

# **Medical Condition Causation Report**

**Concerning the residents of the communities of:**

**Rawl, Lick Creek, Sprigg, and Merrimac  
West Virginia**

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Attached are annexes that outline the medical reasoning for each condition associated with the exposures to contaminated water in the affected communities. For each plaintiff, please refer to the annex(es) that correlate with marks on the disorders worksheet. Please refer to each annex for a discussion of that condition.

Introduction

- Annex A - Tooth Disorder or Periodontal Diseases**
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Introduction

Residents of the affected communities of Rawl, Lick Creek, Sprigg, and Merrimac West Virginia have been exposed to water containing a number of contaminants for many years. These contaminants occurred at levels far in excess of the levels permitted by the EPA for drinking water.

Some of these are trace elements normally found in the human diet, and essential for normal function of the body. For these elements, the body has homeostatic mechanisms which will regulate their levels in the body, however at very high exposure levels these mechanisms can be overwhelmed and toxic effects seen.

Below is an extract of the well monitoring data from Dr Simonton, as abstracted by Ms. Seeberger. I added the columns calculating the average and maximum measurements, based upon the analysis of 82 samples detailed in the spreadsheet.

Contaminant of	er	Cl	as	sif	ica	A	D	W		
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			Avg	Max
		Ug/L		
Aluminum		200	3045.0111 1	26900
Antimony		6	1.56763	4.23
Arsenic	A	50	24.55475	691
Barium	D	2000	566.83902	5380
Beryllium		4	6.63863	39.1
Cadmium (water)		5	1.99440	13.3
Chromium	D	100	3.62256	70.2
Iron		300	52473.907 89	18800 00
Lead	B2	15	23.67803	439
Magnesium		NA	15469.135 80	76200
Manganese (nonfood)	D	50	606.18566	5830
Mercury	D	2	#DIV/0!	#NU M!
Nickel		NA	29.80308	152
Potassium		NA	3110.3225 8	7720
Selenium	D	50	1.60409	8.66
Silver	D	100	#DIV/0!	#NU M!
Sodium		NA	59202.195 12	36100 0
Stontium		NA	896.92073	4280
Sulfate		25000 0	84832.592 59	51500 0
Titanium		NA	81.77000	210
Zinc	D	5000	673.66139	16400

As a result of being exposed to this water for several decades, residents of the area have developed a number of diseases which are either caused directly by the water or exacerbation is significantly contributed to by exposure to the contaminated water.

This document will address each of the exposure-related conditions that were listed as columns in the spreadsheet from Dawn Seeberger, dated April 20, 2007. The final three conditions from the spreadsheet, Attention Deficit Hyperactivity Disorder (ADHD or ADD), Learning Disability, and Autism will be addressed in a separate report by Dr Robert Miller.

The purpose of this document is to review the science connecting each of the listed medical conditions to the exposures in the affected communities, to explain how the contaminated water could cause these conditions, and then to offer an opinion as to causation.

#### **ESTABLISHING CONDITIONS/DIAGNOSES**

The issue of establishing the presence of a particular condition in a particular plaintiff will be addressed as follows:

- For conditions where the patient report is sufficient (a symptom rather than diagnosis), the plaintiff's report will be accepted as true.
  - Diarrhea
  - Recurrent kidney stones
  - Skin Rashes, boils, and cysts
  - Hair Loss
  - Tooth Disorder or Periodontal Diseases
  
- For conditions where a medical diagnosis is needed, the medical records will be reviewed and the physician diagnosis recorded.
  - Kidney Failure / Dialysis / Transplant
  - All cancers
  - Liver Disorder
  - Gall Stones and Gall Bladder Removed
  - Eye Disorder or Blindness
  - Attention Deficit Hyperactivity Disorder (ADHD or ADD)
  - Learning Disability
  - Autism

For all conditions where the medical records include opinions as to causation, the medical records will be reviewed and a specific causation opinion will be offered.

#### **LITERATURE REVIEW**

Many of the effects seen in this community are so commonly accepted as being produced by these exposures that there is little to no current research available. For these conditions the literature review will start with reference to Cecil's Textbook of Medicine, 22<sup>nd</sup> edition from 2004, which was viewed online. This is one of two standard textbooks of internal medicine. Relevant sections of text will be included in this report, along with the reference to the text.

For topics not discussed in Cecil's, references to the peer-reviewed literature will be included.

#### **EXPOSURE OVERVIEW**

The residents of this area are exposed to this water through a variety of routes, including ingestion, bathing, and inhaled volatilized contaminants in the shower<sup>1</sup>. It is noted that in their report ATSDR “eliminated” several of these routes from their consideration. I feel that this omission is incorrect, and resulted in a significant underestimate of the exposure of the residents in the affected areas.

