Message

From: Barnicoat, Dana [Barnicoat.Dana@epa.gov]
Sent: 12/11/2019 5:26:00 PM
To: John Ray [redacted]
CC: Greene, Nikia [Greene.Nikia@epa.gov]
Subject: FW: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Dr. Ray,

Just an FYI to keep you in the loop. Nikia just requested more data from the authors of the meconium study. Please read below.

Sincerely,

Dana

From: Greene, Nikia <Greene.Nikia@epa.gov>
Sent: Wednesday, December 11, 2019 9:40 AM
To: LEAD, JAMIE <JLEAD@mailbox.sc.edu>; Hailer, Katie <KHailer@mtech.edu>; MCDERMOTT, SUZANNE <SMCDERMO@mailbox.sc.edu>
Cc: Partridge, Charles <Partridge.Charles@epa.gov>; Wall, Dan <wall.dan@epa.gov>; Sullivan, Karen <ksullivan@bsb.mt.gov>; Hutchins, David <DHutchins@mtech.edu>
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Professor Lead,

Thank you for the response to my data request. At this time, EPA is not in a position to commit to the development of a new program of study in the area of meconium. However, I am thankful that you would be able to share data from your study. The reasons why I am requesting the data are as followed:

1. A "potential public health emergency" was announced in Butte (as referenced in the Montana Standard November 26, 2019)
2. EPA is tasked with protection of human health and the environment and most all of the city of Butte falls under EPA's Superfund authority.
3. For EPA to validate the data we need the original data/outputs, and QC information from the ICP-MS analysis.
4. The archived data (physical samples) will be challenging to analyze as you discuss below; however, EPA would like the opportunity to perform an independent analysis to confirm the results.

Furthermore, I would like to make a few additional requests from you:

1. You had mention below that "limited literature data in general agrees with our data and interpretation". Could you please point me to the literature you are referring to. EPA's initial review of the literature referenced in your cross-sectional study and others produces the table below.
2. Please let me know if the meconium for your study was sampled under a Quality Assurance Project Plan or a Sampling and Analysis Plan. If so, could you please share the study planning document(s)?

Table

Metal	Meconium Concentration (µg/g)									
	McDermott et al. (2019)*		MIREC (Arbuckle et al. 2016/ Ettinger et al. 2017)			Aziz et al. 2017	Turker et al. 2013	Haram-Mourabet 1998	Baranowski 1996	Friel 1989
	Butte, Median	Columbia, Median	Median	95th %tile	Maximum	Mean Range by Location	Surviving, Median	Mean Range by Gestational Age	Control Mean	Mean, full-term***
Arsenic	0.032	<LOD	NC	0.02	0.55	---	---	---	---	---
Copper	26.311	0.01468	---	---	---	1.6 - 28.7	**	90.3 - 154.2	15.2	27.5
Manganese	5.364	0.00325	4.9	15	40	---	---	9.5 - 35.8	---	7.0
Molybdenum	0.059	<LOD	---	---	---	---	---	---	---	---
Lead	NC (0.005+)	<LOD	NC	0.0085	0.48	1.2 - 14.4	**	---	0.0047	---
Zinc	81.642	0.04334	---	---	---	9.5 - 160.3	**	156.4 - 365.4	68	107.5

NC = not calculated due to infrequent detection

<LOD = all samples less than limit of detection

*McDermott concentrations reported in Table 1 were converted from ug/kg (ppb) to ug/g (ppm)

**Result reported in terms of infant body weight, not as concentration; cannot be directly compared without adjustment

***Results reported in terms of total metal (expressed as concentration assuming the mean reported mass of stool 8.9 g)

Lastly, your cross-sectional pilot study on metals concentrations was surprising to me as the EPA Remedial Project Manager for the Butte Priority Soils Operable Unit and was alarming to the public. Extensive investigations have been conducted in Butte since the early 1980's and EPA has determined that lead, arsenic, and mercury are the primary human health risk drivers and copper, manganese, and zinc were not identified as important contributors to exposure. Thus, the identification of these metals as contaminants of interest in your pilot study is unexpected. After the EPA has had an opportunity to further review the results from your study, the EPA will take the appropriate steps to investigate the concerns or conduct an additional study. Until EPA has had the opportunity to review your original and archived data, we can only make limited statements and assumptions about the content of the 4-page journal article summarizing your study results. Moving forward, the EPA needs to validate and independently confirm the results and conclusions from your study. As a researcher, I am sure that you appreciate and understand that the EPA will follow a scientific process for verifying the results from these types of studies and make data-driven decisions on how to protect human health and the environment.

