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OFFICE OF SECRETARY RULEMAKINGS AND ADJUDICATIONS STAFF

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION ATOMIC SAFETY AND LICENSING BOARD PANEL

Before Administrative Judges: Michael M. Gibson, Chairman Dr. Richard F. Cole Mr. Brian K. Hajek

In the Matter of

CROW BUTTE RESOURCES, INC. (In Situ Leach Facility, Crawford, NE)

Docket No. 40-8943 ASLBP No. 08-867-02-OLA-BD01

September 22, 2008

PETITION FOR LEAVE TO FILE NEW CONTENTION RE: ARSENIC

Judge Gibson, Chair Atomic Safety Licensing Board Panel US Nuclear Regulatory Commission

Dear Judge Gibson:

Pursuant to 10 CFR Section 2.309(f)(2), each of the Petitioners respectfully requests that the presiding officer in this Proceeding grant leave to Petitioners to file a new contention based on the connection between low-level arsenic in the water resulting from Applicant's ISL uranium mine and failures of the pancreas including diabetes and pancreatic cancer in the people living near the mine.

This information was assembled beginning on or about August 20, 2008 when a new study by the Johns Hopkins Bloomberg School of Public Health was published in the Journal of the American Medical Association, an abstract of which is attached as Exhibit A hereto (the "Johns Hopkins Study") ¹. The Johns Hopkins Study shows that low level

¹ <u>Arsenic Exposure and Prevalence of Type 2 Diabetes in US Adults</u>, Ana Navas-Acien, MD, PhD; Ellen K. Silbergeld, PhD; Roberto Pastor-Barriuso, PhD; Eliseo Guallar, MD, DrPH;

exposures of inorganic arsenic in the water such as that resulting from ISL uranium mining increases the risk of Type 2 Diabetes in adults. Diabetes is already an epidemic at Pine Ridge Indian Reservation reported to be 800% higher than the national average.² A related article in the same issue of the Journal of the American Medical Association states that diabetes is the seventh leading cause of death in the United States and complications from diabetes profoundly affect the quality of life and contribute to high morbidity and mortality.³

Section 2.309(f)(2) specifically provides that new contentions may be filed after the initial filing only with leave of the presiding officer upon a showing that—

- (i) The information upon which the new contention is based was not previously available;
- (ii) The information upon which the new contention is based is materially different than information previously available; and
- (iii) The new contention has been submitted in a timely fashion based on the availability of the subsequent information. 10 C.F.R. §2.309(f)(2).

<u>APPLICATION OF SECTION 2.309(f)(2) TO OUR FACTS</u>

First, it should be noted that arsenic is referenced in the Petition in this case as one of the groundwater contaminants of concern. See Petition at p16-17, paragraph (5), paragraph (6) and paragraph (7). Arsenic is also mentioned as the reason for the closures of 98 wells at Pine Ridge Indian Reservation. <u>Id.</u> at p17, paragraph (7). Diabetes was referenced in the Petition in connection with Petitioner Joe American Horse (Affidavit of

Journal of the American Medical Association (August 20, 2008) (Vol. 300(7):814-822). http://www.jhsph.edu/publichealthnews/press_releases/2008/navas_acien_arsenic.html.

² See, e.g., http://www.backpacksforpineridge.com/Stats About Pine Ridge.html.

³ Environmental Arsenic Exposure and Diabetes, Molly L. Kile, MS, ScD; David C. Christiani, MD, MPH, MS; Journal of the American Medical Association (August 20, 2008) (Vol. 300(7): 845-46).

Joe American Horse at paragraph 5 and was mentioned during the January 16, 2008 Oral Arguments in the remarks of Chief Joe American Horse. Transcript (ML080220489) at 129 ("I am a diabetic...we have diabetics. I don't know where it came from.")

