly different health risks for the average population. (EPA, *Environmental Equity: Reducing Risk for All Communities*, Section 5.0)

The Health Risk Assessments conducted the Butte Priority Soils failed to identify ***any population subgroups that have some likelihood of experiencing exposure significantly different from the average exposure.*** "Most risk assessments ignore the fact that exposure to toxic chemicals is unequal and rely instead on estimates of 'average' exposure levels." Ann Misch, "Assessing Environmental Health Risks," in *State of the World.*)

Also, the Health Risk Assessments conducted at Butte Priority Soils failed to consider multiple and indirect toxic exposure pathways and failed to consider indirect sources of potential toxic exposure. (According to the Science Policy Council, the EPA routinely fails to consider multi-pathways and multi-sources in their risk assessments.) Such failure places a discriminatory burden on the poor living disproportionately in the Priority Soils Site who, to a greater extent than the non-poor, are subject to multiple and indirect toxic exposure pathways and indirect sources of potential toxic exposure.

VI. The Health Risk Assessment Process used specifically for Butte Priority Soils Failed to Account for the Disproportionate Health Risks Borne by the Low-income Citizens who Live within the Priority Soils Site.

"There are a number of reasons why risk assessment may methodologically fail to detect health effects in poor communities: (A) failures of risk assessment that disproportionately affect poor and minority communities because these communities are more likely to be

exposed to risk; and (B) failures of risk assessment that disproportionately affect poor and minority communities because these communities are more likely to be susceptible to risk." (Israel, *op.cit.* See also: Laura Montgomery and Olivia Carter-Pokras, *Health Status by Social Class and/or Minority Status: Implications for Environmental Equity Research*, 9 *Toxicology & Indus. Health* 729) The point is that inherent and intrinsic informational biases in the Health Risk Assessments actually done for Butte Priority Soils failed to consider the disproportionate and discriminatory effects the heavy metal contamination has on Butte poor. Such biases mean that the Butte poor will receive less than adequate protection from the Preferred Alternative for Priority Soils. Numerous studies show that the poor have poorer health with regard to the negative health effects caused by the toxics found at Butte Priority Soils. (Montgomery and Carter-Pokras, *op.cit.*) Sexton, *et.al.* in "Environmental Justice': The Central Role of Research in Establishing a Credible Scientific Foundation for Informed Decision Making," 9 *Toxicology and Indus. Health* 685, 713 states: "For disparities in environmental health risks to occur by socioeconomic status of ethnicity/race, these demographic variables must be associated with systemic differences in (1) exposure to environmental agents, (2) susceptibility to the effects of environmental agents, or (3) exposures and susceptibilities.")

Let us consider the above in greater detail in terms, specifically, of the Priority Soils site.

The Risk Assessments conducted at Butte Priority Soils did not consider: (1) Dangers associated with multiple exposures, (2) Dangers associated with mixtures of the toxics, (3) Dangers associated with above-average exposures and (4) Dangers associated with long-term, low-dose exposures. Israel notes that these types of failures, which are found in the Health Risk Assessments conducted at Butte Priority Soils, particularly hurt the poor because of the failure "to adequately incorporate exposure realities" in low income communities. (*op.cit.*)

Health Risk Assessment examines the likelihood of whether or not a person exposed to a particular toxic substance will incur a particular illness related to the toxic. Health risk assessment does not consider multiple exposures. (See: William H. Hallenbeck and Kathleen M. Cuningham, *Quantitative Risk Assessment for Environmental and Occupational Health.*) Therefore, although the EPA claims that the Health Risk Assessments for the Butte Hill were conservative in their assumptions, the assumptions were not as conservative as alleged because of the failure to consider multiple exposures. Such a failure is discriminatory to the poor on the Butte Hill in that: "While this distortion is important to the public in general, it is critical to observe that such a bias may have a disproportionate effect in poor communities and communities of color where exposure to multiple substances tends to be higher." (Israel, *op. cit*, p.12) "Any meaningful analysis intended to protect underserved communities will recognize that multiple-cumulative-combination exposures are occurring." (Ferris, *op.cit.*)

Also, because the Health Risk Assessments for Butte Priority Soils failed to consider or evaluate the **synergistic effects** of the toxics present, **the poor were treated**

discriminatorily. The synergistic effect of multiple toxic compounds can cause an ***additive response***, an ***antagonistic response*** and/or ***a strait synergistic response***. Synergistic response is particularly important. The EPA itself in its *Risk Assessment Guidelines* document states: "while some potential environmental hazards involve significant exposure to only a single compound, most instances of environmental contamination involve concurrent or sequential exposures to a mixture of compounds that may induce similar or dissimilar effects." Calabrese notes: "While nearly the entire thrust of public health risk assessment activities has involved derivations for individual compounds, all agree that the real world involves multiple chemical exposures, either concurrently or sequentially. Despite universal agreement on this, regulatory agencies, especially in the environmental domains, have been slow to directly address and specifically incorporate the knowledge of interactions into the risk assessments process." (*op.cit.*)

