Appendix:

The Value of Consumer Loss Relating to Foodborne Reactive Arthritis

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Introduction

This appendix details the calculation of economic losses to consumers from developing reactive arthritis (ReA) as a result of a foodborne *Salmonella* infection The agency requests comments on all aspects of this appendix, especially the link between ReA and *Salmonella* infections and any variation in that link with the different *Salmonella* species.

This study has relied primarily on the work of Thomson, et al. to describe ReA in terms of attack rate, severity and duration This study was chosen because it represents the most recent primary research into this issue The study is of post-*Salmonella*-infection ReA in a point source cohort concurrently exposed to the same microorganism Because the study is specific to a *Salmonella* outbreak, any variation related to ReA resulting from infections of other pathogens is eliminated. Because the study is based on epidemiological follow-up of an outbreak of foodborne illness rather than reviews of clinical reports and medical records, its results are well suited to applying to epidemiological data on cases of *Salmonella* related to juice consumption

I. Description of Foodborne Relationship

Reactive arthritis commonly occurs in young men and women (and sometimes children). ReA refers to pain, stiffness, redness or swelling in a joint resulting from a previous infection, usually involving the digestive or genito-urinary systems such as *Salmonella*, *Yersinia*, *Shigella* and *chlamydia* infections. (Ref. http://text.arthritis ca/types/reactive.html)

II. Description of ReA

Stiffness and pain are often worse in the morning. Arthritis most often occurs in the joints of the lower limbs (knees, ankles, toes), but the upper limbs can also be involved. Problems may be in the joints only or involve other body systems such as the eyes, skin, or tendons. Occasionally there is heel pain where the Achilles tendon attaches to the bone, or underneath the foot where the tendons supporting the arch of the foot attach to the heel. Sometimes there is back pain resulting from involvement of the sacroiliac joints

Women may develop cervicitis (irritation of the cervix) but there may be no symptoms. In men urethritis (discharge from the urethra, difficult or painful urination) may develop Painful or painless skin ulcers may appear in the mouth, or on the penis, or vagina These features are similar to those in Reiter's syndrome Problems with the eyes may result in mild or severe symptoms including pain or sensitivity to sunlight. Sometimes these problems occur many months prior to the onset of joint problems

Sometimes the disease is self-limiting, meaning it goes away with no remaining problems. Other people have recurrent attacks Most people manage well with treatment Ongoing joint problems may result in stiff joints and weak muscles and it often becomes difficult to fully straighten the joints

Treatments

1 Medication

Short-term antibiotics (usually tetracycline) are sometimes used to treat the initial infection Non-steroidal anti-inflammatory drugs (NSAIDs), most commonly Voltaren (diclofenac) or Indocid (indomethacin), are used to treat joint problems. Intra-articular steroid injections can help the pain and swelling in single joints. Occasionally, stronger medications such as RheumatrexTM (methotrexate) are used.

Eye problems should be managed jointly by a rheumatologist and an ophthalmologist (eye specialist) Treatment for eye problems is usually steroid drops but oral corticosteroids are sometimes needed in more severe cases.

2. Heat/cold

3 Exercise

4. Protecting Joints

Protecting joints means using joints in ways that avoid excess mechanical stress from daily tasks There are three main techniques for protecting joints:

Pacing: alternating heavy or repeated tasks with easy tasks or breaks.

Joint Position: using joints in the best way to avoid extra stress. For example, using larger, stronger joints to carry loads, such as a shoulder bag instead of a hand-held purse, and avoiding keeping the same position for a long time.

Helpful Devices: such as canes, luggage carts, grocery carts, special chairs, etc., can help perform daily tasks. Small appliances such as microwaves, food processors and bread makers can be useful in the kitchen. Grab bars and shower seats are important protection against falls.

5 Weight Control

Lifestyle

Along with the physical symptoms of RA, many people experience feelings of helplessness and depression. (Ref. http://text.arthritis.ca/types/reactive.html)

III. Percent of Cases

The incidence of ReA following *Salmonella* infection is often reported to be about 1-2%. Thomson et al. found an incidence of 6.6% (27/411).[1] This is consistent with studies of other epidemics where a dysenteric population forms the inception cohort. The greater incidence reflects the methodology of surveying an entire dysenteric population.