If you have any questions on my original requests and the requests listed above, please do not hesitate to contact me. Again, I really appreciate your willingness to help the EPA verify the results from your study.

Thanks,

Nikia Greene
Remedial Project Manager
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(406)-457-5019
greene.nikia@epa.gov

From: LEAD, JAMIE <JLEAD@mailbox.sc.edu>
Sent: Tuesday, December 10, 2019 4:23 AM
To: Hailer, Katie <KHailer@mtech.edu>; Greene, Nikia <Greene.Nikia@epa.gov>; MCDERMOTT, SUZANNE <SMCDERMO@mailbox.sc.edu>
Cc: Partridge, Charles <Partridge.Charles@epa.gov>; Wall, Dan <wall.dan@epa.gov>; Sullivan, Karen <ksullivan@bsb.mt.gov>; Hutchins, David <DHutchins@mtech.edu>
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Dear Nikia, all,

I completely agree with Dr Hailer. On the matter of existing samples, in some cases we do not have remaining samples and, where we do, the samples will not provide accurate metal data for a number of reasons. I see no advantage and several problems with attempting to re-analyze any remaining samples. I also encourage you to perform you own study, including importantly any effects, which we have not looked at yet. We have quantified an exposure biomarker and it is more important to investigate possible human health effects.

I'm happy to share disaggregated data as is standard. Although your request for raw data is unusual, I am in principle happy to share but several things give me pause. First, I didn't realize that you had already seen Dr Hailer's data, partly discounted it and also would not or could not quantify the metals which we found to be potentially problematic. Secondly, as mentioned, I have shared data before with colleagues and it is generally disaggregated, but not raw data, for modelling, data comparison etc.. In this case you want raw data and the purpose is not clear. The request for data and samples appears to carry an implicit criticism of our professional capability; either our competence or our honesty. For the SC study, Drs Hailer, McDermott and myself supervised the research and design. Samples were handled and data analyzed by several very experienced PhD students (published and graduated), the analysis was performed by a dedicated university ICP-MS facility with a very experienced laboratory manager. The data was interpreted by the students under my direction and checked by me several times. Thirdly, I think you should have been aware of the issues of re-analysis of archived samples. Now that you are, and given the potential problems for human health, it does seem to the most appropriate way forward is to perform a new and more detailed study building on our preliminary data, including more samples and an assessment of potential health effects rather than re-checking peer-reviewed data. Fourthly, limited literature data in general agrees with our data and interpretation. However, there is clearly a need for more data because of the limited nature of literature data and the preliminary nature of our study. Taken together, the request for raw data does not seem to be scientifically justified and the logical next step is a more detailed study. If you have concerns about the data quality, I suggest you perform another independent preliminary study.

So, although happy to share data, I would like to know the reason for the request and, more importantly, a commitment to develop a program of study in this area. This does seem the best way forward and I would be happy to discuss.

Best,

Jamie Lead,
Endowed Professor of Environmental Nanoscience and Risk,
Director of the SmartState Center for Environmental Nanoscience and Risk (CENR),
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Sent from Mail for Windows 10

From: Hailer, Katie
Sent: Friday, December 6, 2019 3:49 PM
To: Greene, Nikia; MCDERMOTT, SUZANNE; LEAD, JAMIE
Cc: Partridge, Charles; Wall, Dan; Sullivan, Karen; Hutchins, David
Subject: RE: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Dear Nikia,

I am happy to provide you with my raw data from the ICP-MS work. I should have that information to you early next week. I have been in contact with Dr. Jamie Lead from S.C. He is the chemist (who is also in the top 1% of cited scientists worldwide for 2019) that performed the sample analysis in Columbia. He is copied in on this email. He is currently out of the country and only has access to some of his raw data at the moment. He will send you the full set of raw data as soon as possible, once he returns to the US.