The ingested route was “eliminated” by ATSDR, and while some of the residents were able to purchase bottled water for consumption, many others were not.

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<sup>1</sup> Finley BL, Kerger BD, Dodge DG, Meyers SM, Richter RO, Paustenbach DJ. Assessment of airborne hexavalent chromium in the home following use of contaminated tap water. *Journal of Exposure Analysis and Environmental Epidemiology*. 6(2), 229-245.

## **Annex A - Medical Condition: Tooth Loss**

(aka: , “soft teeth”, and periodontal disease)

### **HISTORY RELATED BY THE PLAINTIFF:**

The plaintiff reports suffering from tooth loss. For the purposes of this annex, the term tooth loss refers to loss of tooth due to periodontal disease, or any other cause of edentulousness, unless another cause has been diagnosed by a dentist.

### **MEDICAL RECORDS REVIEWED:**

This is a condition where the plaintiff’s report should be sufficient to verify the presence of the condition. Individual records were not reviewed for this condition

### **EXPOSURE:**

The water in the affected communities contains arsenic, cadmium, iron, lead, manganese, strontium, and many other solutes. Several of these are associated with tooth loss.

There is animal evidence of strontium causing tooth decay and tooth loss, as well as literature discussing the fate of ingested strontium.

Lead is classically associated with gum disease and tooth loss, back to the time of Hippocrates, who commented on the edentulous potters (due to lead in the glazes.)

### **DISCUSSION OF THE MEDICAL CONDITION:**

Tooth loss can result from a number of conditions, including periodontal (Gum) disease, erosion of the teeth, and caries. There is limited information available about many of the plaintiff’s, due to infrequent dental care.

### **MEDICAL OPINION:**

The people of this community have a similar exposure through their consumption of water containing elevated concentrations of chemicals associated with tooth damage and loss. It is my medical opinion that this plaintiff’s tooth damage and loss is causally related to the exposure to the contaminated water by the plaintiff.

## **Annex B - Medical Condition: Liver Disorders**

### **History related by the plaintiff:**

This plaintiff reports suffering from liver disease. Liver disease is generally identified through the presence of abnormal liver tests, although consideration for liver transplantation would also be adequate evidence of liver disease.

### **Exposure:**

The water in the affected communities contains elevated amounts of a variety of solutes, including elevated magnesium, arsenic, and copper.

### **Medical Explanation:**

There are several distinct disease processes that could cause liver failure or liver disorders in this population due to the excess copper and manganese.

Wilson's disease is a disorder of copper metabolism. While this disease is genetic in origin, the progression of the disease is based upon the rate of accumulation of copper in the body. The more copper intake a person has (such as in their drinking water), the faster this disease would progress. Wilson's disease causes liver dysfunction and dementia.

### **Medical Literature Reviewed:**

Cecil's Textbook of medicine, Chapter 20, section *Other Toxic Metals* states:  
"Manganese contamination of dialysates or ingestion has been associated with abdominal pain, liver dysfunction, and evidence of pancreatitis."

Cecil's Textbook of Medicine, in chapter 20, section "Other Toxic metals" references the association of manganese with "Liver Dysfunction".

### **Medical Opinion:**

This plaintiff is at risk from manganese-induced liver dysfunction from consumption of the water in this community.

## **Annex C - Medical Condition: Gall Stones and Gall Bladder Removal**

### **History related by the plaintiff:**

This plaintiff reports suffering from gall bladder.

### **Exposure:**

The water in the affected communities contains a very high osmolar load. Solutes in elevated concentrations include Arsenic, Cadmium, Lead, and Chromium.

### **Medical Explanation:**

Gall stones result when there is an accumulation of material (usually cholesterol) in the gall bladder that forms a stone.

Gall bladder disease often follows the formation of a stone, where either the stones impede the ability of the gall bladder to contract normally, the irritant effects of the stones on the inside of the gall bladder result in inflammation of the gall bladder wall, or one of the stones blocks the outflow of bile from the gall bladder. Any of these three mechanisms can result in the signs of gall bladder disease, with the common treatment for all of these conditions being removal of the gall bladder.

### **Medical Literature Reviewed:**

Laboratory evidence suggests that increasing sodium and magnesium concentration in the bile can increase the rate of gall stone formation<sup>2</sup>.

In this population with markedly increased dietary intake of both sodium and cadmium, I would expect that there would be an increase in sodium and magnesium in the bile, resulting in an increased risk of developing gall stones, and subsequent gall bladder disease.