Unfortunately, the Health Risk Assessments for Butte Priority Soils failed to consider additive response, antagonistic response and/or strait synergistic response. This is true of EPA Health Risk Assessments as a matter of course: "Data systems that compile information on pollutant concentrations in the environment are generally focused on single, or simple, forms of pollutants; complex mixtures are not assessed due to limitations of cost and proper procedures." (Diana K. Wegener, et. al., "Equity in Environmental Health: Data Collect and Interpretation Issues, *9 Toxicology & Indus. Health* 775,783)

The environmental justice significance of this failure is that: "Unfortunately, the points where the (Risk Assessment) Mixture Guidelines are weakest are the exact points in which the exposure data linking minority and poor communities are the strongest. Substantial data demonstrate that low-income and minority people are significantly more likely than the rest of society to live near complex mixture 'scenarios'." (Israel, *op.cit.*, p. 13.) [See also Paul Mohal and Bunyan Bryant, *Environmental Racism: Reviewing the Evidence, in Race and the Incidence of Environmental Hazards: A Time for Discourse*; Robert Bullard, *Dumping in Dixie: Race, Class and Environmental Quality and Commission for Racial Justice*; Untied Church of Christ, *Toxic Wastes and Race in the United States: A National Report on the Racial and Socio-Economic Characteristics of Communities with Hazardous Waste*]

Demographic data regarding the Butte Priority Soils site demonstrates that the Priority Soils site falls within the parameters of exposure to synergistic scenarios described above and this conclusion warrants a finding of environmental discrimination by the EPA against the Priority Soils' poor. A common failing of Health Risk Assessment and a failing of the Health Risk Assessments for Butte Priority Soils is the failure to consider demographic correlations to health risk and exposure to toxic substances. Because the Health Risk Assessments for Butte Priority Soils used only generalized exposure assumptions, the risks that are disproportionately distributed to the detriment of the poor who live within Priority Soils are discriminatorily distorted.

Also, the failure to consider the additive response factors and the antagonistic response factors as part of the Health Risk Assessments for Butte Priority Soils also discriminated against the poor. The poor are more likely to experience an additive response and an antagonistic response to various toxics than are the non-poor. Failure to even consider these factors was discriminatorily detrimental to the low-income citizens living within the Butte Priority Soils site.

In summary, the Priority Soils Health Risk Assessments failed to deal with the synergistic interaction of contaminants. Even the EPA admits that human health risk assessment techniques used for single chemical and simple binary interactions: "cannot be extended to complex mixtures because the data requirements of such extensions lead to experimental designs that are impractical." (U.S. EPA Office of Research and Development and *EPA Journal*. Also see: Langdon Winner, "Risk: Another Name for Danger," pp 60-68 in Theodore Goldfarb, ed., *Taking Sides: Clashing Views on Controversial Environmental Issues*, 4th Ed.) "Perhaps the most important complication (of evaluating risks of exposure to chemical mixtures) is the potential for interaction among the mixture's constituents, including synergistic effects in which the combined effect of two or more substances is greater than the sum of the effects of each agent alone." (Daniel Krewski, et. al., "Carcinogenic Risk Assessment of Complex Mixtures," *Health Hazards Risks from Exposure to Complex Mixtures and Air Toxic Chemicals* at 147,151)

Also the Health Risk Assessments conducted at Butte Priority Soils failed to look at susceptibility to the harms of exposure to the substances of concern at the site in terms of income. This failing discriminatorily affects the low-income citizens of the Priority Soils area. There was no assessment particularly geared to the low-income subgroup of the general population living within the Priority Soils area. In fact the epidemiologic studies used as a basis of the Health Risk Assessments for Priority Soils were based only on studies of healthy white males. (EPA *Equity Report*, Note 12 at 33-34.) Given that the demographic makeup of the Priority Soils poor is definitely not primarily healthy white males, the Health Risk Assessments conduced at Butte Priority Soils failed to adequately characterize the risk factors to the discriminatory detriment of the poor. (U.S. Census Bureau, 2000 Census Data)

Because the focus was on premature death from cancer, the Health Risk Assessments for Butte Priority Soils failed to evaluate low-birth weight, reduced intelligence, asthma, and numerous other environmentally caused diseases. "Once a substance is identified as a potential carcinogen, non-cancer studies often are not pursued, even though the compound may be a toxicant in other respects. It is conceivable that a chemical with a low cancer unit risk might be a potent teratogen, but without a multidisciplinary approach, this will never be know." (Grose, et. al., Interdisciplinary Approach to Assessing the Health Risk of Air Toxic Chemicals: An Overview," *Health Hazards and Risks from Exposure to complex Mixtures and Air Toxic Chemicals* 39, 47)

There is abundant evidence that low-income citizens tend to be more susceptible to the effects of exposure to the toxics present at the Priority Soils site than the non-poor. (See:

Edward J. Calabrese, *Ecogenetic: Genetic Variation in Susceptibility to Environmental Agents*; Richard Rios et. al. *Susceptibility to Environmental Pollutants Among Minorities*, 9 *Toxicology and Indus. Health* at 797 and Edward J. Calabrese, *Pollutants and High Risk Groups: The Biological Basis of Increased Human Susceptibility to Environmental and Occupational Pollutants*.) For example, long-term exposure to toxics can produce intergenerational genetic characteristics that increase susceptibility to the toxics found within the Priority Soils site. (Rios, *op. cit.*, 797) The Health Risk Assessments for Butte Priority Soils considered no issues of intergenerational equity. Also, for example, the low-income citizens of the Butte Priority Soils Site, as do the poor generally, have elevated rates of hypertension that increases the likelihood of kidney disease that, because the kidneys filter toxics such as heavy metals, means that low-income citizens have a lessened ability to combat toxics exposure. (Rios, *op.cit.*)

Also, the poor tend to have less access to information about the dangers of heavy metals and the ways of lessening heavy metals exposure and have less ability to understand and put into practice the recommendations for lessening exposure. (Israel, *op. cit.*, p. 16 and Rios, *op.cit.*)

It is also important to remember that low-income citizens tend to have poorer nutrition than do non-poor citizens which situation disparately increases their susceptibility to heavy metal toxicity. (Calabrese, *op. cit.*) For example, the poor tend to have a greater likelihood of Vitamin C deficiency than the non-poor that increases their vulnerability to lead toxicity. The poor tend to have a greater likelihood of calcium deficiency than the non-poor that also increases their vulnerability to lead toxicity. The poor tend to have a greater likelihood than the non-poor of iron deficiency that increases their vulnerability to lead.

Lifestyle factors also affect the susceptibility of the poor to the toxics found at the Priority Soils Site but lifestyle factors were ignored in the Health Risk Assessments for Butte Priority Soils to the disparate detriment of the poor. "Because minority populations tend to have larger percentages of children and pregnant women than the non-poor, [a statistic evidenced at the Priority Soils site] and because "pregnant women, children, infants, and fetuses are more susceptible to adverse health effects from pollutants than are members of the remainder of the population, exposure to pollutants will disproportionately affect minority communities." (Israel, *op. cit.*, p. 17. See also Rios, *op.cit.* and Calabrese, *op.cit.*) In addition, the poor are more likely than the non-poor to smoke and that increases their susceptibility to heavy metal toxicity. (See: U.S. Department of Health and Human Services, *Health Status of the Disadvantaged*; Rios, *op.cit.* and Calabrese, *op.cit.*)

Moreover, the poor have little chance to participate in the development and execution of health risk assessments. Lack of public participation is particularly evident in low-income communities. The EPA itself has said: "poor and racial minority communities are rarely involved in Agency rulemakings and seem to be unaware" of their rights. (*EPA Equity Report.)* The poor as a group have been ignored as regards to the development and implementation of the Health Risk Assessments at Butte Priority Soils.

Israel sums up the problem: "Risk assessment methodology currently incorporates numerous informational biases that may disproportionately affect poor communities . . . Specifically, risk assessments generally fail to observe those adverse health effects that result from above-average exposure, from exposure to multiple chemicals, and from the interactions of toxic substances. Similarly, risk assessments generally fail to observe susceptibility differences as a function of income or race. Genetic differences, disease patterns, social inequalities, and cultural and lifestyle factors all increase the body's susceptibility to chemical substances." (*op.cit.*) A memo by Robert M. Sussman who was Chair of the EPA's Science Policy Council to the director of the EPA admitted that there were informational biases in the EPA's Health Risk Assessment protocol. Sussman also stated that there were deficiencies in the EPA's incorporation of multi-path and multi-sources exposures and "inter-individual" susceptibilities into the EPA's Health Risk Assessment protocols. He noted that these deficiencies contributed to environmental justice problems for the agency. (EPA Science Policy Council Report of the EPA Science Policy Council on Addressing 'Science and Judgment in Risk Assessment,' A Report by the National Research Council, in *Inside EPA*.)

VII. Therefore, given that the Proposed Plan and the Preferred Alternative for Butte Priority Soils are Based on and Justified by a Risk Assessment Process that Discriminated against Low-income Residents living in the Priority Soils OU, the Proposed Plan and Preferred Alternative for Priority Soils OU are Based on a Process that Violated Environmental Justice.

VIII. Therefore, the Outcome of that Process, i.e. the Priority Soils Proposed Plan and Preferred Remedy Violate the EPA Mandate to Promote Environmental Justice.

IX. In fact, the Proposed Plan and Preferred Alternative for Priority Soils would actually Increase the Toxic Burden of Butte's Low-income Citizens.

X. Therefore, because of 7 and 8 above, the Proposed Plan and Preferred Remedy for Priority Soils should be declared null and void.