The Application in the Expansion Proceeding (relevant because the North Trend Expansion is the satellite facility mention in LRA Section 7.12.4.2) admits that arsenic is rising in the Brule Aquifer. Expansion Proceeding Petition at p13 (re: ER Table 3.4-15) (incorporated by reference at Petition page 6), and these are part of Petitioners environmental and safety contentions in this case. See Expansion Petition at p15 ("the returned water is geochemically different and contains high levels of arsenic and continues to have higher than natural concentrations of radioactivity.")

As this case has progressed, more has been learned about the connections between Applicant's ISL uranium mine in the Chadron Aquifer and the release of arsenic and related health impacts to the people living nearby in the form of diabetes and pancreatic cancer.

(i) New Information Not Previously Available

On or about August 20, 2008, Petitioners became aware of the Johns Hopkins Study and the connection between arsenic in the drinking water and adult onset of Type 2 diabetes. On or about August 28, 2008, WNRC Attorney David Frankel became aware of a high incidence of pancreatic cancer in Chadron. See Affidavit of David Frankel, filed herewith, at paragraph 3. WNRC Attorney Frankel left a message with one of the cancer suffers, Mr. Watson, but failed to reach him. Based on information and belief,

there are at least seven (7) cases of pancreatic cancer in Chadron⁴ which has a population of 5,208⁵ which is about 20 times the national average of 11.5 cases per 100,000 Americans.⁶ See US National Institute of Health National Cancer Center at http://seer.cancer.gov/statfacts/html/pancreas.html; During discovery, the parties can ascertain the exact status of these cases several of which resulted in the death of the cancer patient. Upon information and belief, the families of each of the victims are available for testimony in Chadron.

(ii) Materially Different Information

Although Petitioners cite the 1982 Baseline Study in the Petition (see p22 et seq.), the significance of the information therein related to Arsenic was not revealed until the Johns Hopkins Study was released and the information about the high incidence of pancreatic cancer in Chadron was discovered. See, Baseline Hydrogeochemical Investigation in a Part of Northwest Nebraska, A Report Prepared for the Nebraska Department of Environmental Control; starting at page 126 of the July 28, 2008 Petition at ML082170525 ("the 1982 Baseline"). The 1982 Baseline shows that Arsenic levels increase in an oxidizing environment such as that intentionally created by Applicant's mining activities. The 1982 Baseline concludes in part that:

"Arsenic levels exceeded the MCL of 50 ppb in only one well water...." <u>Id</u>. at ii.

⁴ Including Messrs. Daniels, Hageman, Trafinigan, & Watson; Frankel Affidavit at paragraph 3.

⁵ See http://www.bestplaces.net/city/Chadron-Nebraska.aspx ("as of 2007, Chadron's population is 5,208 people.")

⁶ Statistically, Chadron should have no more than 0.60 cases of pancreatic cancer in its population.

"Arsenic levels were quite variable but showed a generalized increase in older **oxidizing** formation waters. This is demonstrated in a trend towards higher average As concentrations in lower Brule and upper Chadron formation waters than in either the Brule or Arikaree waters.... Therefore, in slightly oxidizing environments such as those reported in the upper Chadron and lower Brule where there are occurrences of relatively high arsenic levels in the sediments, the groundwater could become enriched in As.

Arsenic levels exceeded the maximum contaminant level (MCL) of 50 ppb in only one well. Thus in terms of the water quality, arsenic is not of particular concern in the groundwater of the investigated area. Id. at 52 (emphasis added.)

"Slightly elevated As and Mo appeared in #649 which is believed to be a spring originating in the Chadron formation. Highest concentrations of pathfinder elements result from a relatively high component of White River Group seepage in the base flow of the creeks. Id. at 55.

The connection between Applicant's ISL mine and the high levels of Arsenic (As) in the water are revealed by the fact that Arsenic was said in 1982 not to be a problem and is now a problem. *Res Ipsa Loquitor*; See Petition at p17, paragraph (7). Further, the high incidence of pancreatic cancer in Chadron indicates that the mine's operations during the past 20 years have severely and negatively impacted the water quality through the release of measurable levels of Arsenic. The Arsenic is released due to the oxidizing of the Uranium by Applicant's mining operations. Such levels of Arsenic have adversely impacted public health particularly causing ailments associated with the pancreas such as diabetes and pancreatic cancer. These connections were not fully known until on or about August 28, 2008 and this information taken together constitutes materially different information than what was previously known to Petitioners when the initial Petition was

filed in July 2008.