Cancer of the gall Bladder has been associated with exposure to water contaminated with Cadmium, chromium, and lead<sup>3</sup>.

### **Medical Opinion:**

This plaintiff developed gall bladder disease as a result of their consumption of water with elevated concentrations of sodium and magnesium.

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<sup>2</sup> Neithercut WD. Effect of calcium, magnesium and sodium ions on in vitro nucleation of human gall bladder bile. *Gut*, 1989, 30, 665-670.

<sup>3</sup> Shukla VK, Prakash A, Tripathi BD, Reddy DCS, Singh S. Biliary heavy metal concentrations in carcinoma of the gall bladder: case-control study. *BMJ*. 1998 November 7; 317(7168): 1288–1289.

## Annex D - Medical Condition: (Recurrent) Kidney Stones

### HISTORY RELATED BY THE PLAINTIFF:

This plaintiff reports suffering from kidney stones. While some people seek medical attention when they have a kidney stone, many patients, once they understand the disease process, will treat this condition at home, resulting in their being no medical records generated. As such, I believe that it is appropriate to accept the patients report as to the frequency of the episodes of kidney stones they are experiencing.

Kidney stones occur in up to 12% of Caucasian US males, and 5% of females in the general public. However, the issue at hand here is an increased frequency of kidney stones due to the chemical exposures found in the water in this community.

### EXPOSURE:

The water in the affected communities contains lead, cadmium, arsenic, and high concentrations of many solutes. While there is limited human data on their cumulative effects, the combined risk is likely at least summative, and perhaps greater.

Cecil's Textbook of Medicine, chapter 126, in the introduction states:

It has been estimated that about 12% of U.S. men and 5% of U.S. women have at least one kidney stone by the age of 70.

Cecil's, Chapter 126, section "Physical Chemistry of Nephrolithiasis" paragraph \_\_\_\_ states:

The factors influencing the degree of urinary supersaturation include the amount of the constituent salts excreted per unit of time, urine volume, presence of inhibitors of crystallization, and urine pH. **If a defined amount of salt excretion per 24 hours is obligatory, the urine volume in which that salt is to be dissolved becomes of paramount importance with regard to supersaturation. A low urine volume, which is a function of water intake, is a risk factor for all kinds of kidney stones.** pH exerts variable effects on supersaturation. (emphasis added)

Cecil's, in Chapter 120, in the section on "Heavy Metals" includes in paragraph 4 of this section:

Of the other heavy metals associated with CTIN (see Table 120-4), cadmium is a relatively more common source of renal toxicity. Exposure to cadmium results in the preferential accumulation of cadmium in the proximal tubule, where it is retained with a rather long biologic half-life of at least 10 years. Its local toxic effect results in CTIN whose principal manifestations are those of proximal tubular dysfunction: aminoaciduria, glucosuria, uricosuria, bicarbonaturia, and hypercalciuria. **Urinary calculi occur in one fourth of these cases.** (emphasis added.)

Järup L, Elinder CG. Br J Ind Med. Incidence of renal stones among cadmium exposed battery workers. 1993 Jul;50(7):598-602. This article finds an increased incidence of Kidney Stones in cadmium-exposed workers, especially in those who smoke.

#### DISCUSSION OF THE MEDICAL CONDITION:

The reference from Cecil's emphasizes the importance of concentrated urine in formation of stones. The water in this community, by virtue of the very high load of non-absorbable solutes, caused the body to divert water from urinary system into the GI tract (causing diarrhea), taking away much of the water that would normally have passed through the urinary tract and diluted the urine.

While there is an underlying rate of kidney stones in the general population, the rates and frequency in this population (81 of the plaintiffs report kidney stones or recurrent kidney stones out of 488 adults in the database, or an occurrence rate of 16.6%), which significantly exceeds the 12% that would be expected in an adult US population.

#### MEDICAL OPINION:

The people of this community have a similar exposure through their consumption of water containing elevated concentrations of chemicals associated with kidney stones, specifically both general osmolality of the water and specifically the arsenic contribute significantly to developing this problem. It is my medical opinion that this plaintiff's frequent kidney stones are causally related to the plaintiff's exposure to the contaminated water in the affected communities.

**Annex E - Medical Condition: Kidney Disease / Failure / Dialysis**  
(Specifically including: Kidney Disease, Kidney Failure, Renal Failure, Kidney Dialysis, Kidney Transplant, Renal Transplant)

**Explanatory Note:** The disease in question is kidney disease and/or subsequent renal failure. This disease occurs on a continuum, with initially there being kidney disease, where the kidneys are not working normally, but able to meet the needs of the body. This can progress to the point where the kidneys become unable to meet the needs of the body.