The Proposed Plan and the Preferred Alternative for Butte Priority Soils OU are only as good and sound and valid as the underlying processes that produced the Plan and the Preferred Alternative are good and sound and valid. The Proposed Plan and the Preferred Alternative for Butte Priority Soils OU are only as environmentally just as the underlying processes that produced the Plan and the Preferred Alternative are environmentally just. The environmentally **unjust** Health Risk Assessments conducted at the Butte Priority Soils site, because they are the foundation, grounding, and justification for the Proposed Plan and Preferred Alternative, taint the entire process which the hue of injustice. The environmentally unjust Health Risk Assessments conducted at the Butte Priority Soils OU, because they are the foundation, grounding, and justification for the Proposed Plan

and Preferred Alternative, undermine, contaminate and discredit the entire process. Given that environmental justice concerns must permeate all of EPA's activities and process, this failure to promote and encompass environmental justice in the development of the Proposed Plan and Preferred Alternative warrants the discarding of the entire Proposed Plan for Priority Soils.

From:
Sent: Tuesday, April 29, 2014 5:01 AM
To:

Cc:
Subject: NEW PUBLIC COMMENT--PHASE 1--BUTTE HEALTH STUDY--ADDITIONAL SERIOUS METHODOLOGY AND COMMUNITY INVOLVEMENT ISSUES
Attachments: Additional Methodology Issues.docx

Please see **ATTACHED** document for new public comment submitted during and as part of the public comment period on Phase 1 of the Butte Health Study.

Since the EPA has "back-tracked' on its promise of an independent peer review of Phase 1 of the Health Study, I thought that I would compare the methodology used in Phase 1 with the methodology recommended by leading experts in the field. Doing so clearly shows the inadequacy of the methodology used in Phase 1.

I also have raised new issues regarding community involvement, or the lack thereof, in the development of Phase 1 of the Butte Health Study.

Additional Methodology Issues—Phase I—Butte Health Study

Please consider the following as additional public input regarding Phase 1 of the Butte Health Study. In this paper I have compared the methodology used for Phase 1 of the Butte Health Study to standards expressed in several articles by leaders in the field of environmental epidemiology and toxicology. My conclusion is that the methodology used in Phase 1 of the Butte Health Study has serious problems and should be redone.

Please consider the following:

Hal Morgenstern and Duncan Thomas, "Principles of Study Design in Environmental Epidemiology,' Environmental Health Perspectives Supplements, vol. 101, supplement 4, December 1993, pp. 23-38. "The purpose of this article is to discuss the principles of study design and related methodological issues in environmental epidemiology. The focus is on studies aimed at evaluating causal hypotheses regarding exposures to suspected health hazards."

This article is certainly germane to the methodology of Phase 1 of the Butte Health Study. If the causality arguments in Phase I are weak, as I believe they are, the whole Phase 1 should be redone. The article raises the following issues that have not been correctly or adequately addressed in Phase I of the Butte Study.

1. Failure to properly specify population parameters.
2. Failure to deal with the problem of long latent periods.

3. Failure to consider errors of exposure measurement and exposure misclassification bias
4. Selection Bias
5. Information Bias
6. Confounding including confounder misclassification.
7. Lack of covariate data
8. Methodology not suited to rare outcome events in non-clinical populations
9. Treating exposure as a fixed variable
10. Failure to do any cross-sectional studies. By not doing any cross sectional studies the Health Study inadequately characterizes the population of concern.
11. Failure to do any case-control studies
12. Failure to do any genetic studies
13. Failure to do any space-time cluster studies
14. Failure to do any time trend studies
15. Failure to deal with ecological biases such as within-group confounding, confounding by the group and effect modification by the group
16. Failure to do any multiple-group studies
17. Collinearity
18. Temporal ambiguity of cause and effect
19. Migration
20. Poor ecologic inference making
21. Poor quality measurements
22. Poor consideration of gene-environment interaction

Lesley Rushton and Paul Elliott, "Evaluating evidence on environmental health risks," British Medical Bulletin, Vol. 68, Issue 1, pp. 113-128.

This article has much to say of relevance to the issue that Phase 1 of the Health Study fails to consider environmental justice issues. "Assessment of the impact of a potential adverse health effect from an environmental pollutant is dependent on an understanding of several important issues, including: 1. The hypothesized health outcome or toxics effect, 2. The nature of the exposure, 3. The relationship between dose and response and 4. The variability and susceptibility of the

potentially exposed population, for example regarding sub-groups of the population that might be at especial risk due either to the pattern and distribution of exposures in the population, or to non-environmental factors that might influence the risk of disease."

The Butte Health Study ignores the above issues that should have been considered in Phase I of the study.

"In environmental epidemiology, concern usually centres on chronic effect from low-level exposures." Yet the study only looks at acute effects.

Phase I fails to consider SES of the target population as a confounding factor.