Of those persons with *Salmonella* infections 2.2% (33% of the total that developed ReA) experienced pain that resolved completely within 4 months. Another 2.4% (37% of the total that developed ReA) experienced flares and remissions of pain with periods of wellness in between. Another 1% (15% of the total that developed ReA) experienced waxing and waning of symptoms

[1] Percentages have been recalculated based on the actual number of persons contacted in the 5 year follow-up survey (411) instead of the number of persons which originally experienced acute gastroenteritis (423)

with no periods of wellness. Finally, 1% (15% of the total that developed ReA) experienced chronic unremitting pain.

IV. Duration

Of those persons who experienced pain that resolved completely within 4 months, 22% (2/9) were asymptomatic within 7 days, 67% (6/9) were asymptomatic within 28 days, 11% (1/9) were asymptomatic within 120 days. If symptoms resolved three quarters of the way through each of these periods (i e , 5 days, 20 days, and 80 days respectively), then the weighted average duration for this group is about 25 days.

Persons in the other categories were still experiencing symptoms 5 years after the onset of the gastrointestinal illness. The duration of ReA in such patients is taken to be for the rest of their lives. Thomson et al. found that the mean age of onset of ReA was not statistically different from the mean age of the infected population. Information from CDC indicates that in 1996 the average age of persons contracting salmonellosis is 27. Using an average life span of 77 years, the average person developing long term ReA following a *Salmonella* infection will experience symptoms for 50 years (18,250 days).

V. Functional Status Codes and Disutility

In order to quantify the disutility that individuals experience from developing ReA, the reduction in mobility and physical and social activity must be scaled. This study uses one type of scaling of these effects following the work of Bush et al. Individuals who become ill experience different levels of functional status in terms of mobility, ability to do other physical activity, and ability to engage in social activities. Functional status disutility represents a degree of departure from perfect functionality.

According to Thomson et al "Two thirds [18 out of the 27 that developed ReA] continued to have subjective complaints, mostly of minor significance. However, symptoms were severe enough to force a change in work for 4 patients [15%]." The other third showed signs and symptoms of active inflamation that resolved within a 4 month period with no late exacerbations

Course of Disease	Percent of Total ReA Patients
Resolved Pain within 4 Months	33%
Flares and Remissions with Periods of Wellness	37%
Waxing and Waning with No Periods of Wellness	15%
Chronic Unremitting Pain	15%

For the two categories of patients where there is no indication of change in the course of the illness during its duration (regardless whether the duration is 1 month or 50 years) the functional status code of L35 is assigned. These patients experience no change in mobility but suffer a reduction in physical and social activity.

For the two remaining categories of patients where there is an indication of change in the course of the illness a combination of the functional status codes L41, L42 and L43 is assigned For the 15% of ReA patients which never experience periods of wellness, codes L41 and L42 were assigned in equal portions ((L41 x 5) + (L42 X 5)) For the 37% of ReA patients which do experience periods of wellness, codes L41, L42 and L43 were assigned in equal portions ((L41 x 33) + (L42 X 33) + (L43 X 34))

Function Status Level	Mobility	Physical Activity	Social Activity	Level of Disutility
L35	Drove car & used transportation without help	Walked with physical limitations	Limited in work, school, or housework	3980
L41	Drove car & used transportation without help	Walked without physical limitations	Did work, school, or housework, but other activities limited	3145
L42*	Drove car & used transportation without help	Walked without physical limitations	Did work, school, or housework, and other activities	2567
L43*	Drove car & used transportation without help	Walked without physical limitations	Did work, school, or housework, and other activities	.0000

* Code 42 is used whenever the mobility, physical activity and social activity conditions apply and a person is experiencing a symptom Code L43 is used whenever the mobility, physical activity and social activity conditions apply and a person is experiencing no symptoms.