(iii) <u>Timeliness of Filing</u>

Petitioners understand that general NRC practice is that new contentions are to be filed within thirty days after the new information is received. See Judge Young's remarks during July 23, 2008 Oral Argument in Expansion Proceeding, Transcript at 425-426 (ML082180280). Further, Petitioners understand that NRC practice is to file the petition for leave and the new contention at the same time. The thirty day period should not start until August 28, 2008 when the information was received concerning the high incidence of pancreatic cancer in Chadron. Accordingly, this Petition for New Contention is timely filed on September 22, 2008.

ADMISSIBILITY OF CONTENTION

If the Presiding Officer grants Petitioners leave to file a new contention related to Arsenic as described above, such contention should be admitted under Section 2.309(f)(1) which requires that Petitioners:

- (i) Provide a specific statement of the issue of law or fact to be raised or controverted;
- (ii) Provide a brief explanation of the basis for the contention;
- (iii) Demonstrate that the issue raised in the contention is within the scope of the proceeding;
- (iv) Demonstrate that the issue raised in the contention is material to the findings the NRC must make to support the action that is involved in the proceeding;
- (v) Provide a concise statement of the alleged facts or expert opinions which support the requestor's/petitioner's position on the issue and on which the petitioner intends to rely at hearing, together with references to the specific sources and documents on which the requestor/petitioner intends to rely to support its position on the issue;
- (vi) Provide sufficient information to show that a genuine dispute exists with the applicant/licensee on a material issue of law or fact.

For these purposes, the facts and contentions raised in the Petition are incorporated herein by this reference, including the specific references to the Application. Accordingly, the findings of the Board in LBP-08-06 support the findings that this new contention is within the scope of the proceeding, is material to the findings that NRC must make to support the action involved, may be based on a plausible fact-based argument, and constitutes a genuine dispute with Applicant.

For this new contention, it is only necessary to provide a specific statement of the issue to be raised under (i), a brief explanation for the contention under (ii), and a concise statement of the alleged facts supporting Petitioners' position on the issue and on which Petitioners intend to rely at the hearing under (v).

Under (i), the issue raised by this new contention is that Arsenic being released by the oxidizing of Uranium due to Applicant's injection of lixiviant and that such levels of Arsenic (even if within US drinking water standards) constitutes ongoing low-level exposure to Arsenic which causes failures in the pancreas to people drinking water affected into which the Arsenic flows. Such pancreatic failures result in diabetes and pancreatic cancer.

Under (ii), the basis for this contention is that the AEA and NRC Regulations cited in the Petition require Applicant's operations to be conducted without harm to public health and safety. Further, NEPA requires that the water not be contaminated with Arsenic to the detriment of the health of the people drinking water affected by the mine.

Under (v), the alleged facts and references are those discussed above including that the Johns Hopkins Study shows a link between low-levels of Arsenic in the drinking water and Type 2, Adult-Onset Diabetes. Diabetes reflects a failure in the pancreas.

Chadron appears to have a very high incidence of pancreatic cancer that is 20 times the national average. The testimony of the Chadron victims of pancreatic cancer and further investigation into the incidence of pancreatic cancer at Pine Ridge Indian Reservation is required and contemplated to support this new contention. In addition, further testing needs to be done to show the exact levels of Arsenic in the drinking water of the people of Crawford, Chadron and Pine Ridge Indian Reservation.

Diabetes can be caused by pancreatic failure. <u>See Pancreatic Cancer Symptoms</u> and Signs, Pancreatic Cancer UK, at

http://www.pancreaticcancer.org.uk/PCSymptoms.htm. There is a link between diabetes and pancreatic cancer. <u>See Probability of Pancreatic Cancer Following Diabetes: A Population-Based Study</u>, Journal of the Institute of the American Gastroenterological Association, Vol. 129, No. 2 at 504-511 (August 2005) ("Approximately 1% of diabetes subjects aged ≥50 years will be diagnosed with pancreatic cancer within 3 years of first meeting criteria for diabetes.")