Phase I fails to consider "whether the effect on disease outcomes of one factor is modified by levels of another factor, so-called *effect modification or interaction*. "

Phase I suffers from mischaracterization due to an imperfect appreciation of the mechanisms by means of which lead exposure influences the effect of lead exposure. No is individual variation considered in Phase I.

Phase I suffers from the failure to do Bayesian modeling.

No attempt is made in Phase I of the Health Study to assess the risks to low-income citizens posed by lead exposure.

Phase I also suffers a major problem in that there is no statistical or other evidentiary support given for assuming that the population studied is representative of the low-income population in Butte. It is just assumed that because many WIC program participants were tested and WIC is a low-income program that we have an adequate sample of low income citizens in Butte.

G.M. Paddle and J. M. Harrington, "Environmental epidemiology—strengths and weaknesses," In. Arch Occup Environ Health (2000) 73: pp. 7-14

According to the authors a sound study should:

1. "Communicate, express concern and indicate that the report will be systematically investigated."

2. Give some description of the track record of exposure, particularly exposure clusters
3. Precisely define exposure and health effects and use appropriate data. (The Health Study just assumes the data is appropriate. It is interesting that only the people conducting the study can look at the raw data.)
4. "Investigate the claim of causality using Bradford Hill's criteria."
5. Set up an independent hypothesis testing study.
6. Document all steps of the process clearly.

The Health Study so far has failed to do steps 1-6.

As far as data collection is concerned, the Health Study has failed to:

A. Specify whether or not a particular piece of data or set of data is necessary for the Study.
B. Specify how it has accurately been collected.

Although "Social deprivation has to be recognized as a powerful confounder" the Health fails to look at social deprivation in the Health Study as a confounding factor.

Given that there is no randomization in the populations studied imbalances in the characteristics of those exposed can occur.

Selection bias can occur. ***(Grimes and Schulz, "Cohort studies: marching toward outcomes," The Lancet, Vol. 359, January 26, 2002.)*** I cannot find how the current Health Study avoids selection bias. It seems to be rampant throughout the study.

The above article lists the following as steps/questions to take to avoid selection bias. These steps were not taken in the Health Study nor were these questions asked.

a. Were only people at risk of the outcome included? No, the Health Study has not,
b. Was the exposure clear, specific, and measurable? No, the Health Study has not,

c.
d. Were the exposed and unexposed groups similar in all important respects except for the exposure? No, the Health Study has not,

The above article also lists the following steps/questions to minimize information bias. These steps were not taken in the Health Study nor were these questions asked.

a. Was the outcome clear, specific and measurable? No
b. Was the outcome identified on the same way for both groups? No
c. Was the determination of outcome made by an observer blinded as to treatment? Definitely not.

The above article also lists the following steps/questions to minimize confounding factors and to control for confounding factors in the analysis. These steps were not taken and these questions were not asked in the Health Study.

a. Did the investigators anticipate and gather information on potential confounding factors? No
b. What methods(s) were used to assess and control for confounding? This was a significant failure in the Health Study. Confounding factors were ignored.

The Health Study was marked by control failures as well as failure to assess outcomes equally

In dealing with causality, I am once again struck for the Health Study's failure to abide by Hill's Criteria for Causality:

A. Strength
B. Consistency
C. Specificity
D. Temporality
E. Biological gradient
F. Plausibility
G. Coherence

The Health Study makes numerous causal arguments which violate Hill's criteria. The whole Health Study is in essence a study of causality. If the methodology used to establish whether or not causal links were present is unacceptable, the conclusions of the Health Study become very problematic.

I hope that these comments will be taken seriously. In the past few responsiveness summaries, the EPA has responded in a cursory and dismissive fashion.

Responsiveness summaries are one means by which the agency can show that public input really has an impact on Superfund activities. If this responsiveness summary becomes another example of a perfunctory response by EPA to public comment the EPA is not meeting its community involvement mandate.

Please consider the following as it applies to the role of community involvement in the development of Phase I of the Butte Health Study:

> If men were angels, no government would be necessary. If angels were to govern men, neither external nor internal controls on government would be necessary. In framing a government which is to be administered by men over men, the great difficulty lies in this: you must first enable the government to control the governed; and in the next place oblige it to control itself. A dependence on the people is, no doubt, the primary control on the government; but experience has taught mankind the necessity of auxiliary precautions. (James Madison, *Federalist 51*)
>
> Who will guard us from the guardians? (Juvenal)

The Superfund decision-making process mandates public involvement and numerous institutional mechanisms are provided for public comment. The EPA has a policy mandate that holds that it is: "imperative that EPA pay close attention" to citizen input and that citizens need to be "involved in the decision-making process." (OSWER 9230.0-18-"Incorporating Citizen Concerns into Superfund Decision-making.") The Introduction of the EPA's *Superfund Community Involvement Handbook* (April 2002) notes that the EPA is committed to "early and meaningful community participation during Superfund cleanup." The agency goes on to say that community involvement and participation in decision-making is a

"foundation" of the Superfund program. The *Handbook* talks about citizens "shaping" Superfund decisions. The *Handbook* further notes: "Superfund community involvement is not a public relations effort to sell the Agency or its plans to the community, nor is it just the communication of information. Community involvement is the vehicle EPA uses to get community concerns and interests to the decision-making table." EPA endorses the core values of the International Association for Public Participation that in part include "the promise that the public's contribution will influence the decision." Community concerns should be reflected in agency decisions. (OSWER 9230.0-99, "Early and Meaningful Community Involvement") In its description of the Superfund process in the January 2000 booklet *This is Superfund,* the statement is made that there is community involvement throughout the Superfund process. (p. 8) The above comments present a rather strong commitment on EPA's part to the efficacy of public participation.

