

adverse health effects occur, a point advanced by several in their testimony to the docket (e.g., United Parcel Service, Ex. 500-197, pp. I-68; Vender attachment to UPS post-hearing comments, Ex. 500-118, page 17). Dr. Hadler opined that “whenever a relationship between exposure and effect is not linear (not monotonic), you can be sure there are confounders, \* \* \*.” (Hadler attachment to UPS post-hearing comments, Ex. 500-118, page 4). He offered no evidence in support of this assertion, and in fact there is no requirement in epidemiology that the relationship must either be linear or monotonic. OSHA has relied on non-linear dose-response relationships in other health standard rulemakings (see Formaldehyde, 54 FR46168, Cadmium 57 FR 42101).

Second, most exposure-response relationships do not indicate a single exposure level that unambiguously differentiates risk from no risk. This is especially true if exposure is treated as continuous and the relationship fits a straight line through the origin, in which case each small increment in exposure increases the probability of an adverse health outcome and, extrapolated downward, there may be no discernable point without excess risk above the zero exposure level. Note that in this regard U.P.S. criticized OSHA for the assumption that, in fact, UPS had made: “OSHA has falsely assumed that any increment of human muscle usage is harmful, \* \* \*.” (United Parcel Service, Ex. 500-197, pp. I-68).

On the other hand, when exposures have been categorized and are ordinarily associated with risk of disease, it can be argued that the first exposure level where an elevated risk is observed above baseline represents an appropriate point for a permissible exposure level (at least until subsequent studies clarify whether there is still excess morbidity occurring below that level). This type of approach was taken recently by the American Conference of Governmental Industrial Hygienists (2000), which used essentially the same epidemiologic evidence available to OSHA—with its variety of exposure metrics—to determine the proposed new Threshold Limit Value® for occupational hand activity level (see Exs. 38-162, DC-387).

Several authors have called attention to the complexity of the process of utilizing exposure-response data for quantitative risk assessment in the multi-dimensional domain of physical ergonomics (e.g., Armstrong *et al.*, 1993: Ex. 26-1110; Burdorf *et al.*, 1997: Ex. 500-121-13; Frank *et al.*, 1996: Ex. 502-407; Kilbom, 1999: Ex. 38-406; Viikari-

Juntura *et al.*, 1999: Ex. 500-121-73). OSHA finds that it is reasonable to conclude, as these experts have done, that there is a need for continuing study of those relationships and interactions, while at the same time, that it is appropriate to implement the scientific knowledge in hand in order to reduce the risk of work-related MSDs.

In the preamble to the proposed rule (64 FR 65768), OSHA presented the results of several studies that provided evidence for positive trends between exposure to biomechanical risk factors and the prevalence or incidence of MSDs. Three commenters critiqued twelve of these studies, claiming a variety of design or methodological flaws in the studies, computational errors in the studies, or that OSHA misused some of the data (Exs. 30-276, 500-79, 32-241-4). The comments are those of Dr. Steven Moore, Professor, Environmental and Occupational Health, Texas A&M University (Ex. 30-276), Marathon Ashland Petroleum LLC (Ex. 500-79), and Gibson, Dunn & Crutcher (Ex. 32-241-4). Marathon Ashland Petroleum LLC includes Dr. Moore's comments as an Appendix. Gibson, Dunn & Crutcher summarize the critiques of several experts, whose statements are attached to their comment. OSHA responds to all these comments below.

Dr. Moore and Gibson, Dunn & Crutcher criticized the study on risk factors for CTS by deKrom *et al.*, (1990, Ex. 500-41-28). They claim that the study does not account for psychosocial factors and that it is methodologically flawed in relying on self-reported information about duration of exposure, rendering the results meaningless. With respect to the lack of analysis on psychosocial factors, OSHA acknowledges that this case-control study, with cases mostly of hospital outpatients and controls from the general population, did not examine or control for psychosocial factors. However, OSHA finds nothing in the design and analysis of this study that would invalidate the statistically significant positive associations among work related physical factors and CTS that the study did find. The authors concluded that activities with a flexed wrist or with an extended wrist (exposure-related increased ORs) were risk factors for CTS. Dr. Moore criticized the duration analysis used to estimate exposure-response as a function of time, claiming that the survey questionnaire instrument for collecting exposure information was unreliable. OSHA responds that with little information about the survey questionnaire in the published paper, the agency cannot

determine the reliability. However, from a description in the paper of the blindness with which the survey was administered, OSHA believes that such an imperfect exposure measurement instrument would yield non-differential exposure misclassification. Such non-differential misclassification would bias both the ORs and the slope toward a finding of no increasing trend. The fact the deKrom *et al.* study found statistically significant ORs for each incremental number of weekly hours of activities with extended or flexed wrist separately, plus finding a statistically significant exposure-response trend for both duration variables, despite the negative bias, provides strong evidence that the effect is real. This finding is further strengthened by the final analysis of de Krom *et al.* which used a multiple regression model simultaneously containing both duration of “flex” and “extended” wrist activities as variables, with both variables found to be statistically significant for duration-of-exposure-response trends (Ex. 500-41-28, pg. 1108). The finding of joint statistical significance of collinear variables when simultaneously modeled increases confidence in the significance of the separate variables.

OSHA also responds to the criticism that “in a conclusion that would devastate OSHA's attempt to redesign the American office, [deKrom *et al.*] found no significant risk of CTS related to typing.” OSHA notes that of the 156 cases of CTS, only 12 cases reported any work-related typing at all. In a case-control study such as this with only 12 cases exposed to typing, the statistical ability to determine a significant result is very small. Either a different study recruitment procedure or a much larger sample size would be required. With respect to another criticism by Gibson, Dunn & Crutcher on the apparently spurious finding of an association of CTS with varicosis in men, the authors reported this result of their analysis for the scientific world to contemplate, but found it inconsistent with that of other authors (Ex. 32-241-4).

Dr. Moore also criticizes OSHA's use of the MSD prevalence study by Luopajarvi *et al.*, (1979, Ex. 26-56) used as part of the agency's determination of causality for hand/wrist tendinitis. Dr. Moore claims the study's poor exposure assessment and lack of statistical comparisons provide poor support. In response, OSHA notes that the same exposure assessment methods were used in the study comparisons between the assembly-line packers and the shop assistants, so that the differences should be unaffected. OSHA also notes that

these comparison showed that the assembly-line packers had a highly statistically significant ( $p < 0.001$ ) increased prevalence of (1) syndromes found in the neck, shoulders and elbows; and (2) muscle-tendon syndromes in the hands ( $p < 0.001$ ). The most common neck syndrome in this study was tension neck and the most common shoulder disorder was humeral tendinitis. For hands, Luopajarvi *et al.* noted the prevalence of tenosynovitis/peritendinitis at 53% in the assembly-line packers, but only 14% in the shop-assistants (who endured prolonged standing, but otherwise physically light work). For the assembly-line packers the authors noted especially the repetitive motions at a high speed, and fingers and hands constantly used at the pace of the machine, up to 25,000 cycles per workday. For these packers the authors also noted difficult static muscle work, extreme work positions of the hands, and difficult lifting. OSHA believes that this study provides a good comparison between similar demographic groups, and that it provides good evidence that work-related physical stress factors were causing shoulder and upper extremities injuries.

Dr. Moore also claims that errors in the evaluations of two other studies are materially related to the NIOSH's and OSHA's conclusions (Ex. 30-276, pg. 2). With respect to the study by Kuorinka and Koskinen, he criticizes NIOSH for not specifically mentioning the "non-positive" finding of no evidence of association of with time spent in deviated wrist postures per day. OSHA responds that the Kuorinka and Koskinen study did not specifically mention peritendinitis and tenosynovitis in its analysis, only the total complex of muscle-tendon syndrome. Their definition of muscle-tendon syndrome used in this study came from an accompanying article they coauthored in the same journal (see Ex. 26-1218); the definition included syndromes of the shoulder and elbow, along with the wrist and hands. Every one of the seventeen (out of 93) manual workers with muscle-tendon syndrome also had tension neck syndrome, but none was specifically identified as having either peritendinitis or tenosynovitis (Ex. 26-639). While Dr. Moore is correct that Kuorinka and Koskinen found no correlation between the number of signs in the wrist and the deviation load of the wrist joint (1979, Ex. 26-639). OSHA finds too few details in the analysis for any conclusions with respect to peritendinitis and tenosynovitis.

Dr. Moore also criticizes the NIOSH 1997 (Ex. 26-1) review for its failure to

include the findings of a second study, Armstrong *et al.*, (1987, Ex. 500-41-4) in NIOSH's evaluation on the effect of posture for hand/wrist tendinitis. Dr. Moore claims that NIOSH rated the Armstrong *et al.* study as high quality for other physical risk factors (*i.e.* force and repetition, for which the study found highly statistically significant associations) but didn't include the study at all in the discussion of the effect of posture. Armstrong *et al.* reported no significant associations for differences in posture "comparing the percentage of the time spent in various postures between jobs in which there were workers with tendinitis and those in which there were no workers with tendinitis" (Ex. 500-41-4). Dr. Moore claims that this omission by NIOSH and OSHA is an error in evaluation and that this error "would likely have a material impact on the conclusion" (Ex. 30-276).

OSHA has considered Dr. Moore's claim about NIOSH's evaluation of the Armstrong *et al.* study and has concluded that while Dr. Moore is correct in his claim that Armstrong *et al.* found no associations with the posture variable stated above, there is simply not enough detail in the publication to weight that study highly with regard to the posture variable. With this study group Armstrong *et al.* found a highly statistically significant odds ratio of 29.4 ( $p < 0.001$ ) for high force/high repetitiveness hand/wrist motion compared with a low force/low repetitiveness motion group. These groups appeared well defined and well studied with respect to force and repetitiveness, with 652 workers divided fairly evenly among the four groups increasing the statistical power to detect an effect if one exists. However, no detail is given for the posture analysis, only a short paragraph result (Ex. 500-41-4). To study this same highly force- and repetitiveness-stressed group for the effect of posture differences on hand/wrist tendinitis, (and CTS, see Silverstein *et al.*, 1987, Ex. 26-34, and comment in Ex. 32-241-4, pg.143) would appear to be quite difficult, considering the proven effect of force and repetitiveness as risk factors in this worker group. Silverstein *et al.* (1986) studying essentially the same group, discussed postures, stating:

(W)rist postures required on a job are often determined by the height of the work station with respect to the location of the worker. \* \* \* to test this hypothesis the job of each worker in a job would have to have been videotaped and analyzed. This was not done in this investigation. \* \* \* Awkward postures (wrist deviation, flexion, hyperextension, and finger pinching) \* \* \*

were not controlled for in this investigation. (Ex. 26-1404).

OSHA concludes that NIOSH was correct in not considering the Armstrong *et al.* (Ex. 500-41-4) and Silverstein *et al.* 1986 and 1987, (Exs. 26-1404, 26-34) study further for posture with this particular study group.

Gibson, Dunn & Crutcher also criticize OSHA's omission that the Armstrong *et al.*, study "found no significant association between \* \* \* vibration and [hand/wrist tendinitis] (Ex.32-241-4, pg. 140). OSHA responds that the Armstrong *et al.*, 1987, (Ex. 500-41-4) publication provided less information about vibration in the study group than it did about posture, and that apparently it was not a well studied factor in this group.

Dr. Moore also criticizes the "NIOSH and OSHA reviews [for] inappropriately generaliz[ing] results of some studies beyond the constructs used to measure or categorize MSD risk factor [*i.e.*, force and repetitiveness]" (Ex. 30-276, pg. 2-3), singling out Armstrong *et al.* (Ex. 500-41-4) and Silverstein *et al.*, 1987, (Ex. 26-34). OSHA has considered this comment and disagrees with Dr. Moore. Most authors define risk factors slightly differently and the NIOSH analysis had to categorize the slightly different definitions into categories. OSHA believes this categorization does not detract from either the NIOSH analysis or the ability to generalize that force and repetitiveness are etiologically related to hand/wrist tendinitis. In fact, OSHA believes that the different studies' abilities to detect significant associations using different definitions actually make the overall results more generalizable.

Gibson, Dunn & Crutcher, also criticize the Silverstein *et al.*, 1986 study of hand wrist cumulative trauma disorders (CTDs, Ex. 26-1404, and by implication Exs. 26-34 and 500-41-4) for being methodologically flawed, specifically citing recall bias and observer bias as leading to an overestimation of the associations between risk factors and health effect (Ex. 32-241-4, pg. 142-143). They also cite the study's cross-sectional design, the omission of a number of jobs from the investigation, and lack of analysis on non-biomechanical factors as serious flaws.

OSHA has considered this criticism of the methodology, but disagrees with the characterization that a cross-sectional design cannot establish causation. In another section of this preamble, OSHA discusses the value of all the studies together in forming a database to determine causality. OSHA also notes

the claims of bias in this study, but agrees with the Silverstein *et al.*, 1986 study authors who found significant positive and publishable associations between hand wrist CTDs and high force-high repetitive jobs:

The findings in this investigation may also have underestimated the prevalence of hand wrist CTDs in several ways. Firstly, subject selection was limited to active workers, those away from the job with CTDs at the time of evaluation (potentially severe cases) would not have been available for study. Secondly, the one year seniority criteria for subject selection excluded those who might have had CTDs and transferred before one year as well as those with CTDs but not on the job for at least one year. The finding that hand wrist CTDs were negatively associated with age and years on the job support the argument of selection/survival bias in the study population [which would underestimate the effect] (Ex. 26-1404, pg. 784).

Gibson, Dunn & Crutcher criticize the study of shoulder pain in shipyard workers (welders and steel plate-workers) by Herberts *et al.*, 1984, (Ex. 26-51), for methodological flaws, including cross-sectional design, and the lack of demographic matching between the exposed and control groups. (Ex. 32-241-4, pg. 142). They also criticized OSHA for not recognizing what Herberts *et al.* did, have "chronic shoulder pain is \* \* \* common in people not necessarily active in arduous physical work." (Ex. 26-51, pg. 167). OSHA responds that the Agency does recognize that people other than those in HPW have shoulder pain; that recognition allows researchers, OSHA and other analysts to compare the prevalence of shoulder pain in workers doing HPW to that in workers not so engaged, in order to estimate the contribution from HPW. Herberts *et al.* also did this and concluded that "Rotator cuff tendinitis constitutes a major problem in people with arduous occupations, *i.e.*, shipyard welders (PR=18.3%), and steel plate-workers (PR=16.2%)." By contrast, of the 57 clerks in the comparison group only one (1.7%) reported this disorder. Of this highly statistically significant difference, Herberts *et al.*, note:

Since the clerks are on an average older than the other two groups, there would be a higher likelihood of age-induced tendinitis in this [clerks] group. However, the hypothesis is that those with a high physical workload have tendinitis to a greater extent than normal. (Ex. 26-51).

Gibson, Dunn & Crutcher also criticize OSHA's use of the Punnett *et al.*, 1991 (Ex. 26-39) study of back disorders and nonneutral trunk postures in automobile assembly workers. The study is criticized as methodologically flawed in

that it is a case-control study that does not consider non-biomechanical variables (Ex. 32-241-4, pg. 140). Gibson, Dunn & Crutcher quote the authors' own cautions of the limitations of such a design, which is necessarily retrospective in recalling exposures and pre-existing conditions. OSHA acknowledges the limitations of such as design. However, OSHA considers the design, conduct, and analysis of this study quite persuasive—in terms of strength of association, temporality, and exposure-response—in the overall determination of causality of BT and LBP; see OSHA's section on back disorders in this preamble. The authors in their publication conclude:

Back disorders were associated with mild trunk flexion (OR=4.9 (p5% C.I. 1.4-17.4), severe trunk flexion (OR=5.7, 95% C.I. 1.6-20.4), and trunk twist or lateral bend (OR=5.0, 95% C.I. 1.6-21.4). the risk increased with exposure to multiple postures and increasing duration of exposure. (Ex. 26-39, pg. 337).

Gibson, Dunn & Crutcher also criticize Dr. Punnett's more recent study (1998, Ex. 26-38) of upper extremity disorders in vehicle manufacturing, as being methodologically flawed in that it is a cross-sectional design and does not include an analysis of the relative importance of psychosocial factors. OSHA has considered this comment and disagrees. Even though this study is cross-sectional, OSHA considers it well-conducted and analyzed. Using a primary exposure score relating to responses to psychophysical exposure items, Punnett found both statistically significant PRs and significant exposure-response relationships for both (1) shoulder and upper arm disorders and (2) wrist and hand disorders. The results were consistent when the analyses were done both for the symptom cases and the physical examination cases. The authors concluded that "musculoskeletal disorders of the upper extremities were strongly associated with exposure to combined ergonomic stressors." (Ex. 32-241-4) Gibson, Dunn & Crutcher also criticize OSHA's use of the prospective study by Liles and Deivanayagam, 1984 (Ex. 26-33) on job severity index (JSI) for the evaluation and control of lifting injury of the back. The JSI is a function of lifting frequency of task, maximum required weight of lift, adjusted capacity of the individual, and total lifting frequency. Criticism of the study focuses on a potential bias which Gibson, Dunn & Crutcher call a "nocebo effect", a bias due to differential reporting of pain symptoms by the subjects, knowing that their symptoms are being monitored. OSHA

responds that such a potential bias is purely speculative, and, in any case, does not explain either the increasing injury rate, the cumulative disabling injury rate or the cumulative severity rates seen with increasing JSI. (Ex. 26-33, pgs. 690-691).

Gibson, Dunn & Crutcher also criticize the study by Snook *et al.*, (1978, Ex. 26-35) on three preventive approaches to low back injury. The study is criticized as being methodologically flawed in that it is a cross-sectional study which looks solely at biomechanical risk factors, and cannot establish causation. However, Gibson, Dunn & Crutcher also quote several portions of the article that it wants OSHA to recognize: (1) that most cases of industrial back injury have no known cause, and recovery occurs before any cause is ever found, (2) some workers never suffer from low back pain regardless of their type of work, and others seem to get it in spite of what they do; and (3) "low back injuries are usually not serious; four out of five workers suffering from low back injuries return to the job within three weeks." (Ex.32-241-4). OSHA responds that this Snook *et al.*, case-series study of 191 low back injuries is of limited usefulness in determining causality, but it does suggest that low back injury is associated with excessive manual handling tasks. OSHA also acknowledges the general apparent truthfulness of statement (2), by Snook *et al.*, but can find no reference for it in the article. Statement (1) of Snook *et al.*, references a 1970 published article and a 1971 editorial. There is more recent science available. Statement (3) cites one 1966 study as its reference.

Gibson, Dunn & Crutcher also criticize a study by (1992, Ex. 26-36) on low back and neck/shoulder pain in construction workers. They claim that the study is methodologically flawed in that it is cross-sectional in design, limiting its ability to show causality. At the same time they criticize OSHA for failing to discuss the study's findings of positive associations between LBP and both psychosocial factors and age, as well as the finding(s) of no significant association between sitting posture and LBP (and severe LBP). OSHA responds that with respect to sitting (>4 hours) posture and the Holmstrom *et al.* (Ex. 26-36) finding of no significant association with either LBP or severe LBP, both NIOSH (Ex. 26-1, pg. 6-47) and OSHA (see Table on back studies considered) do consider the finding of this study as "no association" for SWP and LBP. With respect to specific psychosocial factors being significant in this analysis, OSHA concurs. However, the discussion of psychosocial factors

by Holmstrom *et al.* fails to mention whether or not the multiple regression model used also found the physical risk factors simultaneously statistically significant with these data, which would suggest that physical and psychosocial factors are independent risk factors (Ex. 26–36, pg. 667).

#### 4. Comments on the Role of Individual and Non-Work Factors

In their posthearing testimony, Gibson, Dunn and Crutcher assert that:

In developing its unfounded assertion that biomechanical workplace factors play a predominant role in the development of MSDs, OSHA has also ignored a great number of scientifically valid studies establishing that non-work-related factors, such as genetic predisposition, age, general health, smoking, social activities, and psychosocial factors exert a greater influence than biomechanical factors on the development of MSDs (Ex. 500–118).

Other commenters also expressed concern about the role of non-work factors in the etiology of MSDs (*e.g.*, Exs. 30–1722, 60–2037, 30–4184, 30–3077, 30–1352, 30–4130, 30–3922, 30–3114, 30–3354).

While some commenters tended to lump individual factors along with psychosocial factors, these two types of factors are clearly separate and distinct. OSHA has separated its discussion of individual factors from that of psychosocial factors, and has fully addressed comments on psychosocial factors later in this part of the Health Effects section. In this section OSHA presents its response to comments in the record on individual factors, sometimes called “personal” factors. The factors that are discussed in the literature include age, susceptibility, either by genetic predisposition or medical conditions, and other factors that may be thought of as those that modify the capacity of individuals to perform work.

The above post-hearing comment (Ex. 500–18) makes two claims:

(1) that OSHA ignored an entire body of literature relevant to this rulemaking, and

(2) that had OSHA not ignored this body of literature, it would have come to an opposite conclusion than that reached by OSHA, *i.e.*, that these factors “exert a greater influence” presumably than biomechanical risk factors, on the development of MSDs.

OSHA, in fact, did not ignore the literature on individual factors. On the contrary, OSHA introduced the appendices to the proposed Health Effects section with a discussion of “Individual Factors and Epidemiology

of Work-Related Musculoskeletal Disorders,” stating that:

The multifactorial nature of MSDs requires a discussion of individual factors that have been studied to determine their association with or influence on the incidence and prevalence of work-related MSDs. These factors include age (Guo *et al.*, 1995; Biering-Sorensen *et al.*, 1983; English *et al.*, 1995; Ohlsson *et al.*, 1994); gender (Hales *et al.*, 1994; Johansson, 1994; Chiang *et al.*, 1993; Armstrong *et al.*, 1987a); anthropometry (Werner *et al.*, 1994; Nathan *et al.*, 1993; Heliövaara, 1987); physical activity (Holmstrom, Lindell, and Moritz, 1992; Baron *et al.*, 1991; Craig *et al.*, 1998); strength (Chaffin and Park, 1973; Chaffin *et al.*, 1977; Troup, Martin, and Lloyd, 1981); cigarette smoking (Finkelstein, 1995; Owen and Damron, 1984; Svensson and Andersson, 1983; Kelsey, Golden, and Mundt, 1990; Hildebrandt, 1987); and alcohol, caffeine, and vitamins (Nathan *et al.*, 1996, Keiston *et al.*, 1997). In addition, psychosocial factors have been associated with upper-extremity and back disorders (Ex. 27–1, p. 1–1).

OSHA has stated elsewhere that it relied on two major reviews of the evidence for work-relatedness of MSDs available at that time, NIOSH’s “Musculoskeletal Disorders and Workplace Factors: A Critical Review of the Epidemiologic Evidence for Work-Related Musculoskeletal Disorders of the Neck, Upper Extremity, and Low Back” (Bernard, 1997; Ex. 26–1) and the National Research Council/National Academy of Sciences’ “Workshop on Work-Related Musculoskeletal Injuries: The Research Base” (Ex. 26–37). OSHA believes that it was appropriate to place great weight on these two sources, as they are comprehensive reviews of recent peer-reviewed scientific literature conducted by highly-reputable and independent groups of scientists expert in their respective fields.

To the extent that the studies reviewed by NIOSH considered exposure to nonoccupational physical activities, such as nonoccupational VDT use, hobbies, second jobs, and household activities that might increase risk for MSDs, NIOSH included this information in its review, and acknowledges that:

a number of factors can influence a person’s response to risk factors for MSDs in the workplace and elsewhere. Among these are the following: age, gender, smoking, physical activity, strength, anthropometry.