The LRA shows that Applicant is aware that its ISL Uranium mining causes oxidation of the Uranium and the release of Arsenic into the water including the Brule Aquifer. See, e.g., LRA Section 2.9.6 quoted at Petition page 35. Prior findings by the Board in LBP-08-06 show that the Petitioners have met their initial burden that there exist fractures and faults and pathways along The White River which lead to the human and environmental exposure to increased Arsenic levels from Applicant's mine. These exposures to Arsenic from Applicant's mine are related to the high incidence of diabetes and pancreatic cancer and appear to be a causal and contributing factor to such diseases being suffered by the people nearby the mine. The foregoing shows a plausible link

between low levels of Arsenic in the water and failures of the pancreas in the form of diabetes and pancreatic cancer for the people downstream and downgrade of the Mine.

CONCLUSION

For the reasons stated above, the Presiding Officer should grant Petitioners leave to file this new contention in this proceeding and should find this new contention to be an admissible contention.

Dated this <u>22nd</u> day of September, 2008.

Respectfully submitted,

David Frankel

Attorney for Petitioners

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UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION ATOMIC SAFETY AND LICENSING BOARD PANEL

Before Administrative Judges: Michael M. Gibson, Chairman Dr. Richard F. Cole Mr. Brian K. Hajek

In the Matter of

CROW BUTTE RESOURCES, INC. (In Situ Leach Facility, Crawford, NE)

Docket No. 40-8943 ASLBP No. 08-867-02-OLA-BD01

September 22, 2008

CERTIFICATE OF SERVICE

I hereby certify that copies "PETITIONERS' REQUEST FOR LEAVE TO FILE NEW CONTENTION RE ARSENIC" in the above captioned proceeding has been served on the following persons by electronic mail as indicated by a double asterisk (**); on this 22nd day of September, 2008:

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UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION ATOMIC SAFETY AND LICENSING BOARD PANEL

In the Matter of

Docket No. 40-8943 License SUA-1543

CROW BUTTE RESOURCES, INC. (In Situ Leach Facility, Crawford, NE)

September 22, 2008

AFFIDAVIT

I, David C. Frankel, hereby state as follows:

- 1. I make this affidavit in connection with a new contention to be added in the Proceedings related to the application of Crow Butte Resources, Inc. d/b/a Cameco Resources, a/k/a The Crow Butte Project concerning *in situ leach* uranium mine near Crawford, Nebraska (the "Mine"). I am fully familiar with the facts stated in this affidavit.
- 2. I am attorney for Western Nebraska Resources Council which is a petitioner to intervene in the Mine's North Trend Expansion Proceeding and the Mine's Renewal Proceeding.
- 3. During the course of my representation, I interviewed certain persons in the town of Chadron, Nebraska, concerning the incidence of pancreatic cancer. Such interviews included an interview on or about August 28, 2008, with an individual named Mike Waugh at Hills Tire, Chadron, NE, who informed me that at least seven (7) people that he personally knew or knew of had pancreatic cancer, which people included Mr. Watson, Mr. Daniels, Mr. Hageman and Mr. Trafinigan. I left a phone message for Mr. Watson and have not yet attempted to contact the others.

1

- 4. A cursory review of available data shows that the national average for pancreatic cancer is 11.5 out of 100,000 people. <u>See US National Institute of Health National Cancer Center at http://seer.cancer.gov/statfacts/html/pancreas.html. Chadron has a population of about 5,200 people. Accordingly, the seven (7) cases of pancreatic cancer represent a cancer cluster that is 20 times greater than the national average.</u>
- 5. The Journal of the American Medical Association recently published a study showing a linkage between low levels of arsenic in the water and adult onset of diabetes. See Arsenic Exposure and Prevalence of Type 2 Diabetes in US Adults, Ana Navas-Acien, MD, PhD; Ellen K. Silbergeld, PhD; Roberto Pastor-Barriuso, PhD; Eliseo Guallar, MD, DrPH; Journal of the American Medical Association (August 20, 2008) (Vol. 300(7): 814-822). See also,

http://www.jhsph.edu/publichealthnews/press_releases/2008/navas_acien_arsenic.html.