Certainly, the EPA provides numerous institutionalized vehicles of public participation—public meetings, public hearings, comment periods, etc. But the question is whether or not public participation is efficacious or do these venues of participation simply provide environmental theatre and stylized ritual. Does public comment matter? Are the forms of participation at best giving citizens the feeling that they participate in decision making without giving citizens the power to influence decisions? Is there participatory form without substance? Should citizens bother to participate in the process? This issue came to the fore recently with regards to the BSB Health Study mandated by an EPA unilateral order, the Five-Year Review of Butte Superfund sites and the ongoing discussion surrounding the Butte Priority Soils Operable Unit. People raise the legitimate question whether or not they are wasting their time in commenting when their comments seem to have no effect.

Although the EPA has a strong mandate to involve that public regarding the development and implementation of environmental rules and regulations, this mandate does not guarantee the efficacy of public participation in Superfund decision making in Butte. Often agency personnel express exasperation at low levels of public participation in agency functions. The question often gets asked: How can we increase public participation and get more citizens involved?

My answer is that citizens will be involved if three conditions are met:

1. Citizens must know the issue, i.e. are aware of the issue.
2. Citizens must see why the issue is important to them
3. Citizens must feel that their participation will have some efficacy.

If citizens don't' participate, are least one of the above conditions are missing. If citizens are not participating, the EPA should not blame citizens but should evaluate the effective of the agency's public involvement activities.

This discussion will examine three issues: (1) What **should be** the role of public participation in Superfund decision making, (2) What **is** the role of public participation in Superfund decision making, and (3) **How can** public participation in Superfund decision making **be enhanced**. *The focus of this discussion will be the Superfund process in Butte.*

What should be the Role of Public Participation in Superfund Decision Making

While it is indisputably the case that the EPA and MDEQ are necessary for the administration of environmental policy and the implementation of environmental programs, it is also the case that the authority of these agencies springs from the governed. The bureaucracy exists to provide services to the public and to promote the general welfare. Authority is transferred to the bureaucracy in order to achieve some public purpose and accrue some public benefit. Any exercise of bureaucratic power necessarily diminishes individual liberty. Any rule or regulation necessarily prescribes or proscribes or prohibits certain individual action. Under what conditions is this justifiable?
Justification can only come if the public impacts agency decisions and forms agency decisions.

It is a basic tenet of democratic decision making that: "on all matters where social action is substituted for individual action, liberty exists only through participation either in decision making or in control of leaders who make the decisions." (Emmette Redford-*Democracy in the Administrative State*.) It is not just the ethics of democracy that mandates citizen participation, but the quality of public decisions is enhanced by public participation. The more people who are substantively involved in making a decision, the more information and the more perspectives that are brought to that decision. Public participation means that more alternative solutions are considered and the resulting decision will have greater credibility and legitimacy. Meaningful public participation promotes public civic education and increases trust in government institutions. Efficiency is also enhanced by public participation in that public acceptance of an agency decision decreases the likelihood of prolonged challenges to that decision. The law also mandates that most public agencies take into account public comments in rendering their decisions.

Yet, research has indicated that only about one-third of public comments are accepted by decision-making agencies. There are a number of reasons, whether valid or not, for this limited public role: (1) The public does not speak with one voice-segments of the public support a decision, segments oppose it. (2) Not all public comment is of equal discernment and environmental decision-making is not a popularity contest. (3) Agencies have invested their prestige in preferred decisions. (4) There is a view that it is government that is supposed to aggregate all of the articulated interests into sound public policy. (5) Government decision-makers are influenced by their own interests, values and perceptions. (6) Agency personnel see themselves as professional scientists and/or engineers who possess the technical expertise to make the right environmental decisions. Their view is that the ordinary public does not possess this technical discernment. (7) There is a distrust of the public and a view that public participation is often too time consuming, wastes money, and allows for too much obstructionism. There are government officials who would prefer to leave the decisions to the government experts and not needlessly complicate matters by involving the public. I recall the comment of one EPA official, I believe in Ohio, who remarked that they had a pretty good decision until the public got involved and messed it up.

There are also structural limits to the extent of public participation.