The literature, as reviewed by NIOSH (NIOSH, 1997; Ex. 26–1): on each of these individual factors is summarized here:

Age: The prevalence of MSDs increases as people enter their working years. By the age of 35, most people have had their first episode of back pain (Guo *et al.* 1995, Ex. 26–1474; Chaffin

1979, Ex. 26–1489). Once in their working years (age 25 to 65), however, the prevalence is relatively consistent (Guo *et al.* 1995, Ex. 26–1274; Biering-Sorensen 1983, Ex. 26–843). Musculoskeletal impairments are among the most prevalent and symptomatic health problems of middle and old age. Nonetheless, age groups with the highest rates of compensable back pain and strains are the 20–24 age group for men, and the 30–34 age group for women.

NIOSH acknowledges that age-related degenerative disorders may result in decreases in musculoskeletal function, and loss of tissue strength with age may also increase the probability or severity of soft tissue damage. NIOSH also notes that:

Another problem is that advancing age and increasing number of years on the job are usually correlated. Age is a true confounder with years of employment, so that these factors must be adjusted for when determining relationship with work. Many of the epidemiologic studies that looked at populations with a wide age variance have controlled for age by statistical methods.

However,

Several studies found age to be an important factor associated with MSDs (Guo *et al.* 1995; Biering-Sorensen 1983; English *et al.* 1995; Ohlsson *et al.* 1994; Riihimaki *et al.* 1989a; Toomingas *et al.* 1991) others have not (Herberts *et al.*, 1981; Punnett *et al.* 1985). [Ex. 26–1]

Riihimaki *et al.* (1989, Ex. 26–58) found a significant relationship between sciatica and age in machine operators, carpenters, and sedentary workers. Age was also a strong risk factor for neck and shoulder symptoms in these same groups of workers (Riihimaki *et al.* 1989, Ex. 26–58).

When a study does not find a relationship between an increased risk for MSDs and aging, lack of an observed relationship may be due to “survivor bias.” If workers who have health problems leave their jobs, or change jobs to one with less exposure, the remaining population includes only those workers whose health has not been adversely affected at their jobs. As an example, in a study of female plastics assembly workers, Ohlsson *et al.* (1989, Ex. 26–1290) reported that the degree of increase in the odds of neck and shoulder pain with the duration of employment depended on the age of the worker. For the younger subjects, the odds increased significantly as the duration of employment increased, but for the older ones no statistical change was found with length of employment. The older women who had been employed for shorter periods of time had more reported symptoms than the

younger ones, while older workers with longer employment times reported fewer symptoms than younger workers. Ohlsson *et al.* (1989, Ex. 26–1290) interviewed 76 former assembly workers and found that 26% reported pain as the cause of leaving work. This finding supports the likely role of a survivor bias in this study, the effect of which is to underestimate the true risk of developing MSDs, in this case in the older workers.

Some studies report observing an increased risk for MSDs with age, others do not. Where the effects of age have been controlled for in studies, thus eliminating the influence of “age” in the equation, the physical risk factors discussed here have been consistently shown to be associated with the development of MSDs in exposed populations. This means that, regardless of whether or not age plays a role in the development of a particular MSD in a particular population, the influence of physical risk factors is independent.

*Gender* Some studies have found a higher prevalence of some MSDs in women (Bernard *et al.* 1994, Ex. 26–842; Hales *et al.* 1994, Ex. 26–131; Johansson 1994, Ex. 26–1331; Chiang *et al.* 1993, Ex. 26–1117). A male-to-female ratio of 1:3 was described for carpal tunnel syndrome (CTS) in a population study in which occupation was not evaluated (Stevens *et al.* 1988, Ex. 26–1009). However, in the Silverstein *et al.* (1985, Ex. 26–1173) study of CTS among industrial workers, no gender difference could be seen after controlling for work exposure. Franklin *et al.* (1991, Ex. 26–948) found no gender difference in workers’ compensation claims for CTS. Burt, Hornung, and Fine (1990, Ex. 26–698) found no gender difference in reporting of neck or upper-extremity MSD symptoms among newspaper employees using video display terminals (VDTs). Nathan *et al.* (1988, Ex. 26–990; 1992, Ex. 26–988) found no gender differences for CTS. In contrast, Hagberg and Wegman (1987, Ex. 26–32) reported that neck and shoulder muscular pain is more common among females than males, both in the general population and among industrial workers.

Whether the gender difference seen with some MSDs is due to physiological differences or differences in exposure is unclear. One laboratory study, Lindman *et al.* (1991, Ex. 26–976), found that women have more type I muscle fibers in the trapezius muscle than men, and have hypothesized that myofascial pain originates in these type I muscle fibers. Ulin *et al.* (1993, Ex. 26–223) noted that significant gender differences in work posture were related to stature and

concluded that the lack of workplace accommodation to the range of workers’ height and reach may, in part, account for the apparent gender differences.

The fact that more women are employed in hand-intensive jobs and industries may account for the greater number of reported work-related MSDs among women. Bystrom *et al.* (1995, Ex. 26–897) reported that men were more likely to have de Quervain’s disease than women; they attributed this to more frequent use of hand tools.

The reporting bias may exist because women may be more likely to report pain and seek medical treatment than men (Armstrong *et al.*, 1993; Hales *et al.*, 1994). Some studies have reported that workplace risk factors account for increased prevalence of MSDs among women more than personal factors (*e.g.*, Armstrong *et al.* 1987, Ex. 26–1110; McCormack *et al.* 1990, Ex. 26–1334). In a recent evaluation of Ontario workers’ compensation claims for repetitive strain injury (RSI), Asbury *et al.* (1995, Ex. 26–250) reported a relative risk (RR) for female to male claims ranging from 1.3 to 1.6 across industries. Within five different broad occupational categories, females were approximately 2 to 5 times as likely to have a lost-time RSI claim. No information on gender differences in hand-intensive jobs was reported. Many researchers have noted that men and women tend to be employed in different jobs.

*Smoking.* In the Viikari-Juntura *et al.* (1994, Ex. 26–873) prospective study of machine operators, carpenters, and office workers, current smoking (OR: 1.9; 95% CI: 1.0–3.5), was among the predictors for change from “no neck trouble” to “severe neck trouble.” In a study of Finnish adults aged 30 to 64 (Makela *et al.* 1991, Ex. 26–980), neck pain was found to be significantly associated with current smoking (OR: 1.3; 95% CI: 1.0–1.61) when the logistic model was adjusted for age and gender. However, when the model included mental and physical stress at work, obesity, and parity, then smoking (OR: 1.25; 95% CI: 0.99–1.57) was no longer statistically significant (Makela *et al.* 1991, Ex. 26–980). With univariate analysis, Holmstrom (1992, Ex. 26–36) found a prevalence rate ratio (PRR) of 1.2 (95% CI: 1.1–1.3) for neck/shoulder trouble in “current” smokers vs. people who “never” smoked. But using multiple logistic regression, when age, individual, and employment factors were in the model, only “never smoked” contributed significantly to neck/shoulder trouble.

While investigating reasons for higher compensation claims for CTS in certain employee groups, Nathan *et al.* (1996,

Ex. 26–882) evaluated the effects of tobacco, caffeine, and alcohol on the prevalence of median entrapment neuropathy at the wrist, CTS symptoms, and CTS confirmed by nerve conduction studies among industrial workers (nonclaimants and working patients referred for upper-extremity symptoms) who volunteered for the study. Nathan *et al.* (1996, Ex. 26–882) stated that greater use of tobacco combined with greater consumption of caffeinated beverages and alcohol abuse was associated with more median nerve slowing, more specific hand/wrist symptoms, and more electrophysiologically confirmed CTS. However, the effects explained only a small portion of the total risk.

Toomingas *et al.* (1991, Ex. 26–1019) found no associations between multiple health outcomes (including tension neck syndrome, rotator cuff tendinitis, CTS, or problems in the neck/scapula or shoulder/upper arm) and nicotine habits among platers, assemblers, and white collar workers. In a case/referent study, Wieslander *et al.* (1989, Ex. 26–1027) found that smoking or using snuff was not related to CTS among men operated on for CTS.

Several papers have presented evidence that a positive smoking history is associated with low-back pain, sciatica, or intervertebral herniated disc (Finkelstein 1995, Ex. 26–369; Frymoyer, Pope, and Clements 1983, Ex. 26–950; Svensson *et al.* 1983, Ex. 26–1158; Kelsey *et al.* 1984, Ex. 26–152); whereas other papers have found a negative relationship (Kelsey, Golden, and Mundt 1990, Ex. 26–52; Riihimaki *et al.* 1989, Ex. 26–997). Boshuizen *et al.* (1993, Ex. 26–81) found a relationship between smoking and back pain only in those occupations that required physical exertion. In their study, smoking was more clearly related to pain in the extremities than to pain in the neck or the back. Deyo and Bass (1989, Ex. 26–105) observed that the prevalence of back pain increased with the number of pack-years of cigarette smoking and with the heaviest smoking level.

Heliovaara *et al.* (1991, Ex. 26–959) only observed a relationship in men and women older than 50 years. Two studies did not find a relationship between sciatica and smoking among concrete reinforcement workers and house painters (Heliovaara *et al.* 1991, Ex. 26–959; Riihimaki *et al.* 1989, Ex. 26–997).

Several explanations for the relationship with smoking have been postulated. One hypothesis is that back pain is caused by coughing from smoking. Coughing increases the abdominal pressure and intradiscal pressure and puts strain on the spine. A

few studies have observed this relationship (Deyo and Bass 1989, Ex. 26–105; Frymoyer *et al.* 1980, Ex. 26–707; Troup *et al.* 1987, Ex. 26–1307). The other mechanisms proposed include nicotine-induced diminished blood flow to vulnerable tissues (Frymoyer, Pope, and Clements 1983, Ex. 26–950), and smoking-induced diminished mineral content of bone causing microfractures (Svensson *et al.* 1983, Ex. 26–1158). Similar associations with diminished blood flow to vulnerable tissues have been found between smoking and Raynaud's disease.

**Strength.** Some epidemiologic support exists for the relationship between back injury and a mismatch of physical strength and job tasks. Chaffin and Park (1973, Ex. 26–1115) found a sharp increase in back injury rates in subjects performing jobs requiring strength that was greater than or equal to their isometric strength-test values. The risk was 3 times greater in the weaker subjects. In a second longitudinal study, Chaffin *et al.* (1977, Ex. 26–1111) evaluated the risk of back injuries and strength and found the risk to be 3 times greater in the subjects without lower static strength. Keyserling, Herrin, and Chaffin (1980, Ex. 26–970) strength-tested subjects, biomechanically analyzed jobs, and assigned subjects to either stressed or non-stressed jobs. Following medical records for a year, they found that job matching based on strength criteria appeared to be beneficial. In another prospective study, Troup, Martin, and Lloyd (1981, Ex. 26–1456) found that reduced strength of back flexor muscles was a consistent predictor of recurrent or persistent back pain, but this association was not found for first-time occurrence of back pain.

Other studies have not found the same relationship with physical strength. Two prospective studies of low-back pain reports (or claims) of large populations of blue collar workers (Battie *et al.* 1989, Ex. 26–72; Leino, Aro, and Hasan 1987, Ex. 26–1142) failed to demonstrate that stronger (defined by isometric lifting strength) workers are at lower risk for low-back pain claims or episodes. One study followed workers for 10 years after strength testing and the other followed workers for a few years. Neither of these studies included precise measurement of exposure level for each worker, so the authors could not estimate the degree of mismatch between workers' strength and task demands. Battie compared workers with back pain with other workers on the same job (by isometric strength testing) and did not find that workers with back pain were weaker. In

two studies of nurses (Videman *et al.* 1989, Ex. 26–1155; Mostardi *et al.* 1992, Ex. 26–986), lifting strength was not a reliable predictor of back pain.

When examined together, these studies reveal the following: the studies that found a significant relationship between strength and back pain used more thorough job assessment analysis and focused on manual lifting jobs. However, these studies only followed workers for periods of 1 year, and whether this same relationship would hold over a much longer working period remains unclear. The studies that did not find a relationship, although they followed workers for longer periods of time, did not include precise measurements of exposure level for each worker, so they could not assess the strength capabilities that were important in the jobs.

**Anthropometry.** Weight, height, body mass index (BMI) (a ratio of weight to height squared), and obesity have all been identified in studies as potential risk factors for certain MSDs, especially CTS and lumbar disc herniation. Obesity seems to play a small but significant role in the occurrence of CTS (see Section B.4.a). Anthropometric data are conflicting, but in general indicate that there is no strong correlation between stature, body weight, body build, and low-back pain.

Few studies examining anthropometric risk factors in relationship to CTS have been occupational epidemiologic studies; most have used hospital-based populations that may differ substantially from working populations. Nathan *et al.* (1988, Ex. 26–990; 1992, Ex. 26–989; 1994, Ex. 26–517) have published several papers about a single industrial population and have reported an association between CTS and obesity; however, the methods employed in their studies have been questioned in a number of subsequent publications (Gerr and Letz 1992, Ex. 26–384; Mackinnon *et al.* 1997, Ex. 26–1309; Stock 1991, Ex. 26–1010; Werner *et al.* 1994, Ex. 26–237). Several investigators have reported that their industrial study subjects with CTS were shorter and heavier than the general population (Cannon *et al.* 1981, Ex. 26–1212; Dieck and Kelsey 1985, Ex. 26–944; Falck and Aarnio 1983, Ex. 26–1122; Nathan *et al.* 1992, Ex. 26–989; Werner *et al.* 1994, Ex. 26–237; Wieslander *et al.* 1989, Ex. 26–1027).

Werner *et al.* (1994, Ex. 26–237) studied a clinical population requiring electrodiagnostic evaluation of the right upper extremity, patients classified as obese (BMI > 29) were 2.5 times more likely than slender patients (BMI < 20)

to be diagnosed with CTS. These researchers developed a multiple linear-regression CTS model (with the difference between median and ulnar sensory latencies as the dependent variable). The regression highlighted BMI as the most influential variable, but still only accounted for 5% of the variance in the model. In Nathan's (1994, Ex. 26–517) logistic model, BMI accounted for 8.6% of the total risk; however, this analysis used both hands from each study subject as separate observations, although they are not independent of each other. Falck and Aarnio (1983, Ex. 26–1122) found no difference in BMI among 17 butchers with (53%) and without (47%) CTS. Vessey, Villard-Mackintosh, and Yeates (1990, Ex. 26–229) found that the risk for CTS among obese women was double that for slender women.

Nordstrom *et al.* (1997, Ex. 26–900), in a study of risk factors for CTS in a general population, concluded that BMI is one factor that seems to have a causal relation to CTS. These researchers found that for each increase of one unit of BMI, about 6 pounds for the average-sized adult, risk of CTS increases by 8%. Werner *et al.* (1997, Ex. 26–718), in a study at five different worksites (four industrial, one clerical), concluded that obesity (BMI > 29), industrial work, and age were independent risk factors for median mononeuropathies. Their study, which did not define specific work-related exposures, showed no significant interaction between work activity and obesity. However, the authors caution interpretation of the data and urge more investigation. It has been suggested that relationship of CTS with BMI involves increased fatty tissue within the carpal canal or increased hydrostatic pressure throughout the carpal canal in obese persons compared with slender persons (Werner 1994, Ex. 26–237).

Two other anthropometric risk factors, carpal tunnel size and wrist size, have been suggested as risk factors for CTS; however, some studies have linked both small and large canal areas to CTS (Bleecker *et al.* 1985, Ex. 26–934; Winn and Habes 1990, Ex. 26–1029).

Schierhout *et al.* (1995, Ex. 26–403) found that short stature was significantly associated with pain in the neck and shoulder but not in the forearm, hand and wrist, or back, among workers in 11 factories. Height was not a factor for neck, shoulder, or hand and wrist MSDs among newspaper employees (Bernard *et al.* 1994, Ex. 26–842). Kvarnstrom (1983, Ex. 26–1201) found no relationship between neck/shoulder MSDs and body height in a

Swedish engineering company with more than 11,000 workers.

Examples exist where biomechanical or physical risk factors have been labeled as individual factors. During the hearing for this rulemaking, Dr. Niklas Krause mentioned two of these examples, the first refers to people in the military who drive tanks, and found that tall people have more back pain than short people. A very logical explanation for the observation of increased back pain was provided by Dr. Krause:

Well, if you have ever entered a tank, you know that it is not constructed for very tall people. There is not much room in there. [Tr. 1378]

And a second example, also provided by Dr. Krause:

And we have actually found in our bus drivers, too, and we measured. We had their height and their weight. We found that an ergonomic evaluation of the bus fleet showed that the buses that are running in San Francisco were constructed for people—that is what the ergonomics Professor Thompson from Sanford found out when he looked at them—were constructed for people in the upper 10 percent of the North American population.

You can imagine if you hire small people, Asians and women for example, into that work force and put them on this bus that the fit is bad. And actually, what we see is that over the years, the percentage of small drivers drops on that work force rapidly.

When they enter, when people take the job, there is about 6 percent of drivers who are small, defined as \* \* \* the lower half of the population. \* \* \* After one to five years, only 2.9 percent of these small people are in the workforce. After six to ten years, only 1.3 percent. And after eleven to fifteen years, only 0.4 percent. This is a statistically significant trend. And it clearly shows you that people based on their smallness and misfit probably had to leave the occupation. [Tr. 1378–1380]

When used to determine whether a correlation exists between stature, body weight, body build and low back pain, anthropometric data are conflicting, but in general indicate that there is no strong correlation. Obesity seems to play a small but significant role in the occurrence of CTS.

*Genetics.* Another type of factor that affects an individual's capacity is genetic make-up. While the term "genetic susceptibility" is often heard; in reality both the amount of genetic information involved in the response and the variability of possible responses are vast and for the most part, not yet understood. The little bit of work done in this area was done by Videman, and is covered in a brief discussion in the section on the low back.

A worker's ability to respond to work factors may be modified by his or her

own capacity. The capacity to perform work varies with gender and age, among workers, and for any individual over time. The relationship between biomechanical risk factors, both inside and outside the workplace, these individual as well as other factors and the resulting risk of injury to the worker is complex, but not unique to this OSHA standard.

For each of the "individual factors" discussed here, some studies report observing an increased risk for MSDs, others do not. What they have in common, is their ability to effect the capacity of individuals independently from biomechanical risk factors. In other words, in those studies where the effects of age, gender, smoking, etc. have been controlled for, the physical risk factors discussed here have been consistently shown to be associated with the development of MSDs in exposed populations. This means that, regardless of whether or not age plays a role in the development of a particular MSD in a particular population, the influence of biomechanical risk factors is independent from other associated factors. Furthermore, it has been demonstrated repeatedly, that reducing these biomechanical factors in the workplace results in reductions in the incidence of work-related MSDs.

The AFL/CIO found that the record provides some additional evidence that individuals may vary in their susceptibility to developing certain work-related MSDs, such as carpal tunnel syndrome, based on individual factors including age, body weight and gender (Ex. 26–1, Ex. 26–37, Ex. 500–71–93). They also found that other evidence in the record indicates that for back and neck pain or disorders, for example, no association with age, gender, height or weight has been established (Ex. 500–71–24, Tr. 1332).

The AFL/CIO point out that:

Obviously the underlying principle of ergonomics is to fit the job to the worker, and so personal physical characteristics do come into play when evaluating certain MSD risk factors. A worker who is 5'2" may have a much longer reach to an assembly line than her 6'0" co-worker. But other than as relevant to evaluating exposure to known risk factors, personal characteristics and differences in susceptibility are irrelevant to this rulemaking. This regulation, and all other OSHA standards, are designed to regulate risks that are found in the workplace that may result in the development of an adverse outcome (MSDs) in workers who are exposed to risk factors which have been demonstrated to cause MSDs. The ergonomics regulation is consistent with OSHA's responsibility to regulate hazards which are present in the workplace. To shift the focus toward personal characteristics, as some industry

opponents have argued, only clouds this issue by blaming the victims. [Ex. 500–218]

On this same subject, Dr. Frederick Gerr, Emory University (Tr. 1525–26):

Some will argue that personal factors, such as gender and body weight, are the cause of these disorders among American workers, rather than ergonomics hazards in the workplace. The fact that personal characteristics can increase the risk for these disorders in no way undermines the evidence that work has been clearly shown to increase their risk as well.

The blame-the-victim approach to these disorders is both scientifically and ethically bankrupt. Virtually all occupational illnesses, including asthma, cancer, skin disease, peripheral and central nervous system disorders, and many others, have causes that extend outside of the workplace. This fact does not lessen the added burden of disease that occupational exposures produce.

#### *Non-Work Leisure Activities*

The commenters (*e.g.*, Exs. 30–2493, 31–324, 30–3368, 30–605, 30–3783, Tr. 5073) also raise the issue of the relationship of "non-work" to the development of MSDs. By this, OSHA assumes the reference is to those activities such as nonoccupational VDT use, hobbies, second jobs, and household activities, activities that may result in additional exposure to biomechanical factors similar to that the individual is experiencing at the workplace. If this assumption is correct, then "non-work" may actually refer to exposure to the same types of physical/biomechanical factors that may be additive to similar workplace exposure.

And, while it is true that the physical/biomechanical risk factors which increase the risk of MSDs at work can also be found outside of work and may lead to MSDs (Ex. 500–71–93). However, according to Dr. Nicholas Warren from the University of Connecticut (Tr. 1077–78):

It is very seldom the case that home risk factors are encountered with the same intensity or the same duration as they are encountered in the workplace.

On the same subject, the AFL/CIO (Ex. 500–218) notes:

Opponents of the standard, while arguing that there is no evidence that physical factors at work cause MSDs, also simultaneously argue that it is non-work leisure physical activities which cause MSDs and that an OSHA standard cannot regulate adverse health conditions and exposures to risk factors which are partially, primarily or exclusively the result of non-work activities (Ex. 32–241–4).

For most musculoskeletal disorder cases, "workplace factors are the predominant risk and it is upon these risks, obviously, that the OSHA proposed rule focuses (Tr.1079). Other evidence in the record confirms that there is little or no impact on the development of MSDs related to the back from non-work

participation in sports, exercise, and leisure time physical activity (Ex. 500-71-24, Ex. 500-71-32, Ex. 502-510).

The AFL/CIO also states:

Thus the record evidence suggests that the non-work exposures to risk factors rarely, if ever, occur at the same frequency, duration or magnitude as workplace exposures. Even where workers are exposed to non-work risk factors off the job, it is important to point out that this standard is designed only to decrease exposures to biomechanical risk factors occurring at the workplace. An analogy may be drawn to the risks of incurring hearing loss from excessive exposure to noise. Exposure to noise at levels and durations which can cause or contribute to noise-induced hearing loss can and do occur both at the workplace as well as in non-work situations. While these work and non-work exposures and risks of developing hearing loss exist, OSHA's noise standard is confined exclusively to addressing excessive noise exposures in the workplace. [Ex. 500-218]

And from Dr. Nicholas Warren, University of Connecticut (Tr. 1078-79):

When I work with an individual with, for instance, carpal tunnel syndrome, carrying out forceful, repetitive tasks over most of a nominal 40 hour work week and then often into another 10 hours of voluntary overtime, it's painful to hear an insurer gleefully inform me that this person bowls in a league on Saturday night. It is equally painful to hear the worker blame him or herself by saying, "That's probably because I knit," when, in fact, a clear objective assessment of the workplace risk factors reveals that these are much more important in the etiology of his or her disease.

OSHA concludes that, in general, each individual's capacity is affected differently by many factors including some of those presented here: age, gender, smoking, physical activity, strength, anthropometry, genetic factors and activities outside the workplace. This is also true in the more specific case of the development of work-related MSDs. However, it is important to remember that exposure to biomechanical factors in the workplace is independent of those factors that each individual brings to the workplace, *i.e.*, when the influence of individual factors is controlled for in studies, effects due to exposure to biomechanical factors are still observed. It is also true that in the vast majority of cases, where exposure to biomechanical exposures is high, the effects due to biomechanical exposures are far greater than those associated with these types of individual factors.