6. Diabetes can be caused by pancreatic failure. <u>See Pancreatic Cancer</u>
Symptoms and Signs, Pancreatic Cancer UK, at
http://www.pancreaticcancer.org.uk/PCSymptoms.htm. There is a link between diabetes and pancreatic cancer. <u>See Probability of Pancreatic Cancer Following Diabetes: A Population-Based Study</u>, Journal of the Institute of the American Gastroenterological Association, Vol. 129, No. 2 at 504-511 (August 2005) ("Approximately 1% of diabetes subjects aged ≥50 years will be diagnosed with pancreatic cancer within 3 years of first meeting criteria for diabetes.")

7. The foregoing shows a plausible link between low levels of Arsenic in the

water and failures of the pancreas in the form of diabetes and pancreatic cancer for the

people downstream and downgrade of the Mine.

8. The Mine's oxidation of Uranium deposits results in the release of arsenic

into the water. See Baseline Hydrogeochemical Investigation n a Part of Northwest

Nebraska prepared by Nebraska Department of Environmental Control, starting at page

126 of the July 28, 2008 Petition (Renewal) at ML082170525 (the "1982 Baseline").

9. The Mine's operation releases Arsenic which contributes to or causes

diabetes and/or pancreatic cancer in nearby populations in Crawford, Chadron and Pine

Ridge Indian Reservation.

This Affidavit is submitted in accordance with 10 C.F.R. Section 2.304(d) and 28 U.S.C.

Section 1746. I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 22, 2008 at Seattle, Washington.

1 ittle

DAVID C. FRANKEL

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Surveillance Epidemiology and End Results

providing information on cancer statistics to help reduce the burden of this disease on the U.S. population

SEER Stat Fact Sheets

	/ 	
Cancer:	Choose a Cancer Site	↓ ♦ (Go)

It is estimated that 37,680 men and women (18,770 men and 18,910 women) will be diagnosed with and 34,290 men and women will die of cancer of the pancreas in 2008 1 .

The following information is based on NCI's SEER Cancer Statistics Review ².

Incidence & Mortality

SEER Incidence

From 2001-2005, the median age at diagnosis for cancer of the pancreas was 72 years of age 3 . Approximately 0.0% were diagnosed under age 20; 0.4% between 20 and 34; 2.4% between 35 and 44; 9.6% between 45 and 54; 18.9% between 55 and 64; 26.6% between 65 and 74; 29.5% between 75 and 84; and 12.5% 85+ years of age.

The age-adjusted incidence rate was 11.5 per 100,000 men and women per year. These rates are based on cases diagnosed in 2001-2005 from 17 SEER geographic areas.

Incidence Rates by Race

Race/Ethnicity	Male	Female	
All Races	13.0 per 100,000 men	10.3 per 100,000 women	
White	13.0 per 100,000 men	10.0 per 100,000 women	
Black	16.2 per 100,000 men	14.3 per 100,000 women	
Asian/Pacific Islander	10.1 per 100,000 men	8.2 per 100,000 women	
American Indian/Alaska Native a	10.9 per 100,000 men	8.2 per 100,000 women	
Hispanic ^b	10.9 per 100,000 men	10.3 per 100,000 women	

US Mortality

From 2001-2005, the median age at death for cancer of the pancreas was 73 years of age 4 . Approximately 0.0% died under age 20; 0.2% between 20 and 34; 1.8% between 35 and 44; 8.2% between 45 and 54; 17.4% between 55 and 64; 26.3% between 65 and 74; 31.3% between 75 and 84; and 14.8% 85+ years of age.