1. It is a basic principle of government, particularly democratic government, that government agencies, such as EPA, have to aggregate all of the articulated public interests into some decision. Governing means to choose and deciding means choosing between alternatives and those whose alternatives are not selected will be disgruntled. No decision can totally include all perspectives on an issue.
2. The right to participate does not guarantee the right to succeed.
3. Agency rule making is not totally a democratic process.

On the other hand, there are valuable contributions that the public can make to the Superfund decision-making process.

1. Citizens know best how a decision will affect their interests.
2. Citizens know the local area.
3. Because it is concerned with the making and enforcing of government policy decisions, Superfund decision-making is as much, if not more, a political process than it is a scientific process. Cleanup decisions cannot be determined with the certitude of a mathematic or scientific theorem. Although there are those who would seek to avoid conflict by an appeal to the certainty of science (after all you can't argue with science), an appeal to "good science" cannot eliminate conflict. Correct environmental decisions

lie in the realm of the probable and contingent not the certain and absolute. As an inherently political process, the public must not only be involved but also allowed to be effective in their participation by decision makers. For example, consider Superfund's nine criteria for remedial alternatives evaluation. These criteria do not have scientific or technological certainty or precision. How they apply to perspective decisions, what they mandate and what they do not mandate, how they relate to each other, what they mean, and their significance are the result of political processes, bargaining and decision making. If one takes cost, for instance, how do you determine with scientific and technical certainty whether or not an alternative costs too much? The very standards such as contaminant action levels and the risk assessment process are infused with politics. Often action levels are the result of political bargaining and represent the lowest common denominator of what is acceptable to the various groups fighting about where the levels should be placed. The notion of value neutral decisions in Superfund is unobtainable.

4. Even decisions which are based in science and technology have to be open to public scrutiny and comment. The expert must offer his or her expert opinion to the public in the public realm. The expert's opinion must be tested, analyzed and evaluated in the public realm. We do not, even in environmental decision-making, have a government of experts. To this end, it is important to remember that not all expertise resides in government or the PRPs. Members of the general public often have extensive knowledge, experience, and expertise in the areas under consideration in Superfund. The wanton corporate hubris displayed at a recent meeting on Priority Soils where public input was characterized as the articulation of "feelings" is a disservice and mischaracterization of the value of the public participation process.

The issue of public participation in environmental decision-making is a subset of the larger question of how does one make the bureaucracy accountable and responsive to the public while at the same time ensuring that the bureaucracy will perform its functions with effectiveness and efficiency. The personnel of public agencies such as EPA are not elected. Merit and other current personnel systems can isolate agency personnel from the public. The hiring of agency personnel based on technical and scientific qualification does not ensure that these personnel will be attuned to the public process or will value the public process. There will always be tension between efficiency, effectiveness, public accountability and public responsiveness. No totally satisfactory answer has ever been given to the question: How do you balance the desired independence of decision-makers with

accountability to the public? How do you incorporate "good-science" into decisions that are inherently political?

The Current State of Public Participation in Superfund Decision-Making

Are there problems with the public participation process in Superfund decision making in .Butte?

Based on my participation in the Superfund process, I have reached the following conclusions:

1. The EPA seems to be content to provide public forums often more to provide information to the public rather than to involve the pubic in Superfund decision-making. This is directly contrary to EPA's stated position on community involvement in Superfund decision making.
2. The last couple of years have seen overt hostility on the part of some EPA officials to public input and participation, particularly critical public input.
3. Such things as the law, promulgated administrative rules and regulations and the fact that their decisions do have to enjoy some measure of public support limit and define EPA's commitment to public participation.
4. Some project officers see limited utility in public involvement. Their reasoning is that Superfund decisions require technical and scientific expertise that the general public does not possess and that the public's wishes do not contribute to the "good science" required for sound Superfund decisions. Their view is that the Superfund process is basically a technical, scientific process that is aided little by public input which process requires too much time and effort for the results received. I think this is a minority view. We have certainly seen this in regard to Phase 1 of the Health Study.
5. More resources need to be devoted to improving the public participation process.
6. Public participation needs to be conducted in a more comprehensive and systematic way. This will require additional resources being committed to public involvement activities. Community involvement is not a major emphasis of the Montana Office of EPA. Look at how community involvement activities have been assigned to RPMs. Under such an arrangement no wonder community involvement activities will not be a priority.
7. There still is need to sensitize agency personnel to the necessity of clear, non-technical communication with the general public. It is possible to communicate clearly with a general audience while not losing scientific precision or legal accuracy. This necessitates giving people who were hired

on the basis of technical competency the additional competency of being effective spokespersons. Little effort has been made to make the Health Study document easily accessible to the general public. Little effort has been made to make the Health Study document understandable to the public. No wonder so few members of the public, exactly three) attended the open house that EPA sponsored on the Health Study. Perhaps the EPA is trying to overwhelm the public with technical reports.

8. The public may be laboring under a misapprehension as to exactly what is the role of public participation in Superfund decision-making. They may think that they have a greater role than is mandated by the law. The EPA has certainly lead the public to believe that public input will matter in the development of the Butte Health Study. Yet, the EPA has back-tracked from its promise that the Health Study will undergo an independent peer review by qualified experts.