When the kidneys become unable to provide sufficient cleansing of the blood, one of three things occurs, either the patient goes on dialysis, they receive a kidney transplant, or they die. In the histories obtained in this case, it is generally the outcome (dialysis, kidney transplant, or death from renal failure) that is recorded. From a medical perspective these should be combined, since they are different outcomes from one disease process.

**HISTORY RELATED BY THE PLAINTIFF:**

The plaintiff reports that they suffer from renal disease, impaired renal function, renal failure, are on dialysis, or have had a kidney transplant. This is verified in the medical record abstract for this patient.

**MEDICAL RECORDS REVIEWED:**

I have reviewed medical records for this plaintiff. Please refer to the diagnosis confirmation sheet for this plaintiff.

**EXPOSURE:**

The water in the affected communities contains lead, sodium, iron, and cadmium. Each of these exposures alone is associated with renal failure. While there is limited human data on their cumulative effects, the combined risk is likely at least summative, and perhaps greater.

**MEDICAL LITERATURE REVIEWED**

Cecil's textbook of medicine (online version, viewed 6/16/07) starts their discussion of toxic nephropathies with the following table, which lists the accepted metal-related causes of renal diseases:

**Table 120-4 -- HEAVY METAL NEPHROTOXICITY**

<b>Chronic tubulointerstitial disease:</b> bismuth, cadmium, chromium, copper, iron, <b>lead</b> , lithium, mercury, platinum, silicon, uranium
<b>Acute renal failure:</b> arsenic, bismuth, cadmium, chromium, copper, gold, iron, <b>lead</b> , mercury, silver, uranium
<b>Nephrotic syndrome:</b> bismuth, gold, mercury, nickel

**Associating arsenic with renal failure.**

Hong F, Jin T, Zhang A. Risk assessment on renal dysfunction caused by co-exposure to arsenic and cadmium using benchmark dose calculation in a Chinese population. *Biometals*. 2004 Oct;17(5):573-80.

**Associating lead with renal failure**

Lin JL, Lin-Tan DT, Li YJ, Chen KH, Huang YL. *Am J Med*. Low-level environmental exposure to lead and progressive chronic kidney diseases. 2006 Aug;119(8):707.e1-9.

**Associating cadmium with renal failure**

Cecil's, chapter 120, includes the following paragraph:

Of the other heavy metals associated with CTIN (see Table 120-4 ), cadmium is a relatively more common source of renal toxicity. Exposure to cadmium results in the preferential accumulation of cadmium in the proximal tubule, where it is retained with a rather long biologic half-life of at least 10 years. Its local toxic effect results in CTIN whose principal manifestations are those of proximal tubular dysfunction: aminoaciduria, glucosuria, uricosuria, bicarbonaturia, and hypercalciuria. Urinary calculi occur in one fourth of these cases.

Bruce Fowler<sup>4</sup> has looked at the impact of lead, arsenic, cadmium, and mercury on renal cell function. He describes the mechanisms and effects of these exposures on kidney function.

**MEDICAL OPINION:**

By virtue of consuming water from this community, the plaintiff was exposed to elevated concentrations of several chemicals that are associated with causing damage to the kidneys, including disease following low-level chronic exposures. It is my medical opinion that the exposure to the contaminated water in this community substantially contributed to the development of this plaintiff's renal disease/failure.

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<sup>4</sup> Fowler BA, *Mechanisms of Kidney Cell Injury from Metals*. *Environmental Health Perspectives*. Vol. 100, pp. 57-63, 1992

## **Appendix F – Kidney-related Surgery**

**Reserved – Covered under Annex D or E**

## **Annex G - Medical Condition: Chronic Diarrhea**

### **History related by the plaintiff:**

This plaintiff reports suffering from chronic diarrhea. Diarrhea is a condition where the person suffers from frequent watery bowel movements. While many people experience intermittent diarrhea (associated with viruses or diet), this plaintiff reports they have chronic diarrhea, which is NOT a normal medical condition.

### **Exposure:**

The water in the affected communities contains a very high osmolar load. The concept of osmolarity is based upon summing the totality of the dissolved solutes in water, and the calculated osmolality of the water is elevated in the well water throughout the community.

### **Medical Explanation:**

Loose stools occur when there is excess water in the bowels relative to the solids. This can occur when there is either a defect in the mechanisms in the large intestine that normally would reabsorb the water (as occurs in many viruses), or when there is something inside the bowels that draws additional water in.

In chemistry, the concept that the water will follow the solute across a permeable membrane in an effort to dilute the solute is well accepted. The bowel wall is one such permeable membrane, and if the water a person is consuming contains excessive amounts of solute, then water will enter the intestines in an effort to dilute this solute, causing diarrhea.