The age-adjusted death rate was 10.6 per 100,000 men and women per year. These rates are based on patients who died in 2001-2005 in the US.

Death Rates by Race

Race/Ethnicity	Male	Female	
All Races	12.2 per 100,000 men	9.3 per 100,000 women	
White	12.1 per 100,000 men	9.0 per 100,000 women	
Black	15.4 per 100,000 men	12.4 per 100,000 women	
Asian/Pacific Islander	8.0 per 100,000 men	6.9 per 100,000 women	
American Indian/Alaska Native a	8.6 per 100,000 men	7.2 per 100,000 women	
Hispanic ^b	9.1 per 100,000 men	7.6 per 100,000 women	

2 of 5 9/20/08 6:52 AM

Trends in Rates

Trends in rates can be described in many ways. Information for trends over a fixed period of time, for example 1995-2005, can be evaluated by the **annual percentage change (APC)**. If there is a negative sign before the number, the trend is a decrease; otherwise it is an increase. If there is an asterisk after the APC then the trend was significant, that is, one believes that it is beyond chance, i.e. 95% sure, that the increase or decrease is real over the period 1995-2005. If the trend is not significant, the trend is usually reported as stable or level. **Joinpoint analyses** can be used over a long period of time to evaluate when changes in the trend have occurred along with the APC which shows how much the trend has changed between each of the joinpoints.

The joinpoint trend in SEER cancer incidence with associated APC(%) for cancer of the pancreas between 1975-2005

All Races					
Male and Female		Male		Female	
Trend	Period	Trend	Period	Trend	Period
-2.1	1975-1978	-0.9*	1975-1993	1.3*	1975-1983
1.1	1978-1984	0.3	1993-2005	-0.1	1983-2005
-0.9*	1984-1993				
0.4*	1993-2005				

The joinpoint trend in US cancer mortality with associated APC(%) for cancer of the pancreas between 1975-2005

	All Races				
Male and Female		Male		Female	
Trend	Period	Trend	Period	Trend	Period
-0.1*	1975-2003	-0.8*	1975-1986	0.8*	1975-1984
1.2	2003-2005	-0.3*	1986-2003	0.1*	1984-2005
		1.3	2003-2005		

Survival & Stage

Survival rates can be calculated by different methods for different purposes. The survival rates presented here are based on the **relative survival rate**, which measures the survival of the cancer patients in comparison to the general population to estimate the effect of cancer. The overall 5-year relative survival rate for 1996-2004 from 17 SEER geographic areas was 5.1%. Five-year relative survival rates by race and sex were: 5.1% for white men; 4.9% for white women; 3.6% for black men; 5.4% for black women.

The **stage distribution** based on historic stage shows that 7% of pancreas cancer cases are diagnosed while the cancer is still confined to the primary site (localized stage); 26% are diagnosed after the cancer has spread to regional lymphnodes or directly beyond the primary site; 52% are diagnosed after the cancer has already metastasized (distant stage) and for the remaining 15% the staging information was unknown. The corresponding 5-year relative survival rates were: 20.0% for localized; 8.2% for regional; 1.8% for distant; and 4.3% for unstaged.

Lifetime Risk

3 of 5 9/20/08 6:52 AM

Based on rates from 2003-2005, 1.33% of men and women born today will be diagnosed with cancer of the pancreas at some time during their lifetime. This number can also be expressed as 1 in 75 men and women will be diagnosed with cancer of the pancreas during their lifetime. These statistics are called the **lifetime risk** of developing cancer. Sometimes it is more useful to look at the **probability of developing** cancer of the pancreas between two age groups. For example, 0.51% of men will develop cancer of the pancreas between their 50th and 70th birthdays compared to 0.40% for women.

Prevalence

On January 1, 2005, in the United States there were approximately 29,445 men and women alive who had a history of cancer of the pancreas -- 14,355 men and 15,090 women. This includes any person alive on January 1, 2005 who had been diagnosed with cancer of the pancreas at any point prior to January 1, 2005 and includes persons with active disease and those who are cured of their disease. **Prevalence** can also be expressed as a percentage and it can also be calculated for a specific amount of time prior to January 1, 2005 such as diagnosed within 5 years of January 1, 2005.