At this point I would like to add the comments that I made regarding the Health Study Work Plan. They are still valid today and never have been adequately addressed by the EPA.

Additional Public Comment—Health Study Work Plan

As the public comment period on the Health Study Work Plan comes to a close, I would like to offer the following process comments:

I don't need to repeat the details of EPA's written commitment, in terms of policy and procedure, to "meaningful public involvement" and to promoting environmental justice.

We will see if the EPA's reaction to the comments received is congruent with the agency's written commitment to promote efficacious public involvement and to promote environmental justice. If the public comments simply get "blown-off" and become only the subject of a perfunctory responsiveness summary, Butte citizens will see once again that the EPA only pays "lip-service" to meaningful public involvement in Superfund decision-making and to environmental justice.

Butte citizens are not happy with the whole Health Study process.

1. From its inception the Health Study process has been problematic. It appears that the Health Study process that we are going through at the present was *necessitated* because the EPA did not like the results of Stacie Barry's study which showed that Superfund had serious problems in Butte. In all my years of involvement in Superfund, I have never seen such a "hatchet job" done on a study and the author of that study.
2. The process has been marked by secrecy. The public has had to constantly demand information about what was going on. Grudgingly, the EPA has released tidbits of information. How can the public participate in Superfund decision-making if it does not know what is happening? It took me countless emails just to find out, for example, who was on the Health Study advisory board and when it was meeting and what were the results of those meetings.
3. Although central Butte has a disproportionate number of low income citizens, environmental justice concerns have been ignored. Look to the work plan and you will see environmental justice is ignored. In this area I fault not only the Montana Office of EPA but Region 8's office in Denver which has an environmental justice staff. I was shocked to find that Region 8, unlike most EPA regions, does not even have an environmental justice action plan.
4. Butte citizens question the independence and validity of the study. It is the old story of the EPA evaluating itself and finding that it has done a good job. This Health Study has no credibility in the community. The EPA publicly laments a lack of citizen participation. Why should citizens participate when their comments have no efficacy? Why should citizens participate when they are criticized for participating? Time and again I have been told by members of the public that participation in Superfund is a total waste of time and effort. Perhaps it is time for Region 8 to become more involved. The above was not always the case. Years back the EPA in Montana was much more open to public input. Today, it is a defensive, hunker down agency. At a minimum, the Montana Office should have a public meeting

and respond publicly to the comments it has received in addition to putting out a responsiveness summary. The whole Health Study design and execution should be subject to independent peer review.

Will things change? We will see. We will see how seriously EPA takes the comments it receives. We will see if the EPA responds in a substantive manner to the comments it receives. We will see if the EPA makes changes in the Health Study Work Plan to respond to citizen input. We will see if EPA takes seriously its commitment to meaningful public involvement and environmental justice.

I am not optimistic. It is hard to hold an agency publicly accountable. We can't vote agency personnel out of office. I suspect all we will get is some perfunctory response to citizen input. Hopefully, I will be proved wrong.

Conclusion

As I have said on numerous occasions, it would be nice to know if Superfund was effective in Butte. One would think that the EPA would like to know this. At the start of the Health Study process, it was hoped that this Health Study would provide the answer. (As a caveat, at the very beginning there were grave doubts about the efficacy of this Health Study. It came after the hatchet job done on Stacie Barry's report which report reached the conclusion that Superfund had not been effective in protecting human health. When the Health Study was announced the results of the Health Study were announced at the same time before any investigation had been done. It was stated that the EPA was sure the Health Study would show that Superfund was working to protect human health. Citizen groups were initially excluded from the Health Study Working Group. The EPA has consistently failed to show how the current Health Study is any kind of improvement over Stacie's study or the other numerous studies that show Superfund has not achieved its goal of protecting public health.)

Nothing so far has allayed these citizen concerns. The latest Health Study report, the so-called Phase I report, continues to be primarily a propaganda piece with serious methodological problems as well as serious public policy failings such as the failing to address environmental justice issues and the failure to meaningfully

involve the public. One of the most damaging things the Montana EPA Office has done is to back-track on its promise that the peer review process would be subjected to an independent peer review that would be conducted during the process of developing the health study and would actually impact the scope, methodology and conduct of the health study.

Because of all of all of these problems with the way the EPA has conducted the Health Study, how can the public have any confidence in its results???????

The Health Study needs to be re-worked to solve its methodological problems, to provide for meaningful public involvement and to address environmental justice issues. Right now the public has little confidence in the EPA. This Health Study does nothing to restore that confidence.

I want to make it clear that my comments relate to THE HEALTH STUDY.

I feel that the Residential Metals Abatement Program, given the limitations imposed on it by EPA, has done a commendable job. The staff is accessible and treats questions and comments seriously. As I said, the problem I have is with the HEALTH STUDY.