##### 5. Role of Psychosocial Factors in the Etiology of MSDs

The role of psychosocial factors in the etiology of MSDs was a subject of much debate during the rulemaking. Many participants, in particular the Chamber of Commerce (Ex. 500-188), Gibson,

Dunn & Crutcher (Exs. 32-241-4, 500-197), and several research and medical scientists who testified on behalf of UPS (Exs. 32-241-3-2, 32-241-3-3, 32-241-3-5, 32-241-3-8, 32-241-3-12), criticized the proposed rule for its failure to take into account the contribution of psychosocial risk factors to MSD causation and exacerbation, believing that psychosocial factors play a significantly greater role than do biomechanical risk factors in the development of MSDs and the disabilities associated with them.

Much of the scientific literature that addresses the etiology of MSDs has examined aspects of the social and psychological environment that may have a causal or moderating role in MSD development and exacerbation. In this part of the Health Effects section, OSHA first discusses what is meant in the literature by the term "psychosocial factors." Following this discussion, OSHA summarizes the expert testimony of witnesses and rulemaking participants who have evaluated the body of psychosocial literature as it relates to the work-related risk of MSDs. Finally, OSHA presents its own literature review, summarizing specific studies contained in the rulemaking docket that have examined and compared the roles of biomechanical and psychosocial factors in the etiology of MSDs, and summarizes several literature reviews that have been published on this topic.

##### *Definition of Psychosocial Factors*

The study of psychosocial factors as it applies to the study of work-related MSDs is surrounded by a measure of confusion because there are several very different definitions of "psychosocial" used in common and in technical parlance. Lack of clarity and consensus in defining psychosocial factors was addressed by some researchers at the public hearing (Tr. 867-868, 1306, 17443). There are three general concepts of psychosocial factors that apply. Most researchers who have examined the role of psychosocial factors in the etiology of MSDs have emphasized the external aspects of the psychological and social work environment that cause the worker to experience "stress", a condition of chronic or prolonged arousal of the human "flight or fight" mechanisms that has been linked to a wide variety of negative health outcomes, including MSDs. The primary aspects of the psychosocial work environment include level of psychological job demands, level of worker control over the job process, and level of social support received from co-workers, supervisors and the organization. Some researchers

focus on additional conceptualizations of psychosocial exposures, including job security, monotony, and job satisfaction (for example, Krause, 1998, Ex. 38-242, Bigos, 1991b Ex. 26-1242). Psychosocial factors reflecting these external aspects of the work environment have been the subject of investigation in nearly all of the studies and literature reviews discussed in this section.

As is the case with biomechanical risk factors, proposed exposure-outcome relationships for psychosocial factors are multifactorial, *i.e.*, several of these factors may be in play in any given situation, and may combine and interact in complex ways that are difficult to study and understand (Bongers *et al.*, 1993, Ex. 26-1292, Bernard, 1997, Ex. 26-1 Warren *et al.*, 2000a, b, Exs. 38-75, 38-73). It is unlikely that these psychosocial workplace risk factors occur and act in isolation of biomechanical risk factors (Tr. 868-869, 1264, 5942-5943, NIOSH 1997 (Ex. 26-1), NAS 1999 (Ex. 26-37)).

A growing body of literature also identifies aspects of organizational structure, technology, policy, and culture as potential contributors to occupational disease and characterizes them as organizational risk factors (Shannon, *et al.*, 1996, Ex. 26-1368, 1997, Ex. 26-1369, Warren, 1997, Ex. 38-72, Warren *et al.*, 2000a, Ex. 38-75). Organizational risk factors are proposed as the underlying bases of work design in the company; through their effect on work organization, they determine levels of both psychosocial and biomechanical risk factors experienced by employees. It is this common set of roots that results in the strong covariation of psychosocial and biomechanical risk factors noted below. The second concept of psychosocial factors that has been used in the literature relates to the internal characteristics of the worker's psychological makeup that affect how he/she appraises, processes and reacts to external biomechanical and psychosocial factors, and thus moderates how these external factors are experienced internally. There are studies demonstrating that individual psychological factors can increase susceptibility to MSD development and affect MSD recognition and reporting (Linton, 2000, Ex. 502-413, NAS, 1999 Ex. 26-37). Emerging research suggests influence care-seeking and disability than initial onset of disease (Linton, 1992, 2000, Ex. 502-413 ests that internal psychological factors more strongly, Waddell & Burton, 2000, Ex. DC-151-A). Some researchers and physicians combine internal and external psychological factors in their

definition of psychosocial factors; for example, Dr. Raymond Bellamy, an orthopedic surgeon testifying on behalf of UPS *et al.*, included such factors as dislike of job, recent poor performance evaluation, depression and anxiety, hypochondriasis, and desire for narcotics in his description of psychosocial factors (Ex. 32-241-3-3). Dr. Arthur Barsky, also testifying on behalf of UPS *et al.*, stated that psychosocial factors (his use of the term conflates external factors and internal psychological factors) "exacerbate, perpetuate, and maintain these [musculoskeletal] symptoms and amplify the disability they engender" (post-testimony comments, p.1, Ex. 500-118-1). Thus, it is not always clear in the literature or in the testimony contained in the record when the term "psychosocial factors" is being used to refer to external psychological or social workplace factors, internal psychological makeup of the worker, or both.

The third concept of psychosocial factors relates to aspects of the legal, insurance and medical environment that influence a worker's tendency to identify a particular constellation of symptoms as a disease. At its most extreme, this definition is used to claim that workers make up and fake disease, for "secondary gain". A broader interpretation is the argument that these aspects of legal and medical recognition and possible financial gain may subtly, even unconsciously influence a worker's honest identification of symptoms as a disease and predisposition to report it.

Although individual psychological factors or medical/legal factors may affect MSD perception and reporting to a degree, it is unlikely that they play a major causal role in the etiology of MSDs. This is because the increased prevalence and incidence of MSDs seen among workers who are highly exposed to biomechanical risk factors cannot be adequately explained primarily by psychological factors given the present state of the evidence. As the discussion in this Health Effects section has demonstrated, the epidemiological, laboratory, psychophysical, and intervention literature demonstrating quantifiable links between biomechanical exposures and MSD outcomes is overwhelming. Many studies have demonstrated substantial differences in MSD incidence and prevalence between companies and industry sectors that correlate strongly with the presence of physical risk factors (for example, Franklin *et al.*, 1991, Ex. 26-948, NAS, 1999, Ex. 26-37, see also the Risk Assessment section

(Section VI) of this preamble). Thus, it is highly unlikely that an individual with psychological tendencies towards negative reactions at work or tendencies to seek out care-givers would preferentially select themselves into physically demanding jobs. It is also impossible to imagine how prospects for secondary gain would be differentially distributed into occupations or industry sectors that involve highly physical work.

Consequently, this part of the Health Effects section focuses on the large number of studies that have simultaneously examined the roles of biomechanical risk factors along with psychosocial factors that relate to external aspects of the psychological and social work environment. These studies generally represent the most recent studies of work-related MSDs in the literature.

#### *Discussion of Testimony on the Psychosocial Literature*

Based on these studies, the Chamber of Commerce (Ex. 500-188) and Gibson, Dunn & Crutcher representing UPS, Anheuser-Busch, the National Coalition on Ergonomics, and others (*e.g.*, Exs. 32-231-4, 500-197, 32,435, 30-3346, Tr. 3655) were critical of OSHA emphasizing the role of biomechanical risk factors over psychosocial factors in its scientific literature review. For example, in their post-hearing brief, Gibson, Dunn & Crutcher commented that

The science has shown that where psychosocial factors in particular are considered, they generally overwhelm the weak and inconsistent associations between biomechanical exposures and the reporting of MSDs. Yet the \* \* \* [A]gency dismissed the validity of psychosocial factors in cavalier fashion \* \* \* [Ex. 500-197, p. 1-33]

Similarly, the Chamber of Commerce stated that "The Agency has egregiously ignored each and every one of these indisputably relevant factors \* \* \*" (Ex. 500-188), and explained the necessity for OSHA to evaluate the role of psychosocial factors in the workplace:

\* \* \* [D]etermining why individuals feel the need to report and/or to seek medical care for such complaints is a complex problem involving not only the physical exposures, but psychosocial factors such as job satisfaction, ability to control the work environment, interpersonal relationships at work, and the like \* \* \* And, in the vast majority of studies that have assessed whether biomechanical workplace factors and psychosocial factors cause musculoskeletal complaints, psychosocial factors are just as significant, or more

significant than, biomechanical factors. (Ex. 500-188, p. 41)

In addition, several research and medical scientists testifying on behalf of UPS *et al.* stated in written or oral comment that the scientific literature strongly supported that psychosocial factors play a dominant role in the etiology of MSDs (Exs. 32-241-3-2,32-241-3-3, 32-241-3-5, 32-241-3-8, 32-241-3-12). For example,

Dr. Alf Nachemson concluded a review of the literature by stating that

\* \* \* [t]he research indicates that psychosocial factors are not simply an overlay but rather an integral part of the pain disability process that includes emotional, cognitive and behavioral aspects \* \* \* [T]here was strong evidence of the highest level that psychosocial variables generally have more impact than biomedical or biomechanical factors on pain disability." (Ex. 32-241-3-12, p. 13)

Dr. Norton Hadler stated in written comment that

Associations between disabling regional musculoskeletal symptoms and psychosocial variables overwhelm and explain away any and all associations with biomechanical exposures. (Ex.32-241-3-8, p. 18)

Taking a more moderate interpretation of the literature, Dr. Arthur Barsky agreed that MSDs are not entirely a psychosocial problem; however, he felt that ignoring them in designing intervention programs can make the problem worse (Ex. 500-118-1, p. 1). At the public hearing, he explained that

\* \* \* [workers'] symptoms really are better understood as a social communication, as a kind of non-verbal way of responding to difficulties in the workplace—job dissatisfaction, role conflicts, insecurity around the job, a whole variety of psychosocial work conditions—and to hear these as a biomedical complaint is to totally miss the point \* \* \* What really concerns me, is \* \* \* [that complaints of MSD symptoms are] a kind of social communication \* \* \* a metaphor for life stress, for psychosocial distress \* \* \* and the response that too often is made to a symptom like that, is [an inappropriate] referral to orthopedics. Tr. 17043-17044]

Dr. Barsky illustrated his point with an example of a widowed mother of two worked two jobs and visited the emergency room of a hospital complaining of tired feet [Tr. 17043-17044], and viewed the proposed ergonomics standard as an inappropriate response to such an "interpersonal communication" (Tr. 17044).

Other scientists testifying on behalf of the UPS echoed the conclusions reached by Dr. Nachemson in his literature review and Dr. Bigos, who referred to

his groups Boeing study (Ex. 26–1241, 26–1242, 26–1393) in contending that low back pain (LBP) is primarily a psychosocial phenomenon (Exs. 32–241–3–2, 32–241–3–5). Other commenters also remarked on the importance of psychosocial factors in the development of MSDs (e.g., Exs. 32–435, 30–3346, 30–3086, 30–536, 30–4046, 30–1070, Tr. 3655).

Many of OSHA's scientific witnesses disputed these interpretations of the psychosocial literature, stating that the literature is not in conflict with the causal relationship that has been demonstrated between exposure to biomechanical risk factors and development of MSDs, and that psychosocial factors had generally less of an influence than biomechanical factors in these studies (Tr. 842, 874, 1087, 1206, 1364, 1537–1540). For example, Dr. Thomas Armstrong testified that

\* \* \* [M]ore than a critical mass of epidemiological literature shows that biomechanical factors are important predictors of the occurrence of musculoskeletal disorders and the elevated risk of harm.

In studies where we have included both psychosocial and physical risk factors, the physical factors come out as the strongest predictor. [Tr. 842]

Dr. Laura Punnett testified that “\* \* \* the impact of physical exposures at work is beyond that explained by demographics, medical history, psychosocial features of the work environment or other factors” (Tr. 874). Similarly, Dr. Nicholas Warren testified that in studies that have measured both biomechanical and psychosocial factors

\* \* \* we almost always find that both contributed. If you control for psychosocial risk factors[,] which well-designed studies allow you to do, you'll find a strong contribution from biomechanical risk factors and that it generally, not in all workplaces, but in most workplaces, is a larger effect than that of the psychosocial risk factors. [Tr. 1087]

When asked whether he would agree with Gibson, Dunn & Crutcher's statement in their pre-hearing submission that “a majority of medical experts who study the causes of MSDs believe most chronic workplace pain is caused by psychosocial issues” (Ex. 32–241–4, p. 36), both Dr. Bradley Evanoff and Dr. Fred Gerr disagreed. Dr. Evanoff believed the opposite was true, that “the majority of people studying work-related musculoskeletal disorders \* \* \* feel that physical exposures are a very strong risk factor” (Tr. 1358). Dr. Gerr stated that he was “aware of absolutely no basis in the

medical or scientific literature that [would] substantiate that statement” (Tr. 1538). Both also strongly disagreed (Tr. 1538–1539) with Dr. Hadler's statement in his written testimony that psychosocial factors “overwhelm and explain away any and all associations with biomechanical factors” (Ex. 32–241–3–8, p. 18).

Several other researchers and medical scientists appearing at the hearing on their own behalf disagreed with the UPS witnesses assessments that psychosocial factors predominate in the etiology of MSDs (Tr. 2838, 2840, 7857–7858, 9504, 9880). Dr. George Piligian of the Mt. Sinai Center for Occupational and Environmental Medicine, when asked whether it was appropriate for OSHA to emphasize the role of biomechanical factors in its proposed rule given the evidence on psychosocial factors, responded with an analogy:

\* \* \* [Suppose] a person is thirsty and has come from the desert, and if you have only half a glass of water to offer that person[,] \* \* \* Someone argued and said \* \* \* I don't think we should give this person that half a glass of water until it's full \* \* \* I would venture to say that the person who is thirsty would probably beg you to give them that half a glass of water, then, go back and fill it \* \* \* .

We are doing what we can with the knowledge we have rather than using the argument, which I find actually counterintuitive \* \* \* that we must have every single thing that we know of in place before we proceed. [Tr. 7857–7859]

Some of OSHA's expert witnesses who are actively engaged in research on work-related MSDs testified that an important finding from the more recent literature is that biomechanical risk factors have been shown to be associated with MSDs independently from psychosocial factors (Tr. 1327–1328, 1331–1332, 1335, 1343, 1365, 1412). Dr. Niklas Krause, in testifying on his own prospective study of public transit operators and low back disorders (Ex. 500–87–2), stated that

The main result \* \* \* is that both biomechanical and psychosocial job factors were independently associated with spinal disorders \* \* \* [I]ndependent positive dose response relationships were also found for ergonomic problems \* \* \* I conclude from this new high quality evidence [referring to the Loisel *et al.* (Ex. 38–28) randomized trial study] and the literature that has been already collated by OSHA [in its preamble to the proposed rule and Health Effects Appendices (Ex. 27–1)] that high-quality epidemiological studies confirm that physical work place factors cause MSDs independently from individual worker characteristics and psychosocial job factors \* \* \* [Tr. 1331–1335].

Dr. John Frank testified that the Kerr *et al.* case-control study (Ex. 38–82) in

which he participated also found an association between MSDs and exposure to biomechanical risk factors independent from psychosocial factors. When asked about the significance of that finding, Dr. Frank responded

The importance particularly for the proposed standard or any public health efforts to reduce biomechanical hazards at work is that[,] \* \* \* acting on biomechanical risk factors will bring risk reductions according to our understanding of the multifactorial causal process even if we are unable \* \* \* at the present time to conclusively act to reduce psychosocial factors \* \* \* [Tr. 1365–1366]

Dr. Frank also drew a parallel with successful efforts to control cholesterol blood levels to reduce heart disease incidence, despite “two dozen or more” other risk factors that contribute to heart disease because high cholesterol levels are independently associated with an increased risk of heart disease (Tr. 1365–1366).

In the preamble to the proposed rule, OSHA's focus on identification and control of biomechanical risk factors in the workplace was based on two considerations. First, OSHA preliminarily concluded that there was substantial evidence of a clearly demonstrated causal relationship between exposure to physical risk factors and MSD outcomes (64 FR 65926), and that most researchers who studied the etiology of MSDs placed emphasis on biomechanical risk factors. Second, research into role of psychosocial risk factors in the etiology of MSDs was considered to be a less mature field than that addressing the role of biomechanical risk factors, characterized by emerging methodology, as pointed out by Dr. Martin Cherniak at the hearing (Tr. 1307), and sometimes by inconsistent results. Thus, most interventions designed to address work-related MSDs focused on biomechanical, rather than psychosocial factors.

The 1997 NIOSH review (Ex. 26–1) on which OSHA relied heavily, examined psychosocial risk factors that might contribute directly and indirectly to musculoskeletal illness and injury. The review noted that the results from the literature were not entirely consistent, and that a lack of consensus on standard measurements and procedures might be one reason for lack of consistency. Perceptions of intensified workload, monotonous work, low job control, low job clarity, and low social support were associated with MSDs in some studies. NIOSH found that these associations, despite the variance in methods used to assess these factors, were significant in the better studies; however, the size of

effect was relatively weak compared to that of the biomechanical variables.

In his testimony, Dr. Frank (Tr. 1343–1345, 1397–1398) discussed the reasons for this inconsistency, relating it to the field being in the embryonic stage of understanding psychosocial effects, and to imperfect measurement instruments. He pointed out that the Institute for Work and Health study discussed below (Kerr *et al.*, 2000, Ex. 38–82) did not confirm findings of Bigos *et al.* (1991a, b, Exs. 26–1241, 26–1242, 1992, Ex. 26–1393) or Krause (1998, Ex. 500–87–2) that low job satisfaction contributed to risk. In contrast, Dr. Frank (Tr. 1344) noted that, in newer studies that simultaneously assessed the effect of physical and psychosocial factors, biomechanical loads make a consistent and generally stronger contribution to MSD outcomes.

Although psychosocial exposure assessment has grown rapidly in the last decade and is characterized by continually improving methodological developments, it is still a relatively young field. Measurement methodologies are not well standardized; this was addressed by Dr. Barbera Silverstein, who testified that there was no consensus on the kinds of psychosocial issues that should be studied or how they could be assessed “with the same rigor that has been \* \* \* looked at [for] physical load factors” (Tr. 17444).

In addition, less is known about the causal relationship between psychosocial factors and MSDs. Many studies performed so far have been cross sectional, thus making it difficult to evaluate the temporal nature of the association (*i.e.*, whether psychosocial factors preceded the MSD or whether the presence of a disorder led to negative psychosocial outcomes). Dr. Punnett addressed this issue in her testimony:

\* \* \* [S]ince psychosocial factors may be perceived and reported differently by the worker after the development of musculoskeletal disorders, the reported associations are particularly difficult to interpret with respect to \* \* \* [etiology].

The occurrence of a work-related musculoskeletal disorder \* \* \* may itself cause psychosocial strain. And that strain may also subsequently slow or interfere with the recovery process without necessarily having been involved in the initial etiology. In this context, we should note that associations with cross-sectional \* \* \* [studies] with physical exposures are far less ambiguous. [Tr. 869–870]

As a result, associations found between psychosocial exposures and MSD outcomes are, relative to biomechanical associations, less

consistent and generally weaker (NAS, 1999, Ex. 26–37). Further, the underlying mechanisms are still not nearly as well understood as those developed for biomechanical associations (Tr. 1344–1345, NAS, 1999, Ex. 26–37). Similarly, understanding and evaluating psychosocial interventions is also in its infancy, making it difficult to design appropriate interventions.

None of the studies cited by either proponents or opponents of an ergonomics standard can demonstrate that any of the risk factors measured, whether biomechanical, psychosocial, personal, or demographic, can completely explain an increased prevalence or incidence of MSD outcomes. (In other words, the combined contribution of all factors to statistical models never comes close to explaining 100 percent of the variance between exposure groups in the outcome measure; there are always other, unmeasured factors involved.) Dr. Tapio Videman (Ex. 32–241–3–20), Dr. Arthur Barsky (Ex. 500–118–1) and most other researchers agreed that a simple biomechanical model of tissue wear and tear is not sufficient by itself to explain disease development in humans, which is characterized by complicated interactions with external environmental factors and individual characteristics. In fact, testimony at the hearing (Tr. 868, 1264, 5942–5943) made it clear that considering psychosocial and biomechanical factors to be separate kinds of exposures is a somewhat artificial distinction in that the two classes of stressors are strongly linked, both resulting from core aspects of the organization: its technology, culture and work organization.

For example, Dr. Punnett testified that

There is also a recognized overlap between some characteristics of physical and psychosocial work environment.

A repetitive, monotonous job on a machine paced assembly line can be described equally well by the ergonomist as consisting of stereotyped repetitive motion patterns with rigid pacing and few rest breaks or as having poor psychological job content with few opportunities to make decisions, work collaboratively with co-workers, utilize existing skills or learn new ones.

And I suggest that the worker performing that job would be hard pressed to make a distinction between the physical and the psychosocial characteristics of that job. [Tr. 868–869]

Ms. Sue Rahula, an ergonomist technician with United Auto Workers, described how biomechanical exposure and the presence of an MSD can affect worker morale, which can be reflected in negative psychosocial outcomes:

When you're feeling pain your morale is going to be low, your discomfort level is low, your attitude is bad, and you may be one of the silent sufferers. \* \* \* When \* \* \* we take our risk factor checklist out and we verify that, yes, these postures are awkward postures and when you add that along with the forces and the exertions that you're using that that's a possibility it sure could cause pain. It's no wonder the morale becomes low. And they [biomechanical and psychosocial factors] do intertwine. But the pain is usually the cause of [low morale], in my opinion, from what I see. [Tr. 5942–5943]

These underlying sources of biomechanical and psychosocial exposures can themselves be seen as a single exposure category known as organizational exposure (Warren, 1997, Ex. 38–72, Warren *et al.*, 2000a, b, Exs. 38–75, 38–73, Shannon *et al.*, 1996, 1997, Exs. 26–1368, 26–1369), which, as Dr. Warren described, recognizes that “the way work is organized will have an effect on the levels of both biomechanical and psychosocial work stresses” (Tr. 1264).

#### *Summary of Primary Literature on Biomechanical and Psychosocial Factors*

OSHA's review of the literature presented below shows that most of the best studies available suggest that MSDs are the result of a complicated combination of biomechanical and psychosocial factors, with the prevalence or incidence of MSDs being generally more strongly associated with biomechanical risk factors. Given the present state of research into MSD etiology, there can be little doubt that a multifactorial model, incorporating both biomechanical and psychosocial risk factors, would best explain the differences in MSD prevalence or incidence seen among various groups of workers. Nevertheless, from the testimony presented above and the review of the literature that follows, OSHA concludes that biomechanical risk factors contribute independently from psychosocial factors to MSD etiology, that the association between the risk of MSDs and exposure to biomechanical risk factors has been observed to be generally stronger than for psychosocial factors, and that, consequently, it is reasonable to design interventions that focus on exposures to biomechanical risk factors to reduce the risk of MSDs in exposed workers.

Because the scientific literature summarized in this section addresses the relative strength of association between MSD risk and two broad categories of workplace factors, and because of the potential for interacting or modifying effects between biomechanical and psychosocial factors,

it becomes particularly important to consider certain elements of epidemiological study design to ensure that study results are appropriately interpreted. These design considerations include the following:

**Best study design.** Epidemiological studies can be of three general designs: cross-sectional, case-control, and prospective (longitudinal) cohort. Dr. Stanley Bigos presented a comprehensive review of the advantages and disadvantages of each study design (Ex. 32-241-3-4, pps. 7-9). OSHA also addressed general issues regarding study design and causal inference in a previous part of this Health Effects section. All researchers agree that prospective studies can most persuasively establish causality, with cross-sectional studies presenting the most potential problems in this area. In the absence of any other information, prospective studies are generally preferable. However, several factors may recommend against this design: in particular, the high cost of these studies and the dynamic nature of the modern workplace, which may change job classifications (and hence workers' exposures) over the follow-up period of the study.