References

All statistics in this report are based on SEER incidence and NCHS mortality statistics. Most can be found within:

Ries LAG, Melbert D, Krapcho M, Stinchcomb DG, Howlader N, Horner MJ, Mariotto A, Miller BA, Feuer EJ, Altekruse SF, Lewis DR, Clegg L, Eisner MP, Reichman M, Edwards BK (eds). *SEER Cancer Statistics Review, 1975-2005*, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2005/, based on November 2007 SEER data submission, posted to the SEER web site, 2008.

Footnotes

- 1 Table I-1 (http://seer.cancer.gov/csr/1975 2005/results single/sect 01 table.01.pdf)
- 2 Pancreas Section (http://seer.cancer.gov/csr/ 1975 2005/results merged/ sect 22 pancreas.pdf)
- 3 Table I-11 (http://seer.cancer.gov/csr/1975 2005/results_single/sect_01_table.11_2pgs.pdf)
- 4 Table I-13 (http://seer.cancer.gov/csr/1975 2005/results single/sect 01 table.13 2pgs.pdf)
- * The APC is significantly different from zero (p<.05).
- a Incidence data for Hispanics is based on NHIA and excludes cases from Alaska Native Registry and Kentucky. Hispanic death rates exclude deaths from Minnesota, New Hampshire and North Dakota.
- b Incidence and mortality data for American Indians/Alaska Natives is based on the CHSDA (Contract Health Service Delivery Area) counties.

Definitions

Annual percent change (APC)

The average annual percent change over several years. The APC is used to measure trends or the change in rates over time. For information on how this is calculated, go to <u>Trend Algortihms</u> in the SEER*Stat Help system. The calculation involves fitting a straight line to the natural logarithm of the data when it is displayed by calendar year.

Joinpoint analyses

A statistical model for characterizing cancer trends which uses statistical criteria to determine how many times and when the trends in incidence or mortality rates have changed. The results of joinpoint are given as calendar year ranges, and the annual percent change (APC) in the rates over each period.

Survival rates

Survival examines how long after diagnosis people live. Cancer survival is measured in a number of different ways depending on the intended purpose.

Relative survival rate

A measure of net survival that is calculated by comparing observed (overall) survival with expected survival from a comparable set of people that do not have cancer to measure the excess mortality that is associated with a cancer diagnosis.

Stage distribution

Stage provides a measure of disease progression, detailing the degree to which the cancer has advanced. Two methods commonly used to determine stage are AJCC and SEER historic. The AJCC method (see Collaborative Staging Method) is more commonly used in the clinical settings, while SEER has standardized and simplified staging to ensure consistent definitions over time.

Lifetime risk

The probability of developing cancer in the course of one's lifespan. Lifetime risk may also be discussed in terms of the probability of developing or of dying from cancer. Based on cancer rates from 2003 to 2005, it was estimated that men had about a 44 percent chance of developing cancer in their lifetimes, while women had about a 37 percent chance.

Probability of developing cancer

The chance that a person will develop cancer in his/her lifetime.

Prevalence

The number of people who have received a diagnosis of cancer during a defined time period, and who are alive on the last day of that period. Most prevalence data in SEER is for limited duration because information on cases diagnosed before 1973 is not generally available.

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<u>Volume 129, Issue 2, Pages 504-511 (August 2005)</u>

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Probability of Pancreatic Cancer Following Diabetes: A Population-Based Study

Suresh T. Chari * , Cynthia L. Leibson[‡], Kari G. Rabe[‡], Jeanine Ransom[‡], Mariza de Andrade[‡], Gloria M. Petersen[‡]

Received 17 January 2005; accepted 20 April 2005.