Therapeutically physicians will treat patients with constipation by giving medicines that increase the osmolarity inside the intestines by giving the patient a medication with a high non-absorbable osmolarity (called osmotic laxatives), such as lactulose, magnesium citrate, magnesium hydroxide, or sorbitol.

Elevated levels of sulfate in water has a well documented laxative effect (CDC publication listed below), and I would expect that the laxative effects from the sulfate and the other non-absorbable solutes.

### **Medical Literature Reviewed:**

Cecil's Textbook of Medicine, in chapter 141, pathophysiology section, third paragraph, describes the mechanism for osmotic load to cause diarrhea.

Cecil's also refers several places in chapter 141 to the use of Magnesium (Mg<sup>2+</sup>) as an effective osmotic laxative. The chart in the introduction describes how the water in this community contained significant magnesium.

Additionally, Cecil's, in table 141-1, lists arsenic as a toxic cause of increased intestinal secretion.

Mullhaupt B. Diarrhea. Schweiz Rundsch Med Prax. 2002 Oct 16;91(42):1749-56

ATSDR first report on this water. Containing the following:

The levels of sulfate found, up to 408 mg/L, are not expected to cause any harmful health effects in the general population. However, some people who are not accustomed drinking water with this level of sulfates might experience diarrhea. This effect might occur in people moving into or visiting the area or in infants drinking formula reconstituted by use of water high in sulfates.

Centers for Disease Control and Prevention. Health effects from exposure to high levels of sulfate in drinking water study. Atlanta: Centers for Disease Control and Prevention; 1999 Jan; US Environmental Protection Pub. No:815-R-99-001.

**Medical Opinion:**

This plaintiff has suffered chronic diarrhea because their consumption of water with a very high osmolar load, due to the contamination of their well water. Additionally, in the initial ATSDR report, they opine that the level of sulfites in this water could be associated with diarrhea. It is my medical opinion that this plaintiff's chronic diarrhea is directly caused by the contaminated water in their community.

## **Annex H - Medical Condition: Exacerbation of Crohn's Disease**

### **History related by the plaintiff:**

This plaintiff reports they suffers from Crohn's disease.

Medical Records: This plaintiff's records were reviewed to verify a physician diagnosis of Crohn's disease.

### **Exposure:**

The water in the affected communities contains a very high osmolar load.

**Medical Explanation:** Crohn's disease is an inflammatory condition of the digestive tract that can affect any portion of the GI tract, and is characterized by "skip lesions", where portions of the intestines are affected while others are spared.

The primary symptom of Crohn's is diarrhea, which is sometimes bloody. Patients with Crohn's typically suffer these symptoms intermittently.

There is no medical literature associating the development of Crohn's disease with toxic exposures, however, there is literature associating an increased symptoms in Crohn's patients following environmental exposures.

The water in this community has several attributes that can cause diarrhea (see Annex G). The water would increase the frequency and/or intensity of the symptoms suffered by this plaintiff. For example, a patient who might otherwise suffer symptoms from their Crohn's disease once a month if drinking clean water might experience 2-3 flares a month due to the water in this community.

### **Medical Literature Reviewed:**

Sleisenger & Fordtran's Gastrointestinal and Liver Disease, 8th ed., Chapter on Crohn's disease etiology mentions likelihood of exacerbation of Crohn's due to environmental factors.

### **Medical Opinion:**

This plaintiff has experienced an increased frequency and severity of exacerbations of their Crohn's Disease due to their exposure to the contaminated water.

**Annex I - Medical Condition: Colon Cancer**

**Reserved**

## **Annex J - Medical Condition: Brain Cancer**

### **History related by the plaintiff:**

This plaintiff has been diagnosed with brain cancer. The term “brain cancer” refers to a variety of different types of cancer occurring within the skull.

### **Exposure:**

The water in the affected communities contained a very high load of dissolved solutes, especially lead and arsenic.

### **Medical Explanation:**

Several of the contaminants in the water have been associated with increasing the frequency of brain cancer, most notably arsenic and lead.

Cancer epidemiology is different from the epidemiology of non-cancers in that there is less of a direct connection between the dose and the development of disease, as there is no threshold below which exposure does not cause disease. Rather, there is usually a slope, where lower exposure has lower incidence of disease, but disease still occurs, even at lower exposure.