Although cross-sectional studies identify associations and cannot by themselves permit a definite attribution of a causal relationship, it is still possible to draw inferences when one causal direction (*i.e.*, exposure precedes disease) is much more plausible than the alternative explanation (*i.e.*, disease precedes exposure). As Dr. Gerr noted in his testimony (Tr. 1525) the many cross-sectional studies showing an association between carpal tunnel syndrome and physical workplace factors strongly indicate that exposure to these workplace factors causes disease. This conclusion arises in part because it is illogical to postulate that the presence of CTS would cause exposure to physical factors (*i.e.*, workers select themselves into physically harmful jobs on the basis of disease status). Dr. Gerr testified that this would be "like saying cancer causes smoking. It's as wrong as it is silly to hear" (Tr. 1525). However, for psychosocial factors such as poor job satisfaction or low supervisory support, it is more difficult to logically infer or exclude a temporal relationship between a psychosocial factor and an MSD; this was described by Dr. Punnett in her testimony (Tr. 869). That is, it cannot be known whether having poor job satisfaction preceded development of the MSD or whether the presence of the MSD is causing a worker to become less satisfied with their job. Thus, in evaluating the causal nature of

psychosocial factors, the use of a prospective study design that follows groups of workers over time becomes particularly important to evaluate the temporal relationships between exposure to biomechanical risk factors, psychosocial factors, development of MSDs.

In addition, as was the case with the biomechanical literature reviewed in earlier parts of the Health Effects section, determination of exposure and health outcome by objective means, such as direct observation or measurement of exposure and medical assessment of health status, is preferable over sole reliance on worker self-reports because objective measures rule out the possibility of reporting bias (*e.g.*, the possibility that a worker's disease status might influence the self-report of exposure). This design consideration points to another difficulty in studying the role of psychosocial factors in that they can only be assessed by administering questionnaires or interviews.

**Simultaneous assessment.** It is obvious that to accurately assess the relative contribution of biomechanical and psychosocial risk factors to MSD causation and exacerbation, both classes of exposure must be measured.

**Address collinearity.** Levels of both biomechanical and psychosocial risk factors are in large part the result of the way work is organized, the technology and sector of the company, and the organizational policies and culture that drive work organization. Thus the two classes of stressor are generally highly correlated in a workplace (Tr. 868-869, 1264, 5942-5943). Concurrent analysis of exposure-outcome associations must be very careful to avoid modeling problems that arise from collinearity.

**Assess both stressor categories with equal precision.** Some studies assess both categories of exposure, but assess one with more precision or detail than the other. The category characterized in more detail presents fewer opportunities for non-differential exposure misclassification (which biases results towards a lower effect) and will thus show artificially elevated relative associations with outcome. Dr. Wells stated that a factor measured with poor precision in an epidemiological study will often not appear as a risk factor in statistical modeling (Tr. 1355).

**Ensure adequate variance in all measures.** Studies that assess both categories of exposure, but with little variance between exposure groups in one or the other category of exposure will generally not find effects associated with that category or measure. Regression analysis (a standard

modeling method in many studies) cannot assess the contribution of an exposure if its magnitude or intensity is essentially the same in all study participants.

**Assess both stressor categories at the same individual or group level.** Studies that assess both categories of exposure, but at different levels of analysis (*i.e.*, the level of the individual worker versus groups of workers), will generally not find an effect for the variables measured at a higher (group) level of aggregation; this was addressed by Dr. Frank in his testimony (Tr. 1364-1365). For example, the Boeing study (Bigos, *et al.*, 1991a, b, Exs. 26-1241, 26-1242, 1992 Ex. 26-1393) assessed psychological and emotional variables at the individual level and biomechanical variables at the group level. This error also reflects violation of the preceding two criteria since measurement at the group level reduces both precision in the biomechanical exposure measure (compared to measuring exposure at the individual level) and variance in biomechanical exposure between groups. When one variable is aggregated or represented at the group level, as in the Bigos measurement of biomechanical risk, the variations in exposure within each group are lost; internal variance within each group is reduced to zero.

The studies summarized below relied on assessment of both biomechanical and psychosocial factors in the workplace. Thus, in accordance with the second criteria described above, studies were excluded if they did not assess one class of stressor or did not include both classes in multivariate analysis. Such studies are useless for the exploration of combined biomechanical and psychosocial effects.

The majority of the studies below demonstrate at least equal, and often stronger, associations with biomechanical stressors than with psychosocial. This fact, combined with the independent effects of both stressor classes, as discussed above, is sufficient to support OSHA's focus on biomechanical risk factors in the final rule. However, relative magnitude of the associations for biomechanical and psychosocial risk factors should only be seen as a qualitative indicator of relative strength of association with MSD prevalence or incidence. Actual quantitative effect sizes may not be comparable within or between studies for a number of reasons, including:

- Use of different measurement scales;
- Use of different analytical strategies to categorize risk levels; and

• Use of different outcome measures in different studies.

Table V-14. summarizes the key features of the design of each study as well as the range of measures of association for biomechanical and psychosocial factors.

Wickstrom & Pentti 1998 (Ex. 500-121-77). This 2-year prospective study of 117 white-collar and 189 blue-collar workers in two metal industry facilities assessed both biomechanical and psychosocial exposures (4 items each) at baseline, using equivalent levels of detail. Back pain was assessed twice in

the follow-up period by questionnaire, and data on sick leave attributed to back pain and other MSDs (doctor diagnosis if over 3 days) was obtained from company records. The exposure assessment at baseline plus physician diagnosis at follow-up made this design capable of strongly implying causal status to both physical and psychosocial risk factors. As predictors of self-reported LBP, 3 physical exposures were predictive for both white collar (RRs: 2.82-6.19) and blue-collar workers (RRs: 2.49-3.67). Since other authors (Marras, 2000, Ex. 500-121-46) have

hypothesized that psychosocial exposures have less effect if the physical load is high, it is interesting that psychosocial stress was predictive of LBP in white-collar workers, while none of the 4 psychosocial exposures were significantly predictive in blue-collar workers. However, sick leave was predicted for blue-collar workers by both biomechanical exposures (RRs: 1.72-2.04) and psychosocial (RRs 1.58-1.99). In general, this study supports the interpretation that MSDs are caused by both classes of risk factor, with biomechanical showing stronger effects.

TABLE V-14.—STUDIES ASSESSING BOTH BIOMECHANICAL AND PHYSICAL RISK FACTORS

Reference	Number of subjects	Study type	Exposure measure	Outcome measure	Study design	Results: outcome and effect
<b>Association with Biomechanical Factors Stronger than with Psychosocial Factors (or effect size not reported)</b>						
Wickstrom & Pentti (1998).	306	3	1 .....	1, 2, 3 .....	all	LBP & sick leave due to LBP; Physical RR: 1.97-6.19; Psychosocial RR: 1.58-1.59.
Bergqvist <i>et al.</i> (1995) ...	260	1	2 .....	3 .....	all	UE/LBP sympt./MD diag.; Physical OR: 3.1-7.4; Psychosocial OR: 2.1-7.4.
Kerr <i>et al.</i> (2000) .....	381	2	3 .....	1 .....	all	Reporting of LBP; Physical OR: 1.7-3.0; Psychosocial OR: 1.6-2.6.
Koehoorn <i>et al.</i> (1999) ...	4020	3	2 .....	2 .....	a, c	MSD symptoms & claims; Physical RR: 1.41-4.65; Psychosocial RR: 0.45-2.78.
Krause <i>et al.</i> (1998) .....	1449	3	1, 2 .....	2 .....	b, c	Spinal injury through WC; Physical OR: 3.04 (driving cable car); 0.37 (part-time driving: 20-30 hrs); Psychosocial OR: 1.50-1.56.
Latko <i>et al.</i> (1997, 1999)	352	1	2 .....	1, 3 .....	all	Symptoms, MD Dx of CTS; Physical OR (high repetition vs. low rep.): 2.32-3.23; Psychosocial OR: n.s.
Latza <i>et al.</i> (2000) .....	230	3	1 .....	1 .....	all	Self-reported LBP; Physical PR: 1.8-4.0; Psychosocial PR: n.s.
Leclerc <i>et al.</i> (1998) .....	1210	1	1 .....	3 .....	all	CTS by signs or NCV; Physical OR: 1.90-2.24; Psychosocial OR: 1.59-2.24.
Linton (1990) .....	22,180	3	1 .....	1 .....	all	Neck & LBP symptoms Univariate ORs; Physical: 0.86-2.95; Psychosocial: 1.15-2.60; Combined ORs: 2.42-3.65.
Ono <i>et al.</i> (1998) .....	575	1	1 .....	3 .....	all	Epicondylitis, MD Dx; Physical OR: 1.7; Psychosocial OR: 1.2.
Videman <i>et al.</i> (1989) ...	199	3	2 .....	1 .....	b, c	Incidence of back injury; Low skill OR: 37-156 (if also 3 hrs. strenuous working postures)
Bernard <i>et al.</i> (1992, 1994).	973	1	1, 2 .....	1 .....	all	UE symptoms; Physical OR: 1.4-2.5; Psychosocial OR: 1.4-1.7.
Faucett & Rempell (1994).	150	1	2 .....	1 .....	all	UE symptom severity, (effect measured by R <sup>2</sup> change): Physical: 0.11-0.15; Psychosocial: 0.03-.12.
Heliovaara (1987) .....	*592	3	1 (occ.) ...	3 .....	none	Hospital Admission for disc herniation/sciatica; Occupational RR: 2.2-3.0; Psychic Distress: NR.
Josephson & Vangard, 1998.	269	2	1 .....	1 .....	all	LBP medical visit; Physical OR: 2.3-8.7; Psychosocial OR: n.s.
Svensson & Andersson (1981).	940	**1	1 .....	2 .....	all	LBP sickness absence; Heavy Lifting (effect NR); Reduced overtime/monotonous work (effect NR).
Thorbjornsson <i>et al.</i> (2000).	484	2	1 .....	1 .....	all	LBP med. visit or absence; Physical OR: 1.7-2.2; Psychosocial OR: n.s.; Interaction OR: 3.1-3.7.
Vingard <i>et al.</i> (2000) .....	2118	3	1 .....	1 .....	a, b	Care-seeking for LBP; Physical RR: 1.8-2.9; Psychosocial RR: 1.5-1.6.
Warren <i>et al.</i> (2000a) ...	845	2	1 .....	1 .....	all	NIOSH MSD case def.; Physical OR: 1.89-2.13; Psychosocial OR: 1.56-1.69.
Waters <i>et al.</i> (1999) .....	284	1	1, 2 .....	1 .....	all	Prevalence of LBP; Lifting Index OR: 1.04-2.20; Satisfaction OR: 4.57-7.65.
Burt <i>et al.</i> (1990) .....	834	1	1 .....	1 .....	all	UE Symptoms; Physical OR: 2.0-4.1; Dissatisfaction OR: 1.9-2.3.

TABLE V-14.—STUDIES ASSESSING BOTH BIOMECHANICAL AND PHYSICAL RISK FACTORS—Continued

Reference	Number of subjects	Study type	Exposure measure	Outcome measure	Study design	Results: outcome and effect
Lemasters <i>et al.</i> (1998)	522	1	1 .....	3 .....	c	Pain, all body parts, self-report and MD Dx; Physical OR: 2.3–3.5; Psychosocial OR: 1.6–2.9.
Scov <i>et al.</i> (1996) .....	1306	1	1 .....	1 .....	all	UE and low back symptoms; Physical OR: 1.64–2.80; Psychosocial OR: 1.43–2.04.
Warren <i>et al.</i> (2000b) ....	7712	1	1 .....	1 .....	all	MSD symptoms & pain; Physical $\beta$ : 0.06–0.16; Psychosocial $\beta$ : 0.04–0.12.
Hales <i>et al.</i> (1992, 1994)	533	1	1 .....	1 .....	a, b	UE MSD symptoms; Physical OR: 1.1–3.8; Psychosocial OR: 1.1–3.5.
Hoekstra <i>et al.</i> (1994) ....	108	1	1 .....	1 .....	a, b	MSD symptoms; Physical OR: 3.5–5.1; High Control: OR 0.6.
Houtman <i>et al.</i> (1994) ....	5865	1	1 .....	1 .....	b, c	Complaints: muscle/joint & back; chronic back problems; Physical OR: 1.36–1.62; Psychosocial OR: 1.20–1.35.
<b>Association with Psychosocial Factors Stronger than with Biomechanical</b>						
Viikari-Juntura & Riihimaki (2000).	5179	3	1 .....	1 .....	all	Radiating neck pain; Physical OR: 1.2–2.3; Psychosocial OR: 1.1–6.1.
Waters <i>et al.</i> (1999) .....	284	1	1, 2 .....	1 .....	all	Prevalence of LBP; Lifting Index OR: 1.04–2.20; Satisfaction OR: 4.57–7.65.
Elberg <i>et al.</i> (1995) .....	637	1	1 .....	1 .....	all	Neck & shoulder symptoms; Physical OR: 1.2; Psychosocial OR: 1.2–1.3.
Sauter (1984) .....	333	1	1 .....	1 .....	all	Somatic complaints; Physical $\beta$ : 0.16–0.21; Psychosocial $\beta$ : 0.19–0.26.
Warren <i>et al.</i> (submitted)	7712	1	1 .....	1 .....	all	LBP, absenteeism; Physical OR: 1.45–1.88; Psychosocial OR: 1.32–2.27.
<b>Biomechanical Effect Not Significant</b>						
Leino & Hanninen (1995).	902	3	1 .....	1, 3 .....	b, c	Back/limb symp. & MD Dx; Physical $\beta$ : n.s.; Psychosocial $\beta$ : .110–.146.
Bigos <i>et al.</i> (1991a) .....	3020	3	1, 2 .....	2 .....	none	Reporting back injury; Physical RR: n.s.; Psychosocial RR: 1.34–1.70.
Svensson & Andersson (1989).	1746	1	1 .....	1 .....	all	Low back pain; Physical n.s.; effect NR; Fatigue, dissatisfaction, worry; sig., but effect NR.

n.s.: not significant  
 NR: controlled for factor, but effect not reported  
 Table only notes statistically significant effects (p<0.05)  
 Key:

- Study Type:
  - 1—Cross sectional
  - 2—Case-control/Referent
  - 3—Cohort/Prospective
- Exposure Measure:
  - 1—Worker self-report
  - 2—Observation of job
  - 3—Instrumentation
- Outcome Measure:
  - 1—Worker self-report
  - 2—Observation/record
  - 3—Clinical findings
- Study Design
  - a—Biomechanical and psychosocial factors studies with equal precision
  - b—Biomechanical and psychosocial factors assessed at same individual or group level
  - c—Adequate variance between groups in all measures

\* case 2140 con.  
 \*\* retro. outcome

*Bergqvist, Wolgast, Nilsson, Voss 1995 (Ex. 26–1195).* These investigators found a number of upper extremity diagnoses to be consistently associated with standard biomechanical risk factors (especially postural stressors, ORs 2.2–4.4, and lack of rest breaks, ORs 2.7–7.4); some personal factors (especially age and presence of children at home), task flexibility (OR 3.2) and quality of

peer contacts (ORs 2.1–4.5) had independent associations. Although the study was cross-sectional, confidence in study findings is improved by the detailed physical examination used to determine outcome and the broad array of exposure measures (including individual factors, non-work risks, work organizational factors and biomechanical factors). Muscle

problems in each body location showed a different pattern of personal, psychosocial and biomechanical stressor associations.

*Faucett and Rempel 1994 (Ex. 38–67).* His study of 150 newspaper editorial work found that upper extremity pain and numbness symptoms in VDT workers were related primarily to postural variables (R<sup>2</sup> changes 0.11–

0.15), with smaller additions to model R<sup>2</sup>s from psychological demands, decision latitude, and employee relationship with the supervisor (R<sup>2</sup> changes 0.03–0.12). The effects of postural variables on upper torso pain and stiffness were greater than those for pain and numbness (R<sup>2</sup> changes 0.19–0.32), while psychosocial effects were reduced (R<sup>2</sup> changes 0.01–0.08). Interaction terms between keyboard height and psychosocial variables added to the model R<sup>2</sup>s (R<sup>2</sup> changes 0.04–0.15), suggesting that the effect of biomechanical variables can be modified by psychosocial variables. In this study, biomechanical stressors were clearly the dominant factor, but the size of the effect for interaction terms may have meaning for the mechanism of psychosocial action as being an effect modifier.

*NIOSH Health Hazard Evaluations (Exs. 26–439, 26–842, 26–725).* Three cross-sectional NIOSH studies, at the L.A. Times (Bernard, Sauter, Petersen, Fine, & Hales, 1992, Ex. 500–165–20, 1994, Ex. 26–439), *Newsday* (Burt, *et al.*, 1990, Ex. 26–842) and two Social Security Administration teleservice centers (Hoekstra *et al.*, 1994, Ex. 26–725) found associations of biomechanical risk factors (in particular, duration of VDU work) with MSD symptoms, while also finding independent associations of these symptoms with several psychosocial factors. Another NIOSH HHE at U.S. West Communications (Hales *et al.* 1992 (Ex. 26–727), 1994 (Ex. 26–131) did not find associations between symptoms and physical workplace characteristics other than use of bifocal glasses (OR 3.8), because the standardized workstations presented virtually no variance in biomechanical measures. Thus, psychosocial factors were dominant in the models, although work pressure (OR 1.1–1.2), workload surges (OR 1.2) and information processing demands (OR 1.2) probably represent a combination of physical and psychosocial exposures. See Table V–14. for strength of association estimated by multivariate logistic regression models in all these studies.

Kerr, *et al.* 2000 (Ex. 38–82). Researchers at the Institute of Work and Health (IWH) have carried out several well-designed studies measuring both biomechanical and psychosocial stressor levels in detail. These studies demonstrate the independent contributions of biomechanical, psychosocial and organizational factors to models explaining back injury and accidents (Shannon *et al.*, 1996, 1997, Exs. 26–1368, 26–1369). The most recent IWH study (Kerr, *et al.*, 2000, Ex.

38–82), performed in concert with the Ontario Universities Back Pain Study (OUBPS) group, is a case-control study reviewed in detail by John Frank (Ex. 37–27). Subjects reported levels of physical demands (including perceived exertion) as well as psychosocial factors. In addition, videotape analysis and biomechanical modeling provided quantifiable estimates of actual spinal loading. These biomechanical measures acted independently to substantially increase risk of workers reporting new cases of LBP, after controlling for individual and psychosocial factors. In final models, the biomechanical risk factors demonstrated ORs of 1.7–3.0, while psychosocial risks were associated with ORs of 1.6–2.6. This study improved on earlier study designs by directly measuring forces on back during job performance. The case-control study also matched controls by actual job, allowing analysis of the degree to which job exposures influenced self-reported LBP. Compression, peak shear force, peak hand force were associated with doubled risk of LBP reporting. These findings are consistent with much of the other epidemiological data reviewed in this section. Thus this study strengthens confidence in the results of other studies that rely on less detailed exposure assessment and/or self-reported exposures and outcomes.

Krause *et al.* 1997 (Ex. 38–267), 1997 (Ex. 38–266), 1998 (Ex. 500–87–2). Niklas Krause and colleagues, studying a cohort of San Francisco drivers, examined relationships between biomechanical and psychosocial exposures and neck and shoulder outcomes. The cross-sectional analyses (Krause *et al.*, 1997a, Ex. 38–267, 1997b Ex. 38–266) determined that both biomechanical and psychosocial job factors were separately and simultaneously associated with non-disabling neck and back pain. The 5-year longitudinal follow-up of this cohort (Krause *et al.*, 1998, Ex. 500–87–2) found that workers' compensation cases of spinal injury were predicted by a combination of biomechanical (measured by hours driving) and psychosocial risk factors at baseline. (See Krause testimony, Ex. 37–15). The physical risk factors addressed by this measure of hours spent driving included prolonged sitting, twisting/bending, vibration, and use of foot pedal (Krause testimony, Tr. 1376, Ex. 37–15). Although all measures were gathered at the same (individual) level, the surrogate measure for biomechanical exposure (hours spent driving) was a more generalized measure than the

psychosocial data and thus subject to greater non-differential misclassification and consequent dilution of effect in statistical modeling. Psychosocial stressors demonstrated, on average, higher ORs than the surrogate physical measure of hours spent driving. This is an example of the fourth study design criterion discussed above: the factor measured in greater detail has a greater likelihood of showing stronger associations in the modeling. The fact that a biomechanical effect still emerged in the modeling strongly suggests that if physical exposures were measured in the same detail as psychosocial exposures, they would have demonstrated a larger effect in modeling; however, it cannot be known whether the resulting size of the effect for biomechanical factors would have surpassed that for psychosocial factors. For cable car operators, biomechanical factors were more strongly associated with back cases than were psychosocial factors.

In his written comments, Dr. Nortin Hadler (Ex. 32–241–3–8) demonstrated a basic misunderstanding of the research by taking the Krause studies to task for showing a biomechanical effect only for cable car drivers. The data did show that only cable car drivers' injury rate was significantly elevated when compared to diesel bus drivers. However, the pooled data for *all* drivers showed a highly significant increase (2.7 times) in injury rate between drivers who worked 20–30 hrs per week compared to those who worked 31–40, suggesting a significant effect related to biomechanical factors. Hours-per-week-driven was the study's surrogate measure for exposure to physical risk factors.

Latko *et al.* 1997 (Ex. 38–122), 1999 (Ex. 38–123). These researchers performed a cross-sectional study with some of the most detailed exposure assessments to be found in the literature. The study, described elsewhere in the testimony (Franzblau, Ex. 37–3, Armstrong, Ex. 37–21) measured a wide variety of demographic, personal, and exposure variables, including 13 psychosocial parameters. It is distinguished by precise measurement of exposure variables and several levels of outcome measurement objectivity, ranging from symptom reports, through physical findings, to nerve conduction velocity (NCV) results. The contribution of the psychosocial variables did not reach significance in the final modeling, strongly implying that the effect of biomechanical factors predominates in these 3 manufacturing plants (testimony

by Armstrong, Ex. 37-3, Franzblau, Ex. 37-21).

Nortin Hadler (post hearing comments, Ex. 500-118-1, p 7) cited this study as evidence for a lack of a significant association between repetitive motion and decrements in median NCV. These results were, in fact, marginally significant. Moreover, if a more conservative definition of CTS was used, (*i.e.*, 0.8ms threshold plus positive hand diagram report), the association was significant (Franzblau testimony, Ex. 37-21). In addition, Dr. Hadler failed to note either the wide range of significant associations found for repetition, symptom reports and tendinitis as indicated by physical exam findings, and that these associations did demonstrate a positive exposure-response relationship.

Warren 1997 (Ex. 38-72), Warren *et al.* 2000 (Ex. 38-73). Nicholas Warren and colleagues at the University of Massachusetts at Lowell and at TNO, the Netherlands, performed analyses on the Dutch Monitor data set, collected from a broad sample of companies and industry sectors in 1993—a cross-sectional study. The data set contained completed questionnaires from 7,717 Workers in 528 companies that assessed in detail both workplace exposure to biomechanical and psychosocial risk factors and a variety of musculoskeletal and stress outcomes, as well as reports of extended sick leave. Controlling for gender, education and tenure on the job, the multivariate linear analyses found roughly equal contributions of both stressor classes to the pain and MSD symptom reports, with physical factors having a somewhat larger magnitude of effect (standardized regression coefficients of 0.06-0.16) than psychosocial (0.04-0.12). Logistic modeling of low back pain and absenteeism outcomes found similar results, with biomechanical ORs of 1.35-1.88 and psychosocial ORs of 1.32-1.64, excluding social support. However, low social support did demonstrate the highest OR (2.27) in the model explaining low back pain. The study was cross-sectional and thus could not definitively evaluate temporal associations. However its large size and wide range of companies and sectors allowed precise separation of biomechanical and psychosocial exposure-outcome associations, without collinearity problems.