Background & Aims: Although diabetes occurs frequently in pancreatic cancer, the value of new-onset diabetes as a marker of underlying pancreatic cancer is unknown. Methods: We assembled a population-based cohort of 2122 Rochester. Minnesota, residents age ≥50 years who first met standardized criteria for diabetes between January 1, 1950, and December 31, 1994, and identified those who developed pancreatic cancer within 3 years of meeting criteria for diabetes. We compared observed rates of pancreatic cancer with expected rates based on the Iowa Surveillance Epidemiology and End Results registry. In a nested case control study, we compared body mass index (BMI) and smoking status in diabetes subjects with and without pancreatic cancer. Results: Of 2122 diabetic subjects, 18 (0.85%) were diagnosed with pancreatic cancer within 3 years of meeting criteria for diabetes; 10 of 18 (56%) were diagnosed <6 months after first meeting criteria for diabetes, and 3 were resected. The observed-to-expected ratio of pancreatic cancer in the cohort was 7.94 (95% CI, 4.70-12.55). Compared with subjects without pancreatic cancer, diabetic subjects with pancreatic cancer were more likely to have met diabetes criteria after age 69 (OR = 4.52)95% Cl, 1.61-12.74) years but did not differ significantly with respect to BMI values (29.2 \pm 6.8 vs 26.5 \pm 5.0, respectively). A larger proportion of those who developed pancreatic cancer were ever smokers (92% vs 69%, respectively), but this did not reach statistical significance. Conclusions: Approximately 1% of diabetes subjects aged ≥50 years will be diagnosed with pancreatic cancer within 3 years of first meeting criteria for diabetes. The usefulness of new-onset diabetes as marker of early pancreatic cancer needs further evaluation.

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Abbreviation used in this paper: REP, Rochester Epidemiology Project

^{*} Division of Gastroenterology and Hepatology, Department of Internal Medicine, Rochester, Minnesota, USA

 $^{^{}rac{1}{2}}$ Department of Health Sciences Research, Mayo Clinic College of Medicine, Rochester, Minnesota

Address requests for reprints to: Suresh T. Chari, MD, Mayo Clinic College of Medicine, Division of Gastroenterology and Hepatology, 200 First St SW, Rochester, Minnesota 55905. fax: (507) 284 5486.

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The grants and sponsors did not influence design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

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Elizabeth Lorina; Brett Klukan; trsmith@winston.com; shanecrobinson@gmail.com;

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Ryan

Subject: Transmitting Document in Crow Butte (Renewal) - Docket 40-8943 - ASLBP No. 08-867-02-

OLA-BD01

Attachments: Petitioners Request for Leave to File New Contention re Arsenic (Renewal) 09222008.pdf;

Petitioners New Contention re Arsenic (Renewal) EIE conformed COS.pdf

Hello All,

Attached for filing is Petitioners' Request for Leave to file a new contention re Arsenic and related COS (conformed to include all EIE service list recipients) -

Sincerely,

David Frankel Attorney for Petitioners POB 3014 Pine Ridge, SD 57770 Arm.legal@gmail.com 308-430-8160

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Ryan

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08-867-02-OLA-BD01

Attachments: Frankel Affidavit 09222008.pdf; SEER Stat Fact Sheets - Cancer of the Pancreas.pdf;

Probability of Pancreatic Cancer Following Diabetes_ A Population-Based Study.pdf; JAMA -- Environmental Arsenic Exposure and Diabetes, August 20, 2008, Kile and Christiani 300 (7)_ 845.pdf; JAMA -- Abstract_ Arsenic Exposure and Prevalence of Type 2 Diabetes in US Adults, August 20, 2008, Navas-Acien et al. 300 (7)_ 814.pdf; Arsenic Exposure Could Increase Diabetes Risk.pdf; Pancreatic Cancer UK Pancreatic Cancer Symptoms and

Signs.pdf

Attached are the Attachments to the referenced Request:

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- > David Frankel
- > Attorney for Petitioners
- > POB 3014
- > Pine Ridge, SD 57770
- > Arm.legal@gmail.com
- > 308-430-8160

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       Johanna Thibault < Johanna. Thibault@nrc.gov>,
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       <Shahram.Ghasemian@nrc.gov>,
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