### **Medical Literature Reviewed:**

The IARC posting: Volume 87: Inorganic and organic lead compounds  
10–17 February 2004, viewable at <http://monographs.iarc.fr/ENG/Meetings/vol87.php>  
includes:

*Brain cancer:* Four of the six cohort studies reported findings for tumours of the brain and nervous system, but there was no consistent pattern in these studies. In addition, in a separate cohort of workers, a nested case–control study did show a statistically significant, positive dose–response relationship between blood lead concentrations and the risk for glioma: this cohort had lower exposures to lead than the other occupational cohorts. All studies were based on small numbers of deaths.

Navas-Acién A, Pollán M, Gustavsson P, Plato N. Occupation, exposure to chemicals and risk of gliomas and meningiomas in Sweden. *Am J Ind Med.* 2002 Sep;42(3):214-27.

In their results, Navas-Acién, et al, states: “...increased risk of glioma with occupational exposure to arsenic, mercury, and petroleum products and of meningioma with lead. Women in occupational sectors with a higher socio-economic status showed an increased incidence of both, gliomas and meningiomas....”

### **Medical Opinion:**

This plaintiff developed brain cancer as a result of their exposure to the water in the community, especially the lead and arsenic in the water.

## **Annex K - Medical Condition: Skin Cancer (unexposed Areas)**

### **History related by the plaintiff:**

This plaintiff reports that they have been diagnosed with skin cancer. Most skin cancers develop as a result of sun exposure. However skin cancers on non-sun-exposed areas are usually due to toxic exposures. The plaintiff was exposed to excessive arsenic in their drinking water, which is directly associated with developing skin cancers in non-sun-exposed areas.

### **Exposure:**

The water in the affected communities contains a very high level of arsenic, with levels as high as 691 µg/l.

### **Medical Literature Reviewed:**

Cecil's Textbook of Medicine, in chapter on arsenic reviews the diseases caused by arsenic exposure, including the following paragraph:

Chronic exposure is associated with cutaneous lesions, particularly hyperpigmentation (arsenic melanosis) and hyperkeratoses located primarily on the palms and soles. Alopecia and so-called raindrop depigmentation also may occur. In 5 to 10% of patients chronically exposed, skin cancers appear after latent periods of 5 to more than 25 years; these tend to be multiple and are situated mainly on the trunk and upper extremities. An epidemic of skin cancers is under way in India and Bangladesh after arsenic-contaminated deep well waters replaced bacteriologically contaminated surface water. In the United States, the most frequent cause of these skin lesions in past years was the medicinal use of Fowler's solution, an inorganic trivalent arsenical. Currently, most cases arise after occupational exposure, but a few have been ascribed to chronic exposure to well water with high arsenic content. Epidemiologic studies on gold ore and tin miners, vineyard workers, laborers in sheep-dip factories, and smelter workers show a clear increase in the incidence of squamous cell carcinoma of the lung, the risk of bronchogenic cancer correlating with the intensity and duration of arsenic trioxide exposure, and all are potentiated by smoking. Considerable debate continues regarding federal actions to mandate lowering the tolerable levels of arsenic in drinking water supplies from 50 ppm to 10 ppm—based almost exclusively on extrapolations of data from India, Bangladesh, Chile, and Taiwan about both levels of arsenic in drinking water as well as illnesses virtually never seen in the U.S.

The human cancers section of the International Agency for Research on Cancer (IARC) statement on carcinogenicity from Arsenic states:

The available studies point consistently to a causal relationship between skin cancer and heavy exposure to inorganic arsenic in drugs, in drinking-water with a high arsenic content, or in the occupational environment.

The risk of lung cancer is clearly increased in certain smelter workers who inhale high levels of arsenic trioxide. However, the causative role of arsenic is uncertain,

since the influence of other constituents of the working atmosphere cannot be determined. An increased relative frequency of deaths from lung cancer has been found in other occupational groups exposed to high levels of inorganic arsenic compounds (e.g., sheep-dip workers, certain mining and vineyard workers).

Cases of lung cancer occurring after the medicinal use of inorganic arsenic compounds, and of liver haemangioendothelioma following various kinds of exposure to arsenic have been reported, but these may be chance associations.

**Medical Opinion:**

It is widely accepted that excessive arsenic in drinking water is causative for the development of skin cancers in exposed populations. It is my medical opinion that the plaintiff developed skin cancer as a direct result of their exposure to the water in the effected communities.

## **Annex L - Medical Condition: Kidney Cancer**

### **History related by the plaintiff:**

This plaintiff reports that they developed kidney cancer. Kidney cancer is associated with exposure to arsenic and lead.

### **Exposure:**

The water in the affected communities contains very concentrations of lead and arsenic, which were consumed by the plaintiff for an extended period of time.