I'd like some clarification regarding your request of our remaining physical samples. There are many potential issues with re-analyzing these samples. First off, these samples have been sitting in a freezer for over a year. Most of the remaining samples do not contain sufficient amounts to perform an identical analysis (less than 1g of sample present) which means that methods will need to be cut by ½ or a 1/4 . With concentrations in the low ppb for some metals (especially the samples from Columbia), cutting the method in half or more, you run the risk of not detecting any metals, giving you false negatives on the results. In addition, while sitting in the freezer for over a year, there could be sorptive metal loss or even microbial degradation. Conversely, loss of water from the samples could actually concentration metal levels, giving higher concentrations. Having not conducted time lapse studies on meconium samples myself, I can only speculate as to how the sample might degrade or change over time. Instead of trying to re-analyze old samples with a potential myriad of unknown issues, why don't you collect some new samples from Butte and analyze them? Once you get approval, sample collection is essentially free and working with fresh samples will eliminate the concerns listed above. I would be happy to work with you to make the correct connections within St. James to gain approval to verbally consent mothers and gather additional samples.

My second point of clarification is regarding your statement of "contaminates of concern". When I met with you, Charlie, and Chris in March 2019, I shared this data with you. Granted in hadn't been published, but the numbers were the same. At that point in time, all of you indicated that you did not have the ability to look at any metals except for the contaminates of concern, and you seemed largely unconcerned with the data because of the lack of lead (Pb) in the samples. My samples were analyzed for Pb, As, and Cd. Only 1 baby had detectable Pb in the Butte set (low ppb concentrations). All samples had detectable As. Cadmium was not detected in any of the samples. What metals will you be able to analyze for? Specifically will you be looking at Cu, Mn, and Zn levels? I'm curious what has changed between March and now that allows you to analyze for these other metals.

Both Jamie and I have been through our own data a number of times and are sure that the units are correct. Parts per billion or ug/kg is a very common unit to express data from ICP-MS analysis and it is also a unit commonly used in other publications using meconium as a sampling matrix. Columbia's numbers with low ppb to below detection for various metals seems to be similar to other published meconium studies from non-exposed populations. Again, I really wonder why time and resources are being spent on trying to find mistakes in our data rather than collecting additional samples and analyzing them for metals?

I'll have my raw data files to you next week. Dr. Lead will have his sent to you once he is back in the US.

Thanks,
Katie

From: Greene, Nikia <Greene.Nikia@epa.gov>
Sent: Thursday, December 5, 2019 2:32 PM
To: smcdermo@mailbox.sc.edu; Hailer, Katie <KHailer@mtech.edu>
Cc: Partridge, Charles <Partridge.Charles@epa.gov>; Wall, Dan <wall.dan@epa.gov>
Subject: Request for data: Meconium identifies high levels of metals in newborns from a mining community in the U.S., November 13, 2019

Professors McDermott and Hailer,

I was made aware of the accepted journal (November 13, 2019) of your cross-sectional pilot study performed in Butte and Columbia on November 25th 2019. Also, on November 26th 2019 the Montana Standard published an article "Health study shows startling levels of metals in Butte babies' meconium".

I work with the community of Butte on a daily basis as a Remedial Project Manager for EPA. The main objective of my position is to make sure that the cleanup in Butte is protective of human health and the environment. So when I come across a new study that has metals associated with public health and statements like "potential public health emergency" I am responsible to provide a due diligence review of those possible health issues that may be associated with contaminants of concern that are associated with my site. To ensure that my review is thorough and accurate I am making the following request:

My request is for the original laboratory report from the cross-sectional pilot study. If the report was developed through a commercial laboratory I would like to request the ICP-MS instrument output in Form 1. If the report was developed through a University Laboratory I would like to request the raw output for the laboratory instrumentation. Additionally, if there are any physical samples that have been preserved, I would like to request them from Butte and Columbia or both. I am particularly interested in the physical samples from Columbia.

Thank you for the consideration.

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