Dr. Alf Nachemson criticized this study (post-hearing comments, Ex. 500-118-1), confusing it with a completely different study of a different database submitted to *Spine*. The results of this study are reported in a doctoral thesis (Warren, 1997, Ex. 38-72) and an article

submitted to the Scandinavian Journal of Work Environment and Health (Warren *et al.*, 2000b, 38-73). Contrary to Dr. Nachemson's mischaracterization, the express purpose of this study was to simultaneously measure biomechanical and psychosocial MSD risk factors at the same level and degree of detail.

Warren *et al.* 2000 (Ex. 38-75). Warren and colleagues from the University of Connecticut Health Center carried out a separate study of the Connecticut working population, using a random-digit-dialing study design. This cross-sectional study is one of the few to randomly sample workers with unreported cases of MSD (using the NHIS definition; Tanaka *et al.* 1995 (Ex. 26-59)). Psychosocial and biomechanical variables were assessed at equal levels of detail. Logistic regression analysis found case status to be associated with a broad mix of psychosocial and biomechanical stressors, with biomechanical exposures showing somewhat higher odds ratios. Significant psychosocial ORs ranged from 1.56-1.69, while biomechanical ORs were between 1.89 and 2.13. Stressors were measured at equivalent levels of detail and demonstrated independent effects for psychosocial and biomechanical exposures.

Koehoorn, 1999 (Ex. 500-40). This doctoral thesis used a retrospective cohort design to follow 4020 health care workers from an acute-care hospital over a 4-year follow-up period, assessing outcomes of musculoskeletal symptoms and claims. Results varied by body location. In multivariate models explaining upper body symptoms, a biomechanical index showed risk ratios of 1.41-1.84, while psychosocial variables showed RRs ranging from 0.45-2.78. For lower-body symptoms, RRs for biomechanical risk factors ranged from 2.12-4.65; psychosocial variables generally did not reach statistical significance. Outcomes of compensation claims related to these two body areas showed similar ranges of effect. In subcohorts analyzed for departmental sicktime and overtime, increased sick time was associated with symptoms and claims, but increased overtime was not. The study design assessed detailed biomechanical factors by observation, but only by occupational title, while psychosocial factors were assessed by individual questionnaire. Thus, the relative strength of association may have been underestimated for biomechanical stressors. This large, carefully designed cohort study provides evidence for a multifactorial model of MSD causation, with physical factors being more

strongly associated with MSD incidence.

Waters *et al.* 1999 (Ex. 500-41-54). This study was designed to provide epidemiologic data linking the NIOSH lifting index (LI, a quantitative measure of manual lifting stress calculated with the revised NIOSH lifting equation) to prevalence of low back pain. Measurements used to calculate the LI were collected on a sample of workers over a 2-4 day period by trained observers. Workers also completed a self-administered questionnaire that included psychosocial items. In multivariate modeling, increasing values of the LI were associated with increases in period prevalence of LBP over the last 12 months, with an exposure-response relationship that reversed at the highest LI (>3). The authors noted that this drop in negative outcomes in the highest exposure category is seen in other studies and seems to indicate a "healthy worker" or survivor effect (representing the departure of workers with pain or high risk of back injury from highly stressful jobs). Psychosocial factors of demands, control and social support did not enter significantly into these models, perhaps because they were entered as continuous, not categorized, variables. However, a four-category measure of decreasing work satisfaction showed a significant exposure-response relationship with LBP. This high-quality study, which relied on independent measurement of physical job characteristics, demonstrated the combined contribution of physical and some psychosocial stressors to prevalence of LBP, with physical effects predominating in multivariate modeling.

Leclerc *et al.* 1998 (Ex. 500-41-85). This cross-sectional study of 1210 workers in 3 industry sectors incorporated a sophisticated mixture of individual measurement of both physical and psychosocial factors, combined with group-level assessment of cycle time and autonomy. Given the study design principles outlined above, the effects of these group-level factors may thus be underestimated. With this caveat, the research still demonstrated a combined contribution to physician-diagnosed CTS for cycle times less than 10 seconds (OR 1.90) and psychological "problems" (OR 1.41). Other physical and psychosocial factors dropped out of this model. In a final model incorporating the presence of just-in-time production organization at the plant, this factor replaced cycle time, with an OR of 2.24. Other physical and psychosocial risk factors were associated with marginal significance.

The work organization variable of just-in-time production is probably a surrogate for a combination of increased biomechanical and psychosocial risk. This study thus demonstrates the combined contribution of both types of risk. This study also found that industry sector did not enter significantly into the model when both physical and psychosocial risk factors were more precisely measured at the individual level.

Latza *et al.* 2000 (Ex. 38–424). This prospective study of construction workers in Hamburg took detailed observational measurements of biomechanical stressors associated with a wide variety of construction tasks. Of the 571 workers who filled out baseline questionnaires, 285 individuals free of LBP were selected; 230 were followed up after 3 years. The physical stressors at baseline predicted subsequent 1-year prevalence of LBP (PRs: 1.8–4.0), while psychosocial stressors did not enter significantly into the models. This is somewhat surprising since, although the physical stressors were evaluated in detail, they were measured at the job level, while psychosocial factors were measured at the individual level. As noted above, this usually results in an underestimate of the physical stressor contribution relative to psychosocial factors.

Vingard *et al.* 2000, MUSIC study (Ex. 500–41–51). The Swedish MUSIC project has consistently demonstrated combined associations of biomechanical and psychosocial stressors with back, neck and shoulder, and other disorders. This study assessed prospectively the individual and combined effects of physical and psychosocial exposures on subjects' seeking care for LBP over a 5-year period. Gender stratification reduced significance levels but demonstrated somewhat different exposure-outcome associations for males and females. For men, forward bending and manual material handling time, when compared to levels 5 and 10 years ago, were significantly predictive (RR 1.8 and 2.0 respectively) with a combined exposure having a RR of 2.8. This combined exposure was also significant for females (RR of 2.3). For both genders, a combination of physical stressors including metabolic stress was also a risk factor. Although included in these multivariate models, most psychosocial stressors did not enter significantly (exceptions were low work satisfaction and low skill use for males, RRs of 1.6 and 1.5, respectively). A subset of the study sample reflecting a combination of high physical load and high psychosocial load showed much higher RRs, but the sample size was

small. Overall, the MUSIC study provides well-designed and detailed evidence that physical and psychosocial exposure combine in the etiology of LBP, with the physical stressors demonstrating stronger effects.

Houtman *et al.* 1994 (Ex. 26–1230). This paper reported a cross-sectional analysis of pooled 1977–1986 results from the National Work and Living Condition Survey in the Netherlands. The study asked one question on work pace, four on intellectual discretion, and one on physical load. The items were all assessed at the same level of precision (dichotomous, yes/no) and at the same analytical level, but the greater detail in intellectual discretion assessment may have biased the estimated effects of that particular construct upwards. Multivariate logistic regression models were constructed to explain variance in 3 musculoskeletal outcomes: back complaints, muscle/joint complaints, and chronic back problems. Work pace was consistently associated with these outcomes (ORs 1.21–1.29) as was heavy physical load (ORs 1.36–1.62). Of the intellectual discretion items, only one, monotonous work, was consistently associated with musculoskeletal symptoms (ORs 1.29–1.35), but when all four items were combined, the scale demonstrated the strongest association of the study with chronic back pain (OR 2.10). Thus, in addition to providing more evidence for independent association of physical and psychosocial stressors with musculoskeletal outcomes, the study supports the hypothesis that psychosocial stressors have their strongest effect with duration of pain, not its inception.

Videman *et al.* 1989 (Ex. 26–1155). This study is difficult to interpret, but is included because of its relevance to interventions. The researchers dichotomized graduating nursing students by skill level. Half the students had received traditional lifting training; half had received advanced, biomechanically-oriented training. Skill assessment was performed through video analysis of standardized tasks, not by simple assignment to trained or untrained groups. Nurses were also dichotomized by hours/day in strenuous postures (<3 hrs/day, ≥3 hrs/day). In addition, the study collected extensive anthropometric, strength and psychological measures. Incidence of back injury was assessed at a 1-year follow-up. The results seem to confuse training level and activity level, but a combination of >3 hours/day of strenuous activity and low skill level significantly predicted self-reported incidence of back injury (ORs of 37 or 156, further stratified by high and low

abdominal strength, respectively). The authors emphasized that ergonomic interventions must be coupled with training and describe the training as resulting in biomechanically less stressful lifting choices by nurses. They concluded that training is an effective intervention and “the biomechanical and ergonomic components of training in patient-handling appear to be inescapable” (Ex. 26–1155).

Thorbjornsson *et al.* 2000 (Ex. 500–71–49). This retrospective nested case control study examined a cohort of 484 subjects from the general population, examined first in 1969 and again, 24 years later, in 1993. Exposure information was collected retrospectively for the 24-year period and the 12 months previous to the 1993 interview. Outcomes measured were LBP that resulted either in a medical visit or sick leave more than 7 days. The study identified a small number of physical factors (heavy physical work, sedentary work) and psychosocial factors (poor social relations and overtime work) associated with LBP, as well as high load outside of work. Most importantly, the research demonstrated significant ORs for a wide variety of interaction terms between workplace biomechanical and psychosocial risk factors (ORs: 2.2–3.5). In final modeling incorporating the interaction terms, individual psychosocial effects became non-significant, but an interaction between poor social relations and overtime work showed an OR of 3.1–3.7 for men, depending on LBP onset time. The finding of significant interactions between biomechanical and psychosocial factors suggests that control of biomechanical risk factors in the workplace should reduce not only the effects associated with biomechanical risk factors, but the effects of their interaction with psychosocial exposures.

*Boeing Study.* (Bigos *et al.* 1991 (Ex. 26–1241), 1991 (Ex. 26–1242), 1992 (Ex. 26–1393)).

These studies were discussed earlier in the Health Effects section. In addition, several witnesses who appeared at the public hearings (Frank, Krause, others, *e.g.* Exs. 37–27, 37–15) have explored the methodological problems with this study, which explain its finding that the only significant predictor of back pain reporting found was job dissatisfaction. In sum, the study assessed physical factors at the group level (although the articles never make clear the exact methodology), while assessing psychosocial and psychological variables at the individual level. Assessed at the group level, the variance

in predictive physical factors was drastically reduced. For instance, Dr. Bigos stated (Bigos *et al.*, 1991b, Ex. 26–1242, testimony, Tr. 6908) that no-one was required to lift over 20 lbs., and no-one actually lifted more than 50. However, the analysis had no way to assign actual lifting frequency or compressive forces at the individual level. It is difficult to determine whether even the poor characterization of physical load approached statistical significance because the authors elected simply not to report results that were not significantly associated with outcomes (testimony, Tr. 6786). In addition to this measurement problem, psychosocial and psychological factors were measured with much greater precision. As noted above, these assessment differences virtually ensure the primacy of the better-measured factors, in this case the psychosocial factors, in statistical modeling.

In addition, the factors entered in the Boeing study models explained only an extremely small percentage of variance in the outcome; job satisfaction explained 2.2 percent and psychological variables explained 1.9 percent. All of the psychological, physical exam and medical history variables assessed in the study combine to explain only 8.6 percent of the variance (Bigos *et al.*, 1992, Ex. 26–1393). Thus, 91.4 percent of the variance in reporting of back pain is not explained by the combination of poorly measured physical risk factors and the more detailed psycho-emotional factors. This suggests relatively poor characterization of overall exposure.

The flaws noted above also pertain to the psychological factor assessment in this study. Psychological factors were measured at a much finer level of detail than physical factors, which were measured at the group level. Overall explanatory power of any of these measures was poor. As a minor point, specific to the psychological assessment, the study used non-standard and out-of-date instruments (Cherniack testimony, Tr. 1150).

*Svensson and Andersson 1989 (Ex. 26–732)*. This study evaluated the association of a number of physical and psychosocial and psychological variables with incidence (retrospective) and prevalence of LBP in women. Both physical and psychosocial/psychological variables showed univariate associations with the outcome, but multivariate analysis found associations only with 3 “psychological” variables: dissatisfaction with the work environment, worry/tension at the end of the day, and fatigue. The analysis is not helpful to the separation of physical

and psychosocial effects for three reasons. First, the study only reports the p-value range of the significant associations and does not report effect size, thus making it impossible to tell if physical exposures were of near significance and to compare relative strength of association. Second, it is not at all clear whether variables of dissatisfaction and worry/tension represent a psychological exposure or an *outcome*, resulting from an underlying combination of physical and psychosocial/psychological workplace factors, or from underlying symptoms (see, Linton, 2000, Ex. 26–642). Most importantly, it is clearly a mistake to label “fatigue” a psychosocial variable. In fact, fatigue represents an integrated measure of all stressors, physical and psychosocial, encountered by the worker and may well be weighted towards the obvious biomechanical stressors. As such, it is not surprising that this measure might capture variance from the individual physical exposures tested in the study. (Recall how the combined index of psychosocial exposures in the Houtman *et al.* study, (1994, Ex. 26–1230) had the highest ORs in the study, while the individual items composing the index had much lower ORs.) As confirmation, it is interesting to note that these authors’ earlier research (1983, Ex. 26–1158), which assessed a similar set of exposures but did not include the fatigue item, did demonstrate a contribution from a physical stressor (high degree of lifting). Thus, this research appears to be unable to accurately separate the contribution of physical and psychosocial/psychological factors to LBP.

*Leino and Hanninen 1995 (Ex. 38–76)*. This paper reported the results of a prospective study begun in 1973, in 2653 industrial workers, including managerial and office positions. Nine hundred two of these participants were reexamined after 10 years. Outcomes were self-reported musculoskeletal symptoms and evaluations by physiotherapists. At follow-up, both self-reported symptoms and medical findings were predicted by one psychosocial scale (social relations, OR 2.63–3.41) and occupational class (OR 2.67–3.73). The only factor that partly captures physical load in this model is occupational class. A single, 4-level measure of physical load was also entered into the equation. However, this measure is much less precise than the 6-question scale (each item with 5 levels) assessing social relations. This unequal precision would bias the results towards the exposures measured with

greater precision, the psychosocial factors.

The authors noted that their physical load measure did enter into the cross-sectional models at baseline, along with more psychosocial exposures (work content, overstrain) and occupation. It was surprising to find that physical load (a slightly more precise measure of biomechanical exposures than exposure) dropped out of final models while occupation class remained. Both physical load and occupation in this study represent biomechanical exposures assessed at a much less precise level than the psychosocial measures. This study, though provocative, cannot provide useful information about the relative strength of effect.

#### *Summary of Literature Reviews*

Several reviews have been published that have evaluated the literature dealing with work-related MSDs; many of these reviews included evaluations of studies that concurrently examined the effects from exposure to both biomechanical risk factors and psychosocial risk factors. In this section, OSHA summarizes the reviews contained in the rulemaking docket.

*Burdorf & Sorock 1997 (Ex. 502–232)*. These authors reviewed 35 studies that collected quantitative information on exposures and back disorder outcomes. Eight of these studies assessed psychosocial and biomechanical risk factors simultaneously. Of these, six found positive associations of back disorders with a combination of physical and psychosocial exposures and two identified several of the physical factors to be significantly associated, while the psychosocial factor measured (job dissatisfaction) did not show a significant association.

The analysis identified lifting or carrying loads, whole-body vibration, and frequent bending and twisting to be the biomechanical risk factors having consistent associations with work-related back disorders. Unlike some other studies (e.g., Leino & Hanninen, 1995, Ex 38–76), height and weight (as well as gender, exercise and marital status) were consistently not associated with back disorders in these studies. The review identified low job decision latitude and job dissatisfaction as possibly important predictors of MSDs, but the evidence was not consistent across studies with different designs. Although the majority of these eight studies acknowledged the importance of psychosocial factors, the generalization that emerges from them is that biomechanical factors were more

consistently associated with back disorders.

*Punnett and Bergqvist 1997 (Ex. 38-13).* This review of a large international body of literature linking biomechanical and psychosocial factors to upper extremity symptoms and findings in computer users (classified by neck/shoulder, arm/elbow, and hand/wrist). The authors found strong, consistent evidence linking MSD development with biomechanical factors (hours/day and cumulative years of exposure, intensive or repetitive data entry, and non-neutral postures due to poor workstation design), while controlling for work organizational and psychosocial factors in 7 of the 72 papers included in the analysis. The work organizational factors included in 3 papers (repetitive work, work pressure and insufficient rest breaks represent a combination of physical and psychosocial risks. In 4 papers, this review found suggestive but inconsistent associations (making generalization impossible) between MSD symptoms and the psychosocial factors of low decision latitude, low social support, job insecurity and job dissatisfaction (Bergqvist *et al.*, 1995, Ex. 26-1195, Faucett & Rempell, 1994, Ex. 38-67, Kamwendo *et al.*, 1991, Ex. 26-1384, Hoekstra *et al.*, 1994, Ex. 26-725). The authors also noted the difficulty of using job dissatisfaction as a predictor for MSDs since it could easily be either a cause or consequence of an MSD.

*Lagerstrom et al. 1998 (Ex. 38-102).* In this review of studies relating to low back problems in nursing, 42 articles passed the inclusion criteria: 21 cross-sectional, 10 prospective, and 11 intervention (also prospective). One of the reviewers' quality criteria was that the studies include both physical and psychosocial exposure information. The authors noted that a problem in many of the studies was the assessment of physical stressor information at an aggregate or group level, while psychosocial exposures were assessed at the individual level. As noted above, this non-comparability would tend to underestimate biomechanical effect in relationship to psychosocial effect. Still, the authors conclude from their review that biomechanical and psychosocial exposures generally combine in their associations with or (in prospective studies) effects on back disorder outcomes. Looking at well-designed studies with dual exposure measurement, the authors report that "[t]o our knowledge there are no studies that show that work organizational or psychosocial factors, as such, cause low-back problems." They do acknowledge

the importance of these factors in the "consequence and maintenance" of low-back related disorders, through differences in pain perception and reporting behavior.

*Bongers et al. 1993 (Ex. 26-1292).* This article was one of the earliest reviews of the evidence for an association between psychosocial factors and MSD outcomes. The authors looked at 29 cross-sectional and 3 longitudinal studies addressing work-related psychosocial factors. Of these, 22 measured physical load, and the authors of this review did not think that the physical load assessment was of a high enough quality to specifically assign relative association effects to physical and psychosocial factors. Thus, this review is included to demonstrate how far the field has moved since 1993. Subsequent reviews and studies addressed in this section show that research in the intervening 7 years has moved towards more accurate characterization of biomechanical and psychosocial loads and defining their associations with MSD outcomes.

*National Academy of Sciences, 1999 (Ex. 26-37).* The NAS study (cited by Armstrong, Exs. 37-21, 37-1, 37-9 and others, Ex. 37-15, testimony) was discussed in OSHA's preamble to the proposed rule and is described in part B of this Health Effects section. It reviewed a number of studies that found strong evidence for biomechanical contribution to MSD etiology, controlling for psychosocial factors.

*Linton, 2000 (Ex. 26-642).* This paper is a careful literature review of studies addressing the association between psychological factors and back and neck pain. The author concentrated on individual psychological measures (*i.e.*, internal psychological factors) but also included some external psychosocial factors. Since many of the studies also assessed outcomes of disability and time to return-to-work (RTW), the author was able to provide evidence for his suggestion that psychological factors may play a greater role in these long-term outcomes.

The findings of this review are strengthened by its assessment of only prospective studies. This might allow an interpretation that the positive relationship found between various psychological factors and the outcomes of pain, disability, RTW time, etc. might represent a causal connection. However, there are two important caveats. Dr. Linton noted that longitudinal relationships of this sort may still mask reverse causal connections. The studies generally cannot determine whether some psychological "predictor" variables and the outcome variables are

not *both* the result of initial or underlying pain. Secondly, he noted that the psychological variables identified in the 37 reviewed studies explain only part of the variance in outcome. Thus, the review's results are consistent with the multifactorial model of MSD etiology (including biomechanical, psychosocial, psychological and personal variables).

Despite the care with which the studies were selected and analyzed, however, the review did not identify the type of biomechanical exposures assessed in the studies or the level at which they were studied. Instead, it simply noted that 18 studies controlled for miscellaneous confounding factors, one of which was "workplace factors". No indication was given as to the nature of these factors and which of these 18 studies addressed "workplace factors". Given the age of some of the papers, controlling for other factors (instead of simultaneously assessing their effect) is understandable, but it renders the review useless in contributing to the central debate concerning relative contribution of biomechanical and psychosocial factors (*i.e.*, both external psychological and social workplace factors and internal psychological factors). To further compromise the utility of this review, the studies evaluated in this review included several that measured physical exposure at the wrong analytical level (*e.g.*, Bigos *et al.*, 1991, Exs. 26-1241, 26-1242) or at a reduced level of detail (*e.g.*, Leino & Hanninen, 1995, Ex. 38-76, Viikari-Juntura *et al.*, 1991, Ex. 26-1219), compared to the psychological factors. This review, although a significant contribution to the literature overall, provides no useful information concerning relative contribution of physical and psychological factors to MSDs.

*Nachemson 1999 (Ex. 32-241-3-31).* This article is a comprehensive review of the studies purporting to demonstrate that physical workplace factors are irrelevant to the development of back pain, injury and disability. Instead, the studies implicate personal biology and psychological factors, stress and psychosocial factors in the workplace, and the monetary incentives of the compensation system. Some of these studies have been addressed above (*e.g.*, Bigos, 1991b, Ex. 26-1242). In general, Dr. Nachemson's claim that these factors contribute to low back disorders is credible. Very few of the researchers cited above would deny their contribution. What is emphatically not credible is the claim that physical factors are thus not implicated.

There are 3 primary problems with this claim. First, many of the studies cited in the article have not assessed the role of physical factors at all or have assessed them at levels of analysis or detail that make examination of their contribution impossible. The results of these errors have been discussed above. These studies overestimate the role of non-physical risks and thus cannot address the question or relative effects of biomechanical and psychosocial exposures in the workplace.

Second, the basic conceptual gap in the Nachemson review is a failure to acknowledge and address the implications and mechanism of multifactorial causation. There is a broad literature of well-designed studies, both epidemiological and laboratory (reviewed above and in earlier parts of the Health Effects section) demonstrating that psychosocial and psychological factors can add to the effects of physical exposures or even potentiate them (interaction or effect modification) (see Linton, 1990, Ex. 26–977, for a clear example). Dr. Nachemson's reluctance to consider such effects is represented by his citation of the Valfors *et al.* (1985, Ex. 26–685) examination of LBP. This study reported that physical risk factors (poorly characterized by a physiotherapist and a physician) were similar in workplaces of controls and low back cases, while reporting case/control differences in psychosocial work environment (again, poorly characterized). Valfors thus attributed the back injuries in the case group to the psychosocial factors. The logical fallacy, of course, is to assume that this difference removes physical exposures from a causal role. The more logical explanation, especially in light of all the evidence for multifactorial etiology presented in this section, is that the combination of physical exposures and psychosocial exposures presented increased risk. A level of physical risk that is acceptable in a psychosocially benign work environment can combine with elevated levels of psychosocial risk to cause disorders.