### **Medical Explanation:**

Cancer epidemiology is different from the epidemiology of non-cancers in that there is less of a direct connection between the dose and the development of disease, as there is no threshold below which exposure does not cause disease. Rather, there is usually a slope, where lower exposure has lower incidence of disease, but disease still occurs, even at lower exposure.

### **Medical Literature Reviewed:**

The IARC posting: Volume 87: Inorganic and organic lead compounds  
10–17 February 2004, viewable at <http://monographs.iarc.fr/ENG/Meetings/vol87.php>  
includes:

*Kidney cancer:* Five of the six cohort studies reported findings for kidney cancer. In one study, there was a statistically significant two-fold excess of kidney cancer, based on comparison with an external reference population. All five studies were based on small numbers of deaths.

Hopenhayn-Rich<sup>5</sup>, et al, looked at the frequency of cancers associated with arsenic-contaminated drinking water in Argentina, concluding that there is an increased frequency of kidney and Lung cancers.

Bruce Fowler<sup>6</sup> reviewed the effects of several of these toxicants, concluding that there is an important effect on both renal cell function and possible neoplastic changes from these exposures.

### **Medical Opinion:**

It is my medical opinion that this plaintiff's consumption of the contaminated water in the community substantially contributed to the development of kidney cancer in this plaintiff.

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<sup>5</sup> Hopenhayn-Rich C, Biggs ML, Smith AH, Lung and kidney cancer mortality associated with arsenic in drinking water in Cordoba, Argentina. *International Journal of Epidemiology* 1998,27:561-569.

<sup>6</sup> Fowler BA, Mechanisms of Kidney Cell Injury from Metals. *Environmental Health Perspectives*. Vol. 100, pp. 57-63, 1992

## **Annex M - Medical Condition: Liver Cancer**

### **History related by the plaintiff:**

This plaintiff has been diagnosed with liver cancer. The attached record review will review the details of this diagnosis.

### **Exposure:**

The water in the affected communities contains a variety of contaminants, including significantly elevated levels of iron and arsenic.

### **Medical Explanation:**

Liver cancer is a condition which follows a malignant transformation of liver cells. Liver cells can undergo this transformation following exposure at a variety of levels. While there will usually be less cancer that develops in areas of lower exposure and higher rates of liver cancer in areas of higher concentration. However, this does mean that there will still be cases of cancer develop due to the exposure, even at lower exposure levels.

### **Medical Literature Reviewed:**

There is literature<sup>7</sup> associating increased iron exposure with an increased risk of liver cancer.

There is a markedly increased risk of liver cancer in persons with hemochromatosis<sup>8</sup>, which would be accelerated by increased dietary iron intake.

Arsenic is associated with hemangioendotheliosarcoma of the liver. ... Arsenic may also lead to non-cirrhotic portal hypertension<sup>9</sup>.

### **Medical Opinion:**

This plaintiff developed liver cancer as a result of their exposure to iron and arsenic in the drinking water in this community

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<sup>7</sup> Su LP, Guan HY, Zhao LF, Zhang JM, Chen WH. Cohort mortality study of dust exposed miners in iron mine. *Zhonghua Lao Dong Wei Sheng Zhi Ye Bing Za Zhi*. 2006 Jun;24(6):360-3

<sup>8</sup> Kowdley KV *Gastroenterology*. Iron, hemochromatosis, and hepatocellular carcinoma. 2004 Nov;127(5 Suppl 1):S79-86.

<sup>9</sup> Schmid M. Effects of the environment on the liver and gastrointestinal tract *Schweiz Med Wochenschr*. 1976 Feb 28;106(9):289-95.

## **Annex N - Medical Condition: Bladder Cancer**

### **History related by the plaintiff:**

This plaintiff reports that they suffer bladder cancer. This will be confirmed by a physician diagnosis.

### **Exposure:**

The water in the affected communities contains a very high arsenic in the water.

### **Medical Explanation:**

Arsenic is generally associated with the development of bladder cancer, especially based on the increased occurrence of disease in persons living in the “blackfoot endemic” (areas of Taiwan and Bangladesh with high drinking water arsenic) areas, where there is elevated arsenic in the water, much as in this community.

### **Medical Literature Reviewed:**

There are a number of papers looking into the association between arsenic in drinking water arsenic. The best summary is by Lamm, et al<sup>10</sup>, and this includes many references to prior papers on this same topic.

### **Medical Opinion:**

This plaintiff developed bladder cancer as a result of their exposure to the contaminated water in this community, especially the arsenic in elevated arsenic in the water.