Course of Disease	Percent of Total ReA Patients	Functional Status Disutility
Resolved Pain within 4 Months	33%	3980
Flares and Remissions with Periods of Wellness	37%	1885
Waxing and Waning with No Periods of Wellness	15%	2856
Chronic Unremitting Pain	15%	3980

VI. Symptom/Problem Code and Disutility

Additionally, in order to quantify the disutility that individuals experience from developing ReA, the pain and suffering must be scaled Again, this study uses the scaling of these effects by Bush et

al Individuals who become ill experience disutility due to the symptoms of illness

The characteristic pain symptoms of arthritis can be described as pain, stiffness, numbness, or discomfort of neck, hands, feet, arms, legs, ankles, or several joints together This description corresponds to the Bush et al Symptom/Problem Complex code of 19 Therefore, the level of symptom-related disutility assigned to each category of patients for each day they experience symptoms is 0344 For the 37% of ReA patients which do experience periods of wellness, this level of disutility is assigned for only two thirds of the time for an average daily disutility of .0227

VII. Total Disutility per Day per Case

Course of Disease	Percent of Total ReA Patients	Functional Status Disutility per Day	Symptom/ Problem Complex Disutility per Day	Total Daily Disutility	Duration in Days	Total Disutility per Case (in Quality Adjusted Life Days Lost)
Resolved Pain within 4 Months	33%	3980	0344	4324	25	11
Flares and Remissions with Periods of Wellness	37%	1885	0227	.2112	18,250	3,854
Waxing and Waning with No Periods of Wellness	15%	2856	0344	3200	18,250	5,840
Chronic Unremitting Pain	15%	3980	0344	4324	18,250	7,891
Weighted Average of Long-Term Cases		2582	0280	2862		5,223

VIII. Medical Cost Estimate

Direct information on the direct medical cost (cost of medical treatment and patient care) per case of ReA is not available Medical costs for ReA are calculated based on the assumption that medical costs per case of ReA are equivalent to the medical costs per case of the average case of all types of arthritis Information indicates that in 1992 the total cost in terms of direct medical costs and lost wages of all types of arthritis was about $65 billion dollars Of this total 24% was

due to direct medical costs and 76% was due to lost wages (Ref www nih gov/niams/news/lappin htm National Institute of Arthritis and Musculoskeletal and Skin Diseases "Arthritis· What We Know Today," Debra R. Lappin, Esq , May 30, 1997) According to the National Health Interview Survey, an estimated 40 million Americans have arthritis. Approximately 6 million people are self-diagnosed (that is, they believe that they have arthritis, but have not sought medical attention for it)
(Ref http //www arthritis org/offices/al/about/demecoinfo shtml)

Based on this information, the total direct medical cost for all types of arthritis is approximately $16 billion per year ($64 8 billion x 24%) Therefore the average direct medical cost per arthritis sufferer is approximately $400 per year ($16 billion ÷ 40 million). This medical cost estimate is used for long term ReA cases. Discounted at 7% annually the total medical cost for an average case of ReA lasting 50 years is estimated to be $5,860 The medical cost for a short term case of ReA lasting 25 days on average is estimated at $100

IX. Total Value of Losses per Case

To determine the total value of losses per case associated with ReA it is necessary to add the utility losses per case to the medical costs per case. To do this it is necessary to monetize the value of the utility losses. FDA values a Quality Adjusted Life Day at $630.

Course of Disease	Percent of Total ReA Patients	Total Disutility per Case (in Quality Adjusted Life Days Lost)	Value of Utility Losses per Case (Discounted at 7%) (QALD = $630)	Medical Costs per Case (Discounted at 7%)	Total Value of Losses per Case
Resolved Pain within 4 Months	33%	10.8	$6,800	$100	$6,900
Flares and Remissions with Periods of Wellness	37%	3,854.4	$711,500	$5,900	$717,400
Waxing and Waning with No Periods of Wellness	15%	5,840.0	$1,078,000	$5,900	$1,083,900
Chronic Unremitting Pain	15%	7,891 3	$1,456,700	$5,900	$1,462,500
Weighted Average of Long-Term Cases		5,223.2	$962,000	$5,900	$967,900

Printed Reference

Thomson, Glen T. D., Debra A. DeRubeis, Matthew A. Hodge, Cecilia Rajanayagam, Robert D Inman 1995 "Post-*Salmonella* Reactive Arthritis: Late Clinical Sequelae in a Point Source Cohort." *American Journal of Medicine* 98 (January): 13-21.