Finally, many of the studies cited in this article confuse cause with effect. To continue with Dr. Nachemson's citation, Valfors concluded that the measured differences in work satisfaction were the cause of the low back pain episodes, when it is just as likely that the LBP itself affected patients' assessment of their work satisfaction (see Linton, 2000, Ex. 26–642).

These three errors, together or individually, characterize many of the studies in the Nachemson article. In sum, this review, while useful in

collecting a wide variety of studies addressing the complex issues of low back pain, disability, and management, does not demonstrate that physical workplace factors are not involved in the etiology of LBP. Nor does it demonstrate that workplace interventions directed towards reduction of biomechanical risk factors would be ineffective. His citation of the Daltroy (Daltroy *et al.*, 1997, Ex. 38–57) training intervention in the postal service, for example, is not a refutation of the central causal role of biomechanical exposures in the etiology of back injury. Rather, it is emblematic of the general failure of “back schools”, when introduced in the absence of measures directed towards control of physical risk factors. Dr. Nachemson, himself, states in this review: “[I]t is obvious that certain types of lifts and working positions should be avoided and this in particular applies to twisted lifts.” Ideally, this review will advance the development of more effective intervention techniques that address the combination of risk factors presented by Dr. Nachemson.

*Waddell & Burton 2000 (Ex. DC-151-A)*. This thorough review of management protocols for LBP includes evaluation of epidemiological and clinical studies addressing etiology of LBP. Because the review and recommendations focus primarily on medical management issues, it is not surprising that it concentrates on the psychosocial factors involved in pain perception, sickness absence, disability and return-to work. Most of the studies addressed above acknowledge the importance of psychosocial factors in medical management issues, not only for LBP but also for other musculoskeletal disorders. The evidence reviewed above corresponds with these authors' conclusions that low job satisfaction, “unsatisfactory psychosocial aspects of work” and individual psychosocial findings are risk factors for onset of LBP, health care use and work loss, but the size of that association is small to modest (strong evidence). The authors also noted that physical demands of work (manual materials handling, lifting, bending, twisting, and whole body vibration) can be associated with onset of LBP, increased LBP reports, symptom aggravation, and back “injury” (authors' quotes). However, they find that the association “appears to be” weaker than those of individual, non-occupational and unidentified factors (strong evidence).

The authors make an elementary error in ascribing potential LBP causation only to dynamic back activities. Their

noting the high prevalence of LBP in non-dynamic jobs, and even in the unemployed, is, of course, related to the well-established research findings that sedentary and constrained postures are also physical risk factors for back disorders (Putz-Anderson, 1991, Ex. 26–1255, Hoogendoorn *et al.*, 1999, Ex. 38–81, Burdorf & Sorock, 1997 Ex. 502–232).

More importantly, the studies used to provide “strong evidence” for various conclusions are sometimes categorized as being of high quality when, in fact, they violate some of the important epidemiological design criteria cited above. In particular, in making a case for primarily psychosocial causation, the authors used studies that measured biomechanical exposures inadequately (*e.g.*, Bigos *et al.*, 1991b, Ex. 26–1242, and others reviewed above) or studies that did not include both biomechanical and psychosocial factors in statistical modeling (Macfarlane *et al.*, 1997, Ex. 500–41–91, Papageorgiou *et al.*, 1997, Ex. 32–241–3–41). Several reviews are cited that, on closer examination, are only modest in their assessment of both psychosocial and biomechanical risk contribution, noting the problems with study design and, especially, the relatively few studies that assessed both exposures adequately and at equal levels of precision (Burdorf & Sorock, 1997, Ex. 500–232, Bongers *et al.*, 1993, Ex. 26–1292, Davis & Heaney, 2000).

### Conclusions

Based on the rulemaking testimony, scientific studies, and literature reviews considered in this section, OSHA concludes that the evidence contained in the record supports a combined contribution of biomechanical and psychosocial risk factors to the onset, development and prolongation of MSDs. Biomechanical contributions to the etiology of work-related MSDs have been demonstrated to be more consistent than psychosocial factors across different study populations, and most well-designed studies reported stronger associations between exposure to biomechanical risk factors and an increased MSD prevalence or incidence than has been observed for psychosocial factors. However, it is not possible to determine the relative strength of association between biomechanical and psychosocial factors with any precision because of differences in measurement techniques used in the various studies to assess biomechanical and psychosocial factors, and because of the different ways in which psychosocial factors are defined by various investigators. Most importantly is the finding by several investigators that

biomechanical and psychosocial factors influence MSD risk in independent fashion, which suggests that reductions in biomechanical exposures absent any change in psychosocial influences should reduce the risk of work-related MSDs.

Findings from published literature reviews of studies that conform to the epidemiologic design principles discussed above are consistent with the Agency's conclusions. Four reviews (Burdorf, Ex. 502-232, Punnett, 38-13, Lagerstrom, Ex. 38-102, NAS, Ex. 26-37) reported that biomechanical risk factors generally showed stronger and/or more consistent associations with elevated MSD prevalence or incidence than did psychosocial factors.

Three reviews reached an opposite conclusion (Linton, Ex. 26-642, Nachemson, Ex. 32-241-3-31, Waddell, DC-151-A); however, these reviews relied more heavily on studies where biomechanical factors were not evaluated at all, were evaluated in jobs having little variance in physical load, or were evaluated at different analytical levels or with less precision, or than psychosocial factors. All of these design flaws bias results towards increased psychosocial effects in modeling. It is on the basis of these reviews and the underlying studies that the Chamber of Commerce, Gibson, Dunn & Crutcher, and several of their scientific witnesses base their conclusion that psychosocial factors outweigh the importance of biomechanical factors in the etiology of MSDs. Accordingly, OSHA is not persuaded by these arguments, and finds the preponderance of evidence supports a multifactorial model of MSD causation involving both biomechanical and psychosocial factors acting independently on risk.

Moreover, testimony and evidence presented above suggests that biomechanical and psychosocial risk factors are, to a degree, inextricable (Punnett, testimony, Tr. 868, Kerr *et al.*, 2000, Ex. 38-82). The degree of influence each exerts on MSD risk is in large part determined by company characteristics and work organization, and their very separation is somewhat artificial. The final rule's focus on reducing exposures to biomechanical risk factors reflects the intervention strategy that has been emphasized in the literature and implemented by many sophisticated companies. Simply less is known about how to intervene effectively on psychosocial factors. However, this does not mean that biomechanical intervention will have no effect on psychosocial factors in the workplace. Because of the correlation and interactions between biomechanical

and psychosocial factors in their associations with MSD outcomes, interventions focused towards biomechanical stressor reduction are likely to have a positive effect on levels of psychosocial stress. The arguments of Bellamy and Vendor, above (testimony) are addressed by the reality of this close correlation between stressor types.

The intervention literature demonstrates that the very fact of a company's undertaking even a limited program to control biomechanical exposures is, *de facto*, also a psychosocial intervention. If workers report MSD symptoms and the company responds with workplace alterations, medical intervention, training, and the other program elements in the final rule, this response often represents a reduction in excessive psychological demands, an increased sense of control, and an improvement in the social support structure of the workplace. In Sweden, Kvarnstrom (1992, Ex. 38-69) found that changes in the physical work characteristics, combined with changes in the psychosocial work environment (increased variety, decision-making latitude, and individual control over the work situation) in a small department of a large, multi-national company greatly reduced the high rate of absenteeism and turnover due to musculoskeletal disease. In the United States, Smith and Zehel (1992, Ex. 38-70) reported that employee focus groups identified the need for physically-oriented engineering changes as well as psychosocial changes in a meat-processing plant; the combined intervention resulted in decreased physical symptoms for part of the work force. Worker participation in problem identification and solution development is a central feature of many successful approaches to work environment change and is at the core of the proposed rule. For example, Pasmore & Friedlander (1982, Ex. 38-71), addressing an outbreak of upper extremity disorders in a United States electronic assembly facility, designed an intervention in which the employees determined the data to be collected and solutions based on these data. While this level of employee involvement focused on reducing biomechanical risk factors, it also increased employee participation and task control and altered role relationships within the organization.

A number of witnesses testified at the hearing that ergonomic programs designed to address biomechanical factors have positive effects on psychosocial factors that have been implicated in MSD etiology. Dr. Warren explained why this is the case:

I think what happens hypothetically and in my experience is that when you control a biomechanical workplace factor, you are *de facto* making a small psychosocial intervention in the workplace.

When \* \* \* somebody says ["my back hurts(')"] and it's followed \* \* \* immediately by ["and nobody cares(')"], you know that there's a psychological problem in that workplace. So I think that, yes, \* \* \* a control of a biomechanical risk factor with no change in a psychosocial environment would reduce the chance of injury, but that it would probably also change the psychosocial environment to a small degree. [Tr. 1265]

Dr. Rosecrance (Tr. 2319-20) presented a specific example. He noted that the biomechanical intervention in his study of the Cedar Rapids Gazette resulted not only in reductions of MSDs, but also improvements in the company social structure.

Mr. Dave Alexander believed that the employee participation provision of the proposed standard would address psychosocial issues:

\* \* \* the opportunity for worker participation in the form of contributing information, suggesting solutions, having a mechanism to report problems would, in fact, tie in with the psychosocial issues that would be important in the workplace. [Tr. 2713-2714]

Similarly, Dr. Silverstein testified that providing workers with basic information on MSDs and employee involvement in the ergonomics program increases the decision latitude for workers [Tr. 17445].

These studies and testimony indicate that the basic precepts of management commitment and employee participation contained in the final rule, while forming the administrative infrastructure of an ergonomics program focused on physical risk abatement, has the potential to have positive effects on the psychosocial characteristics of the work environment.

#### 6. Final Rule's Consistency With Medical Guidelines

Several commenters questioned whether the program elements of OSHA's final rule were consistent with existing medical practice guidelines, primarily with respect to diagnosing and treating low back pain, but also diagnosing and treating other MSDs. For example, when referring to the Agency for Health Care Policy and Research (AHCPR) low back pain guidelines, Gibson, Dunn and Crutcher stated that the review of evidence published with the guidelines

contradicts OSHA's ergonomic hypothesis that work causes physical injury, contradicts OSHA's view that "ergonomic" interventions can alleviate workplace pain, and contradicts

OSHA's prescription for rest as a response to back pain. [Ex. 500-118]

OSHA disagrees with these commenters. In reviewing the record, OSHA finds that the final rule is consistent with the medical literature, including the AHCPR guidelines, the American College of Occupational and Environmental Medicine (ACOEM) Occupational Medicine Practice Guidelines (Ex. 38-234), The Royal College of General Practitioners' Clinical Guidelines for the Management of Acute Low Back Pain (Royal College guidelines) (Waddell *et al.* 1999; Ex. 32-241-3-38), the Faculty of Occupational Medicine's Occupational Health Guidelines for the Management of Low Back Pain at Work (British guidelines) (Ex. 500-118-2), and other evidence-based medical practice.

The first assertion, that the AHCPR guidelines "contradict[] OSHA's ergonomic hypothesis that work causes physical injury" is incorrect for several reasons. The AHCPR guidelines acknowledge that

\* \* \* several studies have identified an increased incidence of low back problems among individuals whose work involves heavy or repetitive lifting, exposure to total body vibration (from vehicles or industrial machinery), asymmetric postures, and postures sustained for long periods of time. [Ex. 32-241-3-93]

The guidelines also recognize that

Other biomechanical research suggests that certain postures and activities increase the mechanical stress on the spine. It is not clear whether these mechanical stresses are the cause of low back problems. However, once symptoms are present, mechanical stresses correlate with worsening of symptoms. Prolonged sitting and postures that involve bending and twisting have been shown to increase the mechanical stress on the spine according to pressure measurements in lumbar intervertebral discs. Heavy lifting also appears to increase mechanical stress on the spine, but this stress can be reduced if the lifted object is held close to the body rather than at arm's length. [Ex. 32-241-3-93]

These conclusions are clearly consistent with the conclusions of the Health Effects section of the final rule that biomechanical factors are associated with low back pain. It must be recalled that the AHCPR guidelines were

\* \* \* intended to provide primary care clinicians with information and recommended strategies for the assessment and treatment of acute low back problems in adults. [Ex. 32-241-3-93]

They were not intended to provide a comprehensive review of work-related low back pain, ergonomics or low back pain prevention. There are few references to ergonomics, and the guidelines promotes the utility of

ergonomics in return to work decision making by stating that: "Several ergonomic guidelines on lifting and materials-handling tasks are available to help the clinician provide ranges of activity alterations at work." (Ex. 32-241-3-93)

Finally, the AHCPR guidelines (Ex. 32-241-3-93) do not suggest that patients with acute low back pain immediately return to work involving physical factors that may stress the spine. Rather they advise appropriate activity modification to assist in the recovery process. AHCPR guidelines Activity Recommendations panel findings and recommendations state: (1) "Patients with acute low back problems may be more comfortable if they temporarily limit or avoid specific activities known to increase mechanical stress on the spine, especially prolonged unsupported sitting, heavy lifting, and bending or twisting the back while lifting. (Strength of Evidence = D.);" and (2) "Activity recommendations for the employed patient with acute low back symptoms need to consider the patient's age and general health, and the physical demands of required job tasks. (Strength of Evidence = D.);" As to the duration of activity modification, the AHCPR guidelines demonstrate an understanding of the impact that the physical demands of work have on recovery and modified activity. The guidelines state that "The nature and duration of limitations will depend on the clinical status of the patient and the physical requirements of the job."

Several other components of the final rule are supported by AHCPR recommendations, including the use of job hazard analysis and medical management involving communication with the HCP. Pertinent AHCPR guidelines statements are as follows: (1) "In recommending activity modifications for patients who work, the clinician may find it helpful to obtain from the employer a description of the physical demands of required job tasks," and (2) "The panel recommends that clinicians help patients establish activity goals, in consultation with their employer when applicable."

As with the AHCPR guidelines (Ex. 32-241-3-93), the commenters cited above did not accurately represent the findings of the Royal College guidelines (Ex. 32-241-3-38) and British guidelines (Ex. 500-118-2) in criticizing OSHA's proposal. They also failed to acknowledge evidence and recommendations from these reports that are consistent with the final rule.

The Royal College guidelines (Ex. 32-241-3-38) were developed for the purpose of disseminating evidence-

based recommendations on the management of acute low back pain to clinicians. The Royal College guidelines do not purport to relate to, nor were they focused on, the same purpose as OSHA's proposal, that is to reduce MSDs and control MSD hazards in the workplace. These guidelines do not contain information on evidence based conclusions on ergonomics or low back pain prevention. Several elements of the proposal are supported by the Royal College guidelines (Ex. 32-241-3-38). For example, under Initial Assessment Methods, they recommend: "The patient's age, the duration and description of symptoms, the impact of symptoms on activity and work, and the response to previous therapy are important in the care of back problems." Under Information to Patients, the guidelines state: "About 10% of patients will have some persisting symptoms a year later, but most of them can manage to continue with most normal activities. Patients who return to normal activities feel healthier, use less analgesics and are less distressed than those who limit their activities." The Royal College guidelines suggest that most workers can manage with most normal activities, but do not suggest that this includes extremely physical tasks that cause very significant mechanical loading to the lumbar spine and are associated with elevated risks of low back pain.

Similarly, the purpose and findings of the British occupational health low back pain guidelines (Ex. 500-118-2) have also been misrepresented (*e.g.*, Ex. 32-241-3-20). The British guidelines state: "These guidelines represent the main recommendations and evidence statements derived from a detailed Evidence Review and developed by a multidisciplinary group of practitioners. They concern the clinical management of workers affected by non-specific low back pain, including advice on placement, rehabilitation and measures for prevention." The British guidelines further clarify that they were not intended to disseminate information regarding workplace health and safety, job design, and ergonomics when they state: "They focus on actions to be taken to assist the individual and do not specifically cover legal issues, health and safety management, job design and ergonomics." Again, this is a different focus than the proposal, and conclusions should be interpreted in that light. Under evidence review methods, the British guidelines state:

In view of the occupational health focus of the guidelines and the present review, the following areas were excluded from the review, except where they impact directly on the guideline recommendations: chronic

intractable pain, long-term disability and pain management programmes; spinal surgery and post-operative states; primary ergonomic interventions. [Ex. 32-241-3-93]

The British guidelines (Ex. 500-118-2) acknowledge the role of work in contributing to low back pain in its own preface. In reviewing challenges for the review the authors state: "The need for everyone to recognize that work is only one contributor to back pain but that back pain whatever its cause can, if poorly managed, have a devastating effect on a person's ability to work." The review goes on to classify evidence based literature recommendations using the following classification scenarios:

\*\*\* *Strong evidence*—provided by generally consistent findings in multiple, high quality scientific studies.

\*\* *Moderate evidence*—provided by generally consistent findings in fewer, smaller or lower quality scientific studies.

\* *Limited or contradictory evidence*—provided by one scientific study or inconsistent findings in multiple scientific studies.

—*No scientific evidence*—based on clinical studies, theoretical considerations and/or clinical consensus.

Several British guidelines (Ex. 500-118-2) findings are consistent with the final rule. With respect to the relationship of physical work factors and work-related low back pain, the guidelines report the following evidence based findings: There is strong evidence that

Physical demands of work (manual materials handling, lifting, bending, twisting, and whole body vibration) can be associated with increased reports of back symptoms, aggravation of symptoms and "injuries." [Ex. 500-118-2]

These guidelines therefore acknowledge potential for physical work factors to precipitate low back pain episodes, and recognize some evidence of a cumulative effect of spinal loading. In addition, management of work-related low back pain, as noted in the AHCPR low back pain guidelines, may reasonably include elements similar to those in the OSHA final rule, such as \* \* \* temporarily limit[ing] or avoid[ing] specific activities known to increase mechanical stress on the spine, especially prolonged unsupported sitting, heavy lifting, and bending or twisting the back while lifting. [Ex. 32-241-3-93]

In summary, the British guidelines (Ex. 500-118-2) state that there is moderate evidence that "From an organisational perspective, the temporary provision of lighter or modified duties facilitates return to work and reduces time off work."

The British guidelines (Ex. 500-118-2) go on to cite other conclusions about work and low back pain using evidence based literature reviews (Evidence) and consensus opinion (Recommendation). In making recommendations on prevention and case management, the authors advise the "need to be directed at both physical and psychosocial factors." If physical work is not harmful and it does not contribute to low back pain, then why would the authors advise addressing the physical task factors of work in prevention efforts? Similarly, if physical characteristics of work are not significant issues for workers who return to work after developing a low back disorder, then why do the authors state the following?

There is a pragmatic argument that individuals at highest risk of LBP should not be placed in jobs that impose the greatest physical demands. The basic concern is that workers with physically (or psychologically) demanding work report rather more low back symptoms, have more work-related back "injuries" and lose more time off work with LBP. Even if physical demands of work may be a relatively modest factor in the primary causation of LBP (see Background above), people who have LBP (for whatever cause) do have more difficulty managing physically demanding work (T3: (Muller *et al.* 1999) T2: (Waddell 1998)). It may be argued, therefore, that avoiding putting people at highest risk of recurrent LBP and sickness absence into more physically demanding work would be in the interests of the individual worker, the employer and the total societal burden of LBP. [Ex. 500-118-2]

Similarly, the ACOEM guidelines (Ex. 38-234) agree with the observation that specific physical work factors are associated with certain work-related MSDs.

One of the criticisms raised by a commenter was the limited reference to the Cochrane Collaboration Back Review Group in low back sections of the Health Effects section of the preamble to the proposed rule. However, as a significant contributor to this effort, Dr. Nachemson clarified that neither work-related back pain nor ergonomics were the focus of these reviews (Tr. 6779).

Although Dr. Nachemson questioned OSHA's findings of the relationship of work to the development of work-related low back disorders, he contradicts this in the chapter he authored for the International Society for the Study of the Lumbar Spine, entitled "Future of Low Back Pain" (Wiesel *et al.* 1996, Ex. 26-1620). The chapter has a table compiled on the effects of external load on low back structures. The table lists extreme loading activity, several hours of hard training, extreme body position, as

having negative influences on muscle, cartilage, and disc.

Dr. Stanley Bigos admitted that physical work factors could result in the development of low back pain in an exchange with one of the questioners.

MS. GWYNN: Doctor, you believe, do you not, that lifting and bending while lifting and twisting while lifting can aggravate low back pain?

DR. BIGOS: I believe that it can bring on symptoms in people who have had prior back problems. And perhaps, it could bring on symptoms of people who haven't, depending upon the condition they are in. [Tr. 6916]

Along other lines, some commenters raised issues with OSHA's inclusion of symptoms in the definition of an MSD. Gibson, Dunn and Crutcher stated that:

These sensations that the agency treats as tantamount to musculoskeletal injury are ubiquitous in the general population and do not warrant interference by the agency. [Ex. 500-118]

OSHA does not agree with this argument. OSHA is not attempting to regulate common symptoms. Rather, OSHA has proposed strategies to modify physical workplace factors that are associated with the development of MSDs, when the physical factors at work are present in frequency, intensity, and/or duration likely to be responsible for causing observed MSDs. As required in the final rule, the employer's responsibility is that it must evaluate employee reports of MSD signs and symptoms to determine whether an MSD incident has occurred. The evaluation may include an evaluation by an HCP to determine the nature of the condition and assist the employer in evaluating the work-relatedness of the MSD. Many employers presently act in a very similar manner when an employee reports a potential problem. The employer may perform an accident or incident investigation, offer temporary modified duty, correct the problem, and/or refer the employee to a HCP for evaluation.

Gibson, Dunn, and Crutcher also suggested that paying attention to subjective complaints would lead to inaccurate diagnoses. They state that:

One of the challenges presented by MSDs is that, in order to diagnose an affliction (in an effort to determine what response is required to comply with the proposed standard), an employer or the employer's physician must rely principally, if not solely, on subjective reports of pain from employees. [Ex. 500-118]

These assertions are incorrect, and are not consistent with medical literature and opinion. A worker's medical history, including subjective reports like pain, is a key element that has been

utilized since the beginnings of medicine to help physicians diagnose medical conditions. The AHCPR guidelines emphasize the role of the medical history when they state:

A few key questions on the medical history can help ensure that a serious underlying condition, such as cancer or spinal infection, will not be missed \* \* \* Symptoms of sciatica (leg pain) or neurogenic claudication (walking limitations due to leg pain) suggest possible neurologic involvement. Pain radiating below the knee is more likely to indicate a true radiculopathy than pain radiating only to the posterior thigh. A history of persistent numbness or weakness in the leg(s) further increases the likelihood of neurologic involvement. The articles indicate that cauda equina syndrome can be ruled out with a medical history that ascertains the absence of bladder dysfunction (usually urinary retention or overflow incontinence), saddle anesthesia, and unilateral or bilateral leg pain and weakness. [Ex. 32-241-3-93]

The AHCPR guidelines go on to clarify that the examination is used to confirm clinical impressions derived from the medical history, including pain characteristics:

The physical examination supplements the information obtained in the medical history in seeking an underlying serious condition or possible neurologic compromise. [Ex. 32-241-3-93]

The AHCPR low back pain guidelines also indicate that "The physical examination is less useful than the history in searching for underlying serious conditions." Thus OSHA's approach to the use of employee symptoms is similar to the AHCPR rigorous analysis of the literature on acute low back pain evaluation and treatment that concluded that symptoms and history give important information to diagnose and manage adults with acute low back pain.

Both the Royal College and British guidelines support the role of history, including symptoms, in the diagnosis and management of low back pain. The British guidelines state:

The patient's age, the duration and description of symptoms, the impact of symptoms on activity and work, and the response to previous therapy are important in the care of back problems. (B: Moderate research based evidence). [Ex. 500-118-2]

The guidelines confirm AHCPR recommendations by indicating:

The initial clinical history can identify 'red flags' of possible serious pathology. Such inquiries are especially important in patients over age 55. (B: Moderate research based evidence). [Ex. 500-118-2]

OSHA's approach, in particular the acknowledgment of worker symptoms, parallels this literature based analysis.

Further validation of the importance of symptom reporting for low back pain comes from the ACOEM guidelines (Harris *et al.* 1997; Ex. 502-240). The ACOEM guidelines included peer review by Dr. Stanley Bigos, expert witness for UPS and Anheuser-Busch and others. The following quotes are excerpted from the guidelines:

A focused medical history, work history, and physical examination are generally sufficient to assess the worker with a complaint of an apparently job related disorder. [Ex. 502-240]

In this assessment, certain patient responses and findings raise the suspicion of serious underlying medical conditions.

The patient's description of the mechanism of injury (so far as is known), his or her presenting symptoms, the duration of symptoms, exacerbating factors, and the history of previous episodes will help define the problem. [Ex. 502-240]

In Chapter 14, the ACOEM guidelines state:

Thorough medical and work histories and a focused physical examination are sufficient for the initial assessment of the worker with a complaint of potentially work-related low back symptoms. [Ex. 502-240]

These statements from clinical medicine practice guidelines provide further support for the use of symptoms as a trigger in the final rule. The practice guidelines make use of the patient history and reports of symptoms and take a consistent approach to the physical examination referent to patients with low back pain.

This approach is consistent with the one medical text brought to OSHA's attention. The International Society for the Study of The Lumbar Spine publishes a text entitled "The Lumbar Spine" (Wiesel, *et al.* 1996; Ex. 26-1620). In Chapter 3 on clinical evaluation of low back pain by Jeremy Fairbank and Hamilton Hall (History taking and physical examination: Identification of syndromes of back pain), the authors state:

Conventional western medical therapy is practiced on the basis of a diagnosis that is made from a synthesis of information acquired from the patient's history, physical examination, and special investigations. Back pain is a common presenting symptom, and its diagnosis should be approached in the same manner as that of any other symptom. [Ex. 26-1620]

They further state that

A detailed history obtained from the patient is essential for making a diagnosis, assessing disability, and dictating management. Time spent listening to the patient is not wasted. Back pain has a wide variety of causes, and many of these can be revealed during history taking. [Ex. 26-1620]

providing support that

Objective evidence obtained on physical examination should enhance and support the diagnostic hypotheses arising from the patient's history. [Ex. 26-1620]

The authors go on to propose a classification system for low back pain (Pynsent-Fairbank-Hall Classification of Extrapain), which is primarily based upon patient symptoms. The acknowledgment of the importance of symptoms in this text is of particular interest to OSHA due to the fact that two principal expert witnesses who testified on behalf of UPS and others that symptoms are not meaningful, Dr. Stanley Bigos and Dr. Alf Nachemson, are members of The International Society for the Study of The Lumbar Spine, the organization that published the above text.

The classification of low back pain primarily upon patient symptoms is similar to the approach used by the Quebec Task Force (1987; Ex. 26-494). Dr. Nachemson also served as a member of the task force for this publication. The Quebec classification included 11 categories, with 1-4, 8, 9 and 10 based upon symptoms.

The American Medical Association, in its Guides to the Evaluation of Permanent Impairment, 4th edition, (Ex. 38-246) also include symptoms in classifying impairment. In particular, Table 72 in that publication contains a Diagnosis Related Estimate for Lumbosacral Category II: Minor Impairment (5% whole person impairment). The guidance used by the AMA for this is "The clinical history and examination findings are compatible with a specific injury or illness. The findings include significant intermittent or continuous muscle guarding that has been observed and documented by a physician, nonuniform loss of range of motion, or nonverifiable radicular complaints. There is no objective sign of radiculopathy and no loss of structural integrity." There is similar guidance for the cervical spine.

Guidelines for diagnosis and treatment of low back pain that have been published in the United States include the AHCPR guidelines (Ex. 32-241-3-93) and the ACOEM guidelines (Ex. 38-234). These will be addressed in the discussion on rest and activity to follow in this section.

It must also be recognized that low back pain is not the only potentially covered MSD, and other potential MSDs may present as symptoms only. For example, it is clear that patients with CTS may have symptoms of numbness without any physical findings (Erdil and

Dickerson 1997, Ex. 502-18; Katz *et al.* 1991, Ex. 38-101; Moore 1992, Ex. 26-985). Of significance, commonly utilized physical signs to clinically diagnose carpal tunnel syndrome, such as the Tinel's test and Phalen's sign, do not have as high a sensitivity or specificity as the Hand Diagram (Katz and Stirrat 1990; Ex. 500-121-33), a symptom based tool. Clearly, utilizing symptoms to identify possible cases of carpal tunnel syndrome and other MSDs is consistent with the knowledge based upon reviewing the medical literature.

Dr. Malcolm Jayson argued that

\* \* \* if a person has pain in the knee, the most effective form of treatment is knee exercises. When we rehabilitate back problems we prescribe[] exercises with a progressive regime to increase physical capacity. There is now overwhelming evidence that exercise is good for back problems and damaged joints and rest is harmful. [Ex. 32-241-3-9]

However, nowhere does OSHA state that all exercise is harmful, nor does it support rest as the treatment for MSDs. With regard to work factors like repetition, it is important to recognize that biomechanical factors that are present in a sufficient intensity, duration, and/or frequency to cause or contribute to an MSD are addressed. In these circumstances, OSHA recommends modification of exposure to these factors. It is clear that, when excessive, repetition and other cited work factors can cause MSDs. Several studies were presented in the Health Effects Section of the final rule to demonstrate the pathogenic mechanisms through which physical work factors can be responsible for causing or contributing to certain MSDs identified in the epidemiologic review. Unfairly, this statement simplifies physical factors in work settings as solely characterized by repetition, without considering the frequency, duration, and periodicity of the repetitive activities. In addition, it ignores other factors that have potential to cause MSDs in the workplace, such as excessive force, awkward posture, contact stress, and vibration. Also neglected is the observation that combinations of factors like force, posture, etc. with repetition, may compound the effect of repetition on musculoskeletal tissues. Finally, the statement does not differentiate types of tissue affected and whether the tissue is healthy or damaged.

In the preface to The American Academy of Orthopedic Surgeons' book entitled "Repetitive Motion Disorders of the Upper Extremity" (Gordon *et al.* 1995; Ex. 26-1399), the editor states:

There is overwhelming evidence that the number of reported cases of repetitive motion disorders is rapidly growing. These disorders have become an extremely costly public health issue. Although some individuals believe that the underlying issue may be improper reporting or false claims of a medical problem, the organizers and most of the participants believe that for the vast majority of cases, there is an underlying physiologic insult to one or more of the various tissues involved.

The text goes on to cover epidemiologic evidence; pathophysiology of biomechanical loads, connective tissue, muscle and nerve. Chapters on rehabilitation of the wrist, elbow and shoulder all indicate that time limited periods of rest may be indicated for acute MSDs. The book is the result of a workshop organized by the National Institute of Arthritis and Musculoskeletal and Skin Disease, NIH. Co-sponsors included NIOSH, CDC, Orthopedic Research and Education Foundation, the National Center for Medical Rehabilitation Research, and others. One expert witness Dr. Stanley Bigos, who testified on behalf of one industry group organized in opposition to OSHA's proposed standard in general, is a member of AAOS.

In June 1998, Clinical Orthopedics and Related Research (Exs. 26-1310, 26-1322, 26-1316) covered Cumulative Trauma Disorders of the Upper Extremity through a joint sponsorship of the Association of Bone and Joint Surgeons, the Academic Orthopedic Society, the Hip Society, the Musculoskeletal Tumor Society, and the Knee Society. This text again covered sections regarding the effects of physical work factors (*i.e.* repetition) on nerve, muscle, joints, and certain clinical conditions.

Similarly, the National Academy of Sciences, in 1999, (Ex. 26-37) published the results of a workshop they sponsored on work-related MSDs. While there was some variance in opinions about the contribution of physical work factors to MSDs, there was agreement among most that physical work factors contribute to MSDs. "MSDs are multifactorial, with work and biomechanical aspects of work being important contributors." The NAS reviewers also explained the concepts behind temporary rest or activity modification for injured tissues.

Contrary to the view of NAS, Dr. Stanley Bigos provided the following comment:

Contrary to ergonomists' beliefs, usage is a prerequisite to health—using the body, even vigorously using the body, is not intrinsically harmful. That is why repetitive motion that fatigues musculoskeletal tissues is medically prescribed, to the point of being the preferred

method of treatment even of tissues that have sustained traumatic injury or age-related degeneration. Properly conditioned; a traumatically injured joint may be restored to full function by the protection of muscles stronger than before the injury. [Ex. 32-241-3-4]

Dr. Bigos' statement that "repetitive motion that fatigues musculoskeletal tissues is medically prescribed, to the point of being the preferred method of treatment even of tissues that have sustained traumatic injury or age-related degeneration," while having elements of validity, again fails to look at the various work-related MSDs as well as the stage and severity of the condition. There is supporting literature and consensus, including clinical practice guidelines (*e.g.* ACOEM; Ex. 38-234) that recommend periods of splinting and rest for MSDs like acute tendonitis or stenosing tenosynovitis, DeQuervain's disease and carpal and cubital tunnel syndromes. A comparison could be made to a patient who experiences an acute myocardial infarction with muscle damage. In this scenario, rehabilitation often includes carefully controlled exercise appropriate to the stage of recovery and level of function of the remaining heart muscle. It would not be reasonable to presume that a patient one day after a significant myocardial would be improved if forced to run a marathon. Neither would a worker benefit from intensive and uncontrolled exercise after the onset of an acute MSD with significant inflammation, degeneration and loss of function.

The same commenters stated that OSHA's use of the term "rest" in the proposal implied that OSHA recommends or promotes bed rest for workers with MSDs. This statement is incorrect and fails to recognize the purpose and application of the standard. This standard is not intended as a guideline for the medical treatment of MSDs. Medical treatment is left to the licensed health care provider, utilizing sound medical judgement, and evidence based literature and clinical practice guidelines.

What OSHA did intend when it used the term "rest" was appropriate activity modification. The standard supports return to work where there are effective controls of biomechanical factors causing or contributing to the MSD. The preamble to the proposal stated:

Although some covered MSDs are at such an advanced state that complete removal from the work environment is the appropriate treatment, it should usually be the recommendation of last resort. Where appropriate, work restrictions that allow the employee to continue working (*e.g.*, in an

alternate job, or by modifying certain tasks in the employee's job to enable the employee to remain in that job) are preferable during the recovery period.

Dr. Stanley Bigos argued that the proposed ergonomics rule was at odds with the recommendations of the AHCPR guidelines, in that the proposed rule recommended rest, reduced work, and inactivity in response to pain, while the AHCPR guidelines recommend increased activity and conditioning (Ex. 32-241-4).

The AHCPR guidelines (Ex. 32-241-3-93) do recommend that adults with acute low back pain maintain activity. However, the guidelines do not suggest that patients with acute low back pain immediately return to work involving physical task factors that may stress the spine. Rather they advise appropriate activity modification to assist in the recovery process. AHCPR guidelines Activity Recommendations panel findings and recommendations state: "Patients with acute low back problems may be more comfortable if they temporarily limit or avoid specific activities known to increase mechanical stress on the spine, especially prolonged unsupported sitting, heavy lifting, and bending or twisting the back while lifting. (Strength of Evidence = D.);" and, "Activity recommendations for the employed patient with acute low back symptoms need to consider the patient's age and general health, and the physical demands of required job tasks. (Strength of Evidence=D.)"

The AHCPR guidelines acknowledge that

several studies have identified an increased incidence of low back problems among individuals whose work involves heavy or repetitive lifting, exposure to total body vibration (from vehicles or industrial machinery), asymmetric postures, and postures sustained for long periods of time." [Ex. 32-241-3-93]

The guidelines also recognized that

Other biomechanical research suggests that certain postures and activities increase the mechanical stress on the spine. It is not clear whether these mechanical stresses are the cause of low back problems. However, once symptoms are present, mechanical stresses correlate with worsening of symptoms. Prolonged sitting and postures that involve bending and twisting have been shown to increase the mechanical stress on the spine according to pressure measurements in lumbar intervertebral discs. Heavy lifting also appears to increase mechanical stress on the spine, but this stress can be reduced if the lifted object is held close to the body rather than at arm's length." [Ex. 32-241-3-93]

As to the duration of activity modification, the AHCPR guidelines (Ex. 32-241-3-93) demonstrate an

understanding of the impact that the physical demands of work have on recovery and modified activity. They state that "The nature and duration of limitations will depend on the clinical status of the patient and the physical requirements of the job."

While the AHCPR guidelines (Ex. 32-241-3-93) did not find evidence that bed rest was beneficial for the majority of individuals with acute low back pain, the panel did acknowledge that, in some circumstances, bed rest may be required for select patients with acute low back pain ("The majority of low back patients will not require bed rest. Bed rest for 2 to 4 days may be an option for patients with severe initial symptoms of primarily leg pain.")

Program elements in OSHA's proposal are also consistent with the British guidelines, that state that there is moderate evidence that

From an organisational perspective, the temporary provision of lighter or modified duties facilitates return to work and reduces time off work. [Ex. 500-118-2]

Some commenters appeared to confuse the concepts relevant to the practice of sports medicine with concepts relevant to the prevention of MSDS in workers. For example, Gibson, Dunn & Crutcher state

Increase in physical activity (compared to past activity level) is a guiding principle in musculoskeletal rehabilitation, and has been the primary intervention and treatment in many musculoskeletal disorders. These treatment protocols include many of the physical stresses that OSHA recommends avoiding. [Ex. 500-118]

This again is an overly simplistic statement, since there are differences in the intensity, duration, and/or frequency of guided rehabilitation of an injury that is tailored to the individual's type of injury, severity of the condition, stage of rehabilitation and the individual's conditioning, as opposed to intensity, duration, and/or frequency of physical job factors that are based upon delivery of goods or services and have no bearing upon individual capabilities or injuries. Dr. Tapio Videman, another expert witness for the UPS attempted to explain the importance of physical activity as follows:

Sports medicine—and much of modern mainstream medicine—views physical loading as a means of increasing fitness, strength, and function, and is part of most related intervention today. Why would physical loading be harmful in work but beneficial in leisure time? \* \* \* Physical activity can promote physical adaptation to loading, and restore and maintain functional capacity. This may explain why there is some evidence of the benefits of exercise for spinal disorders. [32-241-30-20]

However, comparisons of workers with young and highly skilled athletes is not appropriate. This is pointed out by the ISSLS text on the Lumbar Spine (Wiesel *et al.* 1996; Ex. 26-1620). The following quote is from the chapter on biomechanics:

Comparison of athletic exercises with industrial labor is complicated because, in the athletic field, (1) one deals with young, healthy subjects; (2) there is a selection of individuals for the specific tasks; (3) the specific task is always accompanied by remedial exercises. In industrial labor, one is dealing with the average population. There is almost no selection of the individuals, and there are many monotonous tasks that are not interrupted by remedial exercise. [Ex. 26-1620]

Dr. Michael Vender explained his belief that soft tissue has almost limitless capacity to recover from injury.

We cannot explain the natural process of aging and gradual deterioration of all body parts by the concept of cumulative trauma. The most basic flaw in this logic revolves around the comparison of the human body to a piece of metal [as reflected in the biomechanical model espoused by ergonomists]. [Unlike metal], the body, when stressed or even injured, has the ability to heal and recover.—When one repeatedly bends a piece of plastic, it becomes permanently deformed. When one repeatedly exercises a muscle, it becomes stronger and more functional. [Ex. 32-241-3-19]

This belief is in contrast to the opinion of the NAS workshop (1999) (Ex. 26-37) noted above, and fails to recognize concepts of muscle disruption, tendon and ligament viscoelastic deformation and creep discussed in the Health Effects Preamble.

#### 7. Additional Criticisms of Epidemiological Studies Raised by Commenters

Gibson, Dunn & Crutcher in their post-hearing comments (Ex. 500-118, Section B, pgs. 65-81) supply critiques of additional "studies on which OSHA relies or may rely in support of the proposed rule." (*id.*, pg. 65). OSHA's response to these critiques is given below.

Gibson Dunn & Crutcher criticize the study by Latza *et al.* (2000, Ex. 38-424) that examined occupational risk factors of low back pain among construction workers. Among their criticisms, Gibson Dunn & Crutcher argue that the authors drew causal inferences from a study that is only an exploratory analysis. Further, they claim that the researchers were vague in their methods and did not come up with a single promising association.

OSHA disagrees with these criticisms. First, the study as a whole cannot be

fairly characterized as an “exploratory analysis.” This study is an adequately designed longitudinal epidemiological study where construction workers who reported no low back pain at baseline were followed for three years. The “exploratory approach” reported by the authors refers not to the study as a whole but rather to a detailed analysis of the data to identify potential risk factors that might be used to predict low back pain. The authors describe a detailed process for focusing on factors most likely to have caused the observed reports of low back pain. Second, OSHA disagrees that the authors were vague in their methods. Various aspects of the study, such as the selection of study subjects, data collection, and data analysis, were described in clear enough detail that would allow the reader to assess the results reported. Finally, the authors noted that causality cannot be established with this study. However, the purpose of the study was to identify possible risk factors for low back pain among these workers that might aid in the identification of hazardous components in the work that can guide effective primary intervention. In this regard, the authors report positive associations that show that certain occupational risk factors can be predictive of low back pain.

Gibson, Dunn & Crutcher criticize a study by Punnett *et al.* “A comparison of Approaches to Modeling the Relationship between Ergonomic Exposures and Upper Extremity Disorders” (2000, Ex. 500–71–43). This is a methodology study concerning approaches for combining independent and dependent variables for the purpose of exposure-response analysis. This study uses the information on upper extremity disorders in vehicle manufacturing found in an earlier Punnett *et al.* (1998, Ex. 26–38) study), which these same commenters criticized previously (Ex. 32–241–4, pg. 144). OSHA has responded to those criticisms elsewhere in this preamble.

Gibson, Dunn & Crutcher have two main criticisms of the Kurppa *et al.*, (1991, Ex. 26–53) study concerning the incidence of tenosynovitis or peritendinitis and epicondylitis in a meat-processing factory. The commenters claim that the diagnostic definition of the response tenosynovitis or peritendinitis (agreed to by the plant physician), “boils down to focal soreness/tenderness and nothing more specific or mysterious than that.” (Ex. 500–118, pg. 71). In response, OSHA notes that, in order to be included as a response in the study, the condition needed to be severe enough in each case to qualify for sick leave (Ex. 26–53, pg.

33). As a result, OSHA believes that the response is a meaningful health effect, *i.e.*, because it was serious enough to warrant time away from work for recuperation. Gibson, Dunn & Crutcher (Ex. 500–118 pg 71) also claim that, “By its very nature, a surveillance study perturbs the experience of discomfort.” However, this type of physiological biasing factor would appear to have only a minimal or no effect on the end results since the rate of occurrence of tenosynovitis or peritendinitis and epicondylitis, for both men and women, was shown typically to be an order of magnitude higher for strenuous compared to non-strenuous meat processing jobs (Ex. 26–53, pg. 34).

Gibson Dunn & Crutcher correctly point out (Ex. 500–118, pg. 72–73) that the utility of participatory ergonomics was not evaluated in the Roquelaure *et al.* (1997, Ex. 38–96) study. However, OSHA used this study only to show an association between stress variables and carpal tunnel syndrome (CTS). The role of participatory ergonomics in reducing CTS was not alluded to by OSHA.

Gibson Dunn & Crutcher correctly point out (Ex. 500–118, pg. 73) that in the Viikari-Juntura *et al.* (1994, Ex. 26–873) study what is defined as severity of neck trouble is in fact the frequency of self-reported symptoms (pain, ache, stiffness or numbness). As a result, Gibson Dunn & Crutcher believe the possibility exists that the subject’s statements concerning severe neck trouble could be misleading. OSHA used the Viikari-Juntura *et al.* study to only show an association between neck symptoms and stress factors. OSHA did not comment on the severity of the symptoms.

Gibson Dunn & Crutcher note (Ex. 500–118, pgs. 73–74) that the authors of the Kearns *et al.* (2000, Ex. 500–71–34) study did not intend that the results of the study on the prolongation of median motor and sensory nerve latency be generalized beyond the effects of work related to pork processing. OSHA agrees that the study supplies limited information about the relationship between workplace physical factors and CTS.

*Stenlund et al. studies, Exs. 26–733 and 26–1479*

Gibson Dunn & Crutcher (Ex. 500–118 pg. 70–71) have criticized the 1992 study by Stenlund *et al.* (Ex. 26–733) of osteoarthritis and the 1993 Stenlund *et al.* (Ex. 26–1459) of shoulder tendinitis. First, the 1992 Stenlund *et al.* study is criticized for its conclusion that radiographic evidence of osteophytes (spurs) in the acromioclavicular joint is a predictor of osteoarthritis causing

cartilage loss and abnormal reparative processes. Gibson Dunn & Crutcher argue that in other joints, such as the knee, increased usage leads to osteophytosis (spurs) and increased preservation of cartilage, which is good. They question whether the Stenlund *et al.* (1992) paper is detecting a “bad” outcome. Gibson Dunn & Crutcher also criticize the 1993 Stenlund *et al.* paper for using shoulder tendinitis as an adverse effect measure, arguing that shoulder tendinitis is subject to overt reporting and recording bias. They conclude that these types of outcome measures are not appropriate to be used in epidemiological studies.

With regard to the 1992 Stenlund *et al.* study, the critics are comparing minimal changes commonly observed with habitual usage of a joint such as the knee (*e.g.*, increased preservation of cartilage) to severe osteoarthritis, from heavy manual work and vibration, of a joint, in this case the shoulder. In the Stenlund study, radiographs were classified into 5 grades of osteoarthritis (0 = normal; 1 = minimal changes; 2 = moderate changes, more severe changes to cartilage and bone structure begins to be affected; 3 = severe osteoarthritis, and 4 = totally destroyed joint). Those classifying the radiographs were blinded as to exposure. The authors did not find significant differences in lower grade changes. However, they did observe that among rock blasters and bricklayers who had exposure to heavy load and vibration compared to foremen who did not, there was a significant increase in grade 2 and 3 osteoarthritis. Therefore, OSHA believes that Gibson Dunn & Crutcher are actually confusing two different health outcomes in their criticism. The study by Stenlund *et al.* (1992) would support the hypothesis that normal habitual use of the shoulder might cause increased preservation of the cartilage. However, shoulder joints exposed to heavy loads and vibrations such as those examined in the study show radiographic evidence of severe osteoarthritis.

With regard to the 1993 Stenlund *et al.* study, the authors noted the potential for misclassification when using tendinitis as a measure of outcome. They agree that in some epidemiological studies, clinical diagnosis of tendinitis may not be an appropriate measure of prevalence in the population, since some individuals with tendinitis may not see a physician for their symptoms, thus creating a selection bias. However, the authors assert that this type of bias is overcome in their study by the use of a cross sectional study design. In order to further lessen the potential for misclassification, the authors also

included symptoms of pain during the last year that could have originated from structures other than the tendons or muscle attachment inflammation in addition to using palpation and isometric contraction. They reasoned that persons experiencing pain in their shoulder in the last year and who on examination have pronounced pain reaction to palpation and contraction, have probably had a disorder in the muscle attachment or tendon, that in clinical practice would have been classified as tendinitis. OSHA believes that, with proper study design and control for misclassification, as was done in the Stenlund study, clinically diagnosed shoulder tendinitis is an adequate measure of effect. Thus, the Stenlund *et al.*, 1993 study can be used with other studies in the record to form a reliable weight of evidence on which to base the agency's health effects conclusions.

Gibson Dunn & Crutcher also criticized the 1990 study on degenerative disc disease among concrete workers and house painters by Riihimaki *et al.* (Ex. 502-455). They argue that the results of this study are "not compelling" because the authors found insignificant risk ratios and, thus, are very likely to be influenced by unmeasured variables. OSHA finds this argument unconvincing for the following reasons. Number one, the authors did, in fact, find a statistically significant risk of detectable degenerative changes in the lumbar spine among concrete workers (38%) compared to house painters (26%). (Relative Risk=1.4, (CI 1.1-1.8;  $p < 0.01$ )) In this study, concrete reinforcement workers were compared to house painters. The authors noted that the load on the back is distinctly different among concrete workers compared to house painters. The authors also note that in Finland, persons in these trades have very similar socio-economic status and lifestyles, thus making it more likely that the detected difference between these groups is due to occupational exposures rather than other factors. Moreover, as a part of the study design the concrete reinforcement workers and house painters were matched by age, earlier back accidents, height, body mass index and smoking. These covariates were included in a multivariate logistic regression to perform the statistical analysis to control for possible confounding factors likely to affect disc degeneration. After controlling for these factors, the authors still reported statistically significant effects. In addition, the authors noted that workers, to be included in the

study, had to have at least 5 years seniority, thus creating the possibility for negative bias due to health-based self-selection of workers in the more physically demanding job (*i.e.* concrete workers). The effect of this negative bias, however, would underestimate the risk ratios. In an attempt to understand the underlying etiology of this disc degeneration, the authors did additional analyses looking at different segments of the lumbar region and different degenerative spinal changes (*e.g.* disc space narrowing, spondylophytes, and endplate sclerosis). In some of these sub-analyses for certain lumbar regions, there was no statistically significant effect. Overall, however, the authors found a significant association between work and disc degeneration while controlling for confounders. Therefore, OSHA does find these results compelling and generally supportive of its health effects assessment.

Gibson Dunn & Crutcher criticized the 1994 study of sciatic pain among men in machine operating, dynamic physical work and sedentary work by Riihimaki *et al.* (1994, Ex. 26-1188). They claim that the associations observed in this study are "barely significant" (Ex. 500-197, pg. 69) and are no more significant than the associations observed with physical exercise. In addition, they state that the observed increases are negatively influenced by workers' self reporting of tasks, "an inadequate definition of sciatica" and recall bias.

OSHA is unsure as to what these critics mean by "barely" significant. The authors reported a statistically significant increase in sciatic pain among machine operators and carpenters compared to office workers. For machine operators the relative risk =1.6 (95% CI 1.2-2.2) and for carpenters was 1.7 (95% CI 1.3-2.4). This statistical significance remained even after controlling for a variety of risk factors (*e.g.* age, seniority, education, physical exercise, smoking, car driving, and prior back accidents). Adjusted relative risks were 1.4 and 1.5.

The authors do acknowledge that the reporting of symptoms of sciatica can be subjective, as can a worker's perception of physical task. In order to minimize this type of bias, they used explicit descriptions of symptoms and tasks to ensure uniform understanding of the concepts. The authors also recognize the potential of recall bias to negatively influence the results. However, they note that this misclassification also depends not only on the recall error but also the incidence rate of the symptoms. They conclude that the recall error bias in the observed risk ratios is small if "by the end of follow-up" the rate of

reporting symptoms among the misclassified subjects does not deviate much from the overall incidence rate. Thus, while OSHA acknowledges the potential bias pointed out by the critics of this study, the agency believes that these sources of bias have been taken into consideration in this study to such an extent that the observed increased risk ratios can be accepted with some confidence. In addition, OSHA believes that these observed risk ratios are more than barely significant and, when viewed in the context of other positive epidemiological evidence, contribute to the weight of evidence and the strength of the agency's overall health effects assessment.

Gibson Dunn & Crutcher also criticize four other epidemiology studies OSHA relied on in contributing to the strength of the agency's overall health effects assessment: two studies by Silverstein *et al.* (Exs. 26-34 and 26-1404), a study by Venning *et al.* (Ex. 500-41-49), and a study by Punnett *et al.* (Ex. 26-39). OSHA responds to criticisms of these 4 studies in on Section G:3-Exposure-Response.

## VI. Risk Assessment

### A. Introduction

The United States Supreme Court, in the *Benzene* decision (*Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980)), has ruled that the OSH Act requires, prior to the issuance of a new standard, that a determination be made that there exists a significant risk of material impairment and that issuance of the new standard will substantially reduce that risk. The Court stated that "before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices" (448 U.S. 642). The Court also stated that "the Act does limit the Secretary's power to require the elimination of significant risks" (448 U.S. 644).

In the *Cotton Dust* case (*American Textile Manufacturers Institute v. Donovan*, 452 U.S. 490 (1981)), the Court reaffirmed the position it had previously taken in the *Benzene* decision that a risk assessment is not only appropriate but required to identify significant health risks in workers and to determine if a new standard will reduce those risks. Although the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as

a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible.

The weight of evidence presented in the Health Effects section of this preamble (Section V) demonstrates a causal relationship between exposure to workplace risk factors and work-related musculoskeletal disorders. As discussed in that section, the major workplace risk factors include exposure to repetitive motion, force, awkward postures, contact stress, and segmental vibration. The Health Effects section also demonstrates that the risk associated with occupational exposure to these risk factors increases with frequent or prolonged exposure to these risk factors, and that the risk is increased when workers are exposed to more than one risk factor in a job.

OSHA has determined that there is substantial evidence that exposure to these biomechanical stressors at work can cause or contribute to the development of MSDs and that reductions in these stressors can reduce the number and severity of these work-related MSDs. The underlying evidence falls into three broad categories:

Studies of groups of workers showing a relationship between exposure to biomechanical risk factors in the workplace and an increased incidence or prevalence of MSDs;

Biomechanical studies that show that adverse tissue reactions and damage can occur when tissues are subjected to high forces and/or a high number of repetitive movements, which occur when workers are substantially exposed to biomechanical risk factors; and

Scientific and case studies that demonstrate that workplace interventions designed to reduce exposures to biomechanical risk factors are effective in reducing the internal forces imposed upon tissues and the incidence and severity of MSDs.

In the Health Effects section of this preamble, OSHA summarizes data and findings from more than 170 epidemiological studies of the incidence or prevalence of MSDs in groups of workers who are exposed to physical risk factors in their jobs. In most of these studies, the MSD prevalence of a group of exposed workers is compared to that in another worker group that is not exposed to the risk factors of interest. If the exposed group shows a higher MSD prevalence than does the reference group, the study provides evidence of an association between exposure and an increased risk of developing MSDs, particularly if the study is of good quality and adequately controlled for potentially confounding factors (such as age and gender) and biases.

Many of these epidemiological studies were reviewed by the National Institute for Occupational Safety and Health (NIOSH) in 1997 (Ex. 26-1) to evaluate the strength of the evidence for a causal relationship between several types of MSDs and the workplace risk factors of force, repetitive motion, awkward posture, and vibration. More than 600 peer-reviewed studies were critically reviewed, making this one of the largest human data bases ever built to examine work-related adverse health outcomes. NIOSH found that for most combinations of MSDs and risk factors, the evidence in humans that a causal relationship existed between workplace exposure to risk factors and the development of MSDs was either "sufficient" or "strong." For a few MSD/risk factor combinations, there was insufficient evidence of a causal relationship, but in no case did NIOSH determine that there was evidence for the absence of a relationship between exposure to workplace risk factors and the development of MSDs. NIOSH concluded that " \* \* \* a substantial body of credible epidemiologic research provides strong evidence of an association between MSDs and certain work-related physical factors when there are high levels of exposure and especially in combination with exposure to more than one physical factor \* \* \*" (NIOSH 1997, ES p. xiv, Ex. 26-1).

A similar conclusion was reached by the experts participating in a workshop conducted by the National Academy of Sciences/National Research Council (NRC) (Ex. 26-37). For the NRC report, a panel of experts critically reviewed the methods used to select and evaluate the human studies relied on in the 1997 NIOSH study (Ex. 26-1). The 1999 NRC report concluded as follows:

[the association between MSDs and exposure to risk factors at work that have been] identified by the NIOSH review \* \* \* as having strong evidence are well supported by competent research on heavily exposed populations.

There is a higher incidence of reported pain, injury, loss of work, and disability among individuals who are employed in occupations where there is a high level of exposure to physical loading than for those employed in occupations with lower levels of exposure. (Ex. 26-37)

In this context, NAS's use of the phrases "heavily exposed" and "high level of exposure" does not refer to any specific quantitatively defined level of exposure to biomechanical risk factors, but simply reflects that, in the epidemiological studies, groups of workers who were considered to be "exposed" to biomechanical risk factors

experienced higher intensities and durations of exposure than did the comparison, or referent, groups of workers. In general, workers in the exposed groups were exposed to biomechanical risk factors on a nearly daily basis, and were usually exposed for most of each work shift. However, as shown by OSHA's summary of exposure-response data in the Health Effects section (Section V), many of these epidemiological studies placed workers in the exposed group even if they were exposed for only about one-quarter to one-half of the work shift. Later in this section, OSHA defines "higher-risk" workers as those who are exposed in excess of the final rule's job screening criteria, which generally reflects those workers as having two or more hours per shift of exposure to biomechanical risk factors.

Since the NIOSH and NAS reports, many additional epidemiological studies have been published and are contained in the rulemaking record. These studies have been reviewed by OSHA in detail in the Health Effects section, and their results add to the already substantial weight of evidence originally evaluated by NIOSH and NAS. OSHA is not alone in its determination that the epidemiological data base for ergonomics convincingly establishes a causal relationship between workplace exposure to risk factors and MSDs. Many experts who provided testimony in the record and appeared at OSHA's informal hearing agreed that sufficient epidemiological evidence exists to conclude that biomechanical factors at work cause or contribute to MSDs. These experts included researchers, medical professionals, and ergonomists (Exs. 37-1, 37-2, 37-9, 37-10, 37-13, 37-10, 37-15, 37-16, 37-17, 37-18, 37-21, 37-27; Tr. 843, Tr. 1048; Tr. 1112, Tr. 1103-1103, Tr. 1367, Tr. 9808-9809, Tr. 16802, Tr. 17566-17567, Tr. 8261, Tr. 2834, Tr. 9297, Tr. 16145, Tr. 1959-1960, Tr. 17358, Tr. 13330-13331, Tr. 3412).

That exposure to workplace risk factors can cause or contribute to MSDs is made more plausible by the growing body of studies of biomechanical effects, also summarized in the Health Effects section (Section V of this preamble), that are designed to explore how tissues react to mechanical stress and how those reactions are related to disease processes. OSHA presented detailed scientific information on the biomechanics and pathophysiology of MSDs in its Health Effects Appendices, prepared at the time of the proposed rule (Ex. 27-1); the discussion below briefly summarizes the information

reviewed in the Health Effects Appendices and in the Health Effects section.

Although all soft musculoskeletal tissue can tolerate certain physical loads, these tissues will respond adversely if the load becomes excessive. Muscles, ligaments, tendons, and tendon sheaths can become inflamed with repetitive or prolonged loading, cartilage can deteriorate when subjected to abnormal loads, and nerves can exhibit dysfunction and eventually permanent damage if compressed or subjected to extended tension. Other studies have shown that the kinds of risk factors present in many industrial occupations can impose internal forces on soft musculoskeletal tissue sufficient to cause the kinds of physiologic responses described above. The relationships between external and internal loads have been demonstrated using both biomechanical models and direct measurement and observation in the workplace (see Section V, Health Effects).

Finally, evidence of the work-relatedness of MSDs comes from several studies and case reports that document the effectiveness of ergonomic interventions in reducing exposures to risk factors and the successes of individual companies' ergonomics programs in reducing the incidence or prevalence of MSDs and the severity of MSDs among their workers. After reviewing intervention studies, including both field and laboratory studies, the NRC (1998, Ex. 26-37) concluded that

\* \* \* specific interventions can reduce the reported rate of musculoskeletal disorders for workers who perform high-risk tasks. No known single intervention is universally effective. Successful interventions require attention to individual, organizational, and job characteristics, tailoring the corrective action to those characteristics.

The scientific evidence and case studies demonstrating that ergonomic interventions reduce excessive tissue loads and the associated tissue pathology, and reduce MSD incidence and severity, are summarized later in this section).

In addition to biomechanical risk factors present at work, the risk of developing an MSD is also influenced by individual, organizational, and social factors. Factors that affect individual susceptibility include age, general conditioning, and pre existing medical conditions. Although some of these individual factors have been identified in human studies as being statistically significant predictors of disease, they are generally much weaker predictors than are biomechanical factors of force,

repetition, posture, and vibration (NRC 1998, Ex. 26-37). Organizational factors that have been linked to MSDs include poor job content (e.g., lack of job variety) and job demands (e.g., excessive or highly variable workload and time pressure). The importance of poor job content is difficult to evaluate, since this factor can coexist with biomechanical factors (for example, excessive workload can result in a worker needing to increase repetitive movement and/or force). Social factors refer to a lack of social support from management and supervisors, which can lead to psychological stress and dissatisfaction with work, both associated with an increased prevalence of MSDs. However, after evaluating the nature of psychosocial factors and their role in contributing to the risk of MSDs, OSHA has determined that, although psychosocial factors appear, at least in some studies, to have some relationship to the observed increases in the incidence of MSDs among workers exposed to risk factors, their effect is independent of that of biomechanical factors and is generally not as predictive of MSD risk as are biomechanical factors. The evidence reviewed by the Agency suggests that psychosocial factors may have a greater influence in determining the length of disability following development of an MSD than do biomechanical factors, but have shown weaker associations with the prevalence or incidence of MSDs than have biomechanical factors (see Section V.G.5 of the Health Effects Section for a discussion of the literature dealing with psychosocial effects). OSHA's finding is in accord with that of the NAS review (1999, Ex. 26-37).

OSHA believes that the human epidemiologic studies, the biomechanical and physiological studies, and the studies of the effectiveness of workplace ergonomic interventions together constitute a compelling body of evidence that demonstrates that exposure to risk factors at work is a major factor in the development of MSDs, and that reducing or eliminating exposures to these risk factors will reduce the number and severity of these MSDs.

The epidemiological data base that describes the associations between exposure to workplace risk factors and increased prevalence or incidence of MSDs is vast. The nature of the hazard and of the available data require OSHA to perform a different type of risk assessment than it performs to assess occupational risks from chemical exposures. There are many reasons for this, in particular the complex interactions among different kinds of

exposures that lead to tissue injury and disorders and the difficulty of defining exposure metrics that reflect all of the various combinations of risk factors to which workers are exposed across industry. This is not to say that exposure-response relationships have not been observed or cannot be defined in specific circumstances; in fact, there are many cases in which the risk of MSDs has been quantitatively related to the degree and intensity of exposure. In the Health Effects section of this preamble (Section V), OSHA describes scientific studies that demonstrate a positive association between the magnitude and/or duration of exposure to workplace risk factors and the prevalence of MSDs, including upper extremity disorders and back injuries. OSHA concludes that these studies provide compelling evidence of the work-relatedness of MSDs, since a finding of positive exposure-response trends is one of the key findings necessary to establish a causal relationship between exposure and disease.

Using data on the incidence of work-related MSDs, risk can be quantified using a population-based approach similar to the one used by OSHA to quantify the risk of Hepatitis B among workers with frequent occupational exposure to blood and other potentially infectious material (56 FR 64004). For this final ergonomics program rule, OSHA uses a similar approach in its final risk assessment. In this assessment, OSHA relies on data from the Bureau of Labor Statistics (BLS) to estimate the annual incidence of work-related MSDs in different industry sectors and occupations, by type of injury and type of exposure. A description of these data and OSHA's analytical approach are described in part B below, and the results of this analysis appear in part C.

Having quantified the risk, it is important to determine the extent to which the standard is likely to reduce that risk. In the case of this ergonomics program standard there is abundant evidence of the effectiveness of ergonomic programs. This evidence comes from a variety of published studies, articles, and unpublished data that describe the reductions in risk ergonomics programs have actually achieved in the workplace. Most commonly, this evidence is expressed in terms of reductions in injury rates and decreases in the numbers of lost workdays caused by MSDs. OSHA's discussion of these data appears in part D, below. The Agency presents the results of its risk analysis in parts C and D; comments on the preliminary risk

assessment (64 FR 65926) follow these sections.

#### *B. Data Sources and Analytical Approach*

The annual Survey of Occupational Injuries and Illnesses conducted by the Bureau of Labor Statistics (BLS) is the principal data source for evaluating the risks to employees of developing a work-related musculoskeletal disorder. This survey is conducted under a joint federal/state program that collects workplace injury and illness data from about 165,000 private industry establishments. The survey requests information only on non-fatal injuries and illnesses, and excludes the self-employed, farms with fewer than 11 employees, private households, and employees in federal, state, and local government agencies.

For this survey, selected employers are required to provide statistics on the total number of injuries and illnesses recorded on the OSHA Form 200 (the "OSHA Log"), as well as information describing the nature and causes of their lost workday injuries and illnesses. Thus, according to the BLS, the data provided by employers " \* \* \* reflect not only the year's injury and illness experience, but also the employer's understanding of which cases are work-related under current record keeping guidelines of the U.S. Department of Labor." Information from employers is

provided in sufficient detail to permit the BLS to systematically code each reported case and develop estimates of the numbers and incidence of each specific type of LWD injury and illness for the United States as a whole, by industry sector and by occupation.

Although the BLS data are the best available data on the number and kinds of job-related injuries and illnesses occurring among U.S. workers in any given year, there is no single BLS-reported number that represents all employer-reported musculoskeletal injuries and illnesses occurring in that year. Instead, employer-reported injuries and illnesses are coded by the BLS according to a classification system that categorizes each incident by type of injury or illness and by nature of the exposure event leading to the injury or illness (Ex. 26-1372). The types of disorders that are addressed by the standard fall into several of these BLS injury and illness categories.

To use these data, OSHA identified the kinds of cause-specific injuries and illnesses, as coded by the BLS, that reflect MSDs of the kinds that will be covered by the ergonomics program standard. An OSHA panel, which included an occupational physician and two professional ergonomists, examined the BLS listing of occupational injury and exposure event codes and their definitions from the manual provided to state personnel who code the data from

the BLS employer survey. The table contained in Appendix VI-A at the end of this Risk Assessment section provides the list of injury categories that were initially selected by this panel as being likely to include at least some work-related MSDs. From this initial list, the panel selected a subset of injury categories that predominately included work-related MSDs of the type that has been associated with exposure to the biomechanical risk factors addressed by the final rule; these categories appear in Table VI-1. Of the injury categories selected, OSHA chose to base its analysis exclusively on six injury categories that were deemed by these experts to be most relevant and most likely to represent a large proportion of lost workday MSDs; in other words, OSHA deliberately excluded several categories such as "traumatic injuries to bones, nerves, and spinal cord," "symptoms involving nervous and musculoskeletal systems, unspecified," and "disorders of the peripheral nervous system, unspecified." The injury categories included by OSHA for the risk assessment were:

Sprains, Strains, and Tears;  
Back Pain, Hurt Back;  
Soreness, Hurt, except back;  
Carpal tunnel syndrome;  
Hernia; and  
Musculoskeletal and connective systems diseases and disorders.

**Table VI-1. BLS Injury Categories Consisting Predominately of Employer-Reported Musculoskeletal Disorders (Continued)**

BLS Code	Nature of Injury	Description
021	Sprains, strains, tears	This nature group classifies cases of sprains and strains of muscles, joints tendons, and ligaments. Diseases or disorders affecting the musculoskeletal system, including tendonitis and bursitis, which generally occur over time as a result of repetitive activity should be coded in Musculoskeletal system and connective tissue diseases and disorders, major group 17. Includes avulsion, hemarthrosis, rupture, strain, sprain, or tear of joint capsule, ligament, muscle, or tendon. Excludes hernia (153), lacerations of tendons in open wounds (034), torn cartilage (011).
0972 0973	Back pain, hurt back Soreness, pain, hurt, except the back	Subcategories under nature group 097, Nonspecified injuries and disorders, which includes traumatic injuries and disorders where some description of the manifestation of the trauma is provided and generally where the part of body has been identified. Subcategory 0972 includes hurt back, backache, low back pain.
1241	Carpal tunnel syndrome	Subcategory under nature group 124, Disorders of the peripheral nervous system, which includes the nerves and ganglia located outside the brain and spinal cord.
153	Hernia	This nature group classifies hernias of the abdominal cavity. Includes: femoral (1539), esophageal (1539), hiatal (1532), inguinal (1531), paraesophageal (1539), scrotal (1531), umbilical (1539), and ventral (1533) hernias. Excludes: herniated disc (011), herniated brain (1231), and strangulations (091).
17	Musculoskeletal system and connective tissue diseases and disorders.	This major group classifies diseases of the musculoskeletal system and connective tissue.
170	Musculoskeletal system and connective tissue diseases and disorders, unspecified	
171	Arthropathies and related disorders (arthritis)	This nature group classifies joint diseases and related disorders with or without association with infections. Includes: ankylosis of the joint, arthritis, arthropathy, and polyarthritis. Excludes: disorders of the spine (172), gouty arthropathy (1919), rheumatic fever with heart involvement(131).

**Table VI-1. BLS Injury Categories Consisting Predominately of Employer-Reported Musculoskeletal Disorders (Continued)**

BLS Code	Nature of Injury	Description
172	Dorsopathies	This nature group classifies conditions affecting the back and spine. Includes: spondylitis and spondylosis of the spine (1729); intervertebral disc disorders, except dislocation (1723); sciatica (1721); lumbago (1722); and other nontraumatic backaches (1729). Excludes: dislocated disc (011), curvature of the spine (1741), fractured spine (012), herniated disc (011), ruptured disc (011), traumatic sprains and strains involving the back (021), and other traumatic injuries to muscles, tendons, ligaments, or joints of the back (02), and traumatic back pain or backache (0972).
173	Rheumatism, except the back	This nature group classifies disorders marked by inflammation, degeneration, or metabolic derangement of the connective tissue structure of the body, especially the joints and related structures of muscles, bursae, tendons and fibrous tissue. Generally, these codes should be used when the condition occurred over time as a result of repetitive activity. Includes: rotator cuff syndrome (1739), rupture of synovium (1739), and trigger finger (1739). Excludes: rheumatism affecting the back is included in code (172), traumatic injuries and disorders affecting the muscles, tendons, ligaments and joints (02).
174	Osteopathies, chondropathies, acquired deformities	This group is comprised of diseases of bones, diseases of cartilage, and acquired musculoskeletal deformities. Includes: osteomyelitis, periostitis and other infections involving bone; and acquired curvature of the spine.
179	Musculoskeletal system and connective tissue diseases and disorders, n.e.c.	This nature group classifies musculoskeletal system and connective tissue diseases and disorders that are not classified elsewhere.

Source: Occupational Injury and Illness Classification Manual, Bureau of Labor Statistics, December 1992 (Ex. 26-1372)

For this analysis, OSHA is interested in capturing only those injuries and

illnesses that are associated with exposure to the risk factors addressed in

the final rule. These risk factors are repetitive motion, excessive force,

awkward postures, contact stress, and segmental vibration. The annual BLS survey does not break out the causes of injuries and illnesses captured by the survey in a manner that precisely matches the kinds of risk factor exposures covered by the rule. However, the OSHA panel did identify the three exposure event categories defined by the BLS that are the most closely related to these risk factors. These are:

- “Repetitive motion,” which reflects the risk factors of repetitive motion, sometimes combined with force and/or awkward posture, and contact stress, which is a combination of repetitive motion and force;

- “Overexertion,” which includes activities such as lifting/lowering, pushing/pulling, holding/carrying, and throwing, and thus reflects the risk factor of force, sometimes combined

with repetitive motion and/or awkward posture; and

- A subcategory of “bodily reaction