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<sup>10</sup> Steven H. Lamm, SH, Engel A, Kruse MB, Feinleib M, Byrd, DM, Lai S, Wilson R. Arsenic in Drinking Water and Bladder Cancer Mortality in the United States: An Analysis Based on 133 U.S. Counties and 30 Years of Observation. Journal of Occupational and Environmental Medicine - Volume 46, Issue 3 (March 2004)

## **Annex O - Medical Condition: Skin rash / boils / cysts**

### **History related by the plaintiff:**

This plaintiff suffers from rash, boils, and/or cysts. This most frequently followed showering and/or bathing in the contaminated water. It should be noted that even the plaintiffs who used bottled water for drinking or cooking still used the local (well) water for bathing, resulting in significant skin contact.

### **Exposure:**

The water in the affected communities contains a very high solute load, including many which are irritants to the skin.

### **Medical Literature Reviewed:**

Wakhlu A, Aggarwal A, Misra RJ. Rheumatol. Chronic arsenic poisoning mimicking Gottron's rash. 2003 Feb;30(2):415-6.

Middleton's Allergy: Principles and Practice, 6th ed., chapter 87 on Contact Dermatitis, Clinical Aspects reports:

The North American Contact Dermatitis Group (NACDG) studied the prevalence of allergic reactions as determined by patch testing between 1994 and 1996. They determined that the 12 most common sensitizers were nickel sulfate, fragrance mix, thimerosal, quaternium-15, neomycin sulfate, formaldehyde, bacitracin, thiuram mix, balsam of Peru, cobalt chloride, PPDA, and carba mix (see [Table 87-1](#)). The hands were the primary site of involvement in about one third of all cases. Generalized eruptions and facial involvement were the next most likely affected areas, followed by the arms, legs, and trunk

### **Medical Explanation:**

There are two distinct effects at work here. The first is chemicals contained in the water which directly cause skin changes, such as arsenic. The second is chemicals which cause a direct contact dermatitis.

### **Medical Opinion:**

This plaintiff has developed rashes and boils from their contact with the water in this community. The arsenic ingestion is associated with several skin diseases, and the high amount of sulfate and other non-neutral chemicals in the water is triggering contact and/or allergic reactions in the skin of this plaintiff.

## **Annex P - Medical Condition: Hair Loss**

### **History related by the plaintiff:**

This plaintiff reports that they suffer hair loss. While hair loss is a normal condition of aging, this plaintiff reports hair loss in excess of or different from normal male-pattern or aging.

### **Exposure:**

The water in the affected communities contains a very high osmolar load, and contains

The concept of osmolarity is based upon summing the totality of the dissolved solutes in water, and the calculated osmolality of the water is elevated in the well water throughout the community, and varies up to XXX, the YYY.

### **Medical Explanation:**

Arsenic, in drinking water, is commonly accepted as causing skin cancer. Studies from Taiwan, Chile, and Bangladesh.

### **Medical Literature Reviewed:**

Cecil's Textbook of Medicine chapter on Arsenic includes the following paragraph:

Chronic exposure is associated with cutaneous lesions, particularly hyperpigmentation (arsenic melanosis) and hyperkeratoses located primarily on the palms and soles. **Alopecia and so-called raindrop depigmentation also may occur.** In 5 to 10% of patients chronically exposed, skin cancers appear after latent periods of 5 to more than 25 years; these tend to be multiple and are situated mainly on the trunk and upper extremities. An epidemic of skin cancers is under way in India and Bangladesh after arsenic-contaminated deep well waters replaced bacteriologically contaminated surface water. In the United States, the most frequent cause of these skin lesions in past years was the medicinal use of Fowler's solution, an inorganic trivalent arsenical. Currently, most cases arise after occupational exposure, but a few have been ascribed to chronic exposure to well water with high arsenic content. Epidemiologic studies on gold ore and tin miners, vineyard workers, laborers in sheep-dip factories, and smelter workers show a clear increase in the incidence of squamous cell carcinoma of the lung, the risk of bronchogenic cancer correlating with the intensity and duration of arsenic trioxide exposure, and all are potentiated by smoking. Considerable debate continues regarding federal actions to mandate lowering the tolerable levels of arsenic in drinking water supplies from 50 ppm to 10 ppm—based almost exclusively on extrapolations of data from India, Bangladesh, Chile, and Taiwan about both levels of arsenic in drinking water as well as illnesses virtually never seen in the U.S.

### **Medical Opinion:**

The development of skin cancer in this plaintiff has been significantly contributed to by the contaminants in their drinking water, especially the arsenic. It is my medical opinion

that this plaintiff's skin cancer was directly caused by the contaminated water in their community.

**Annex R - Medical Condition: Eye Disorder or Blindness**

**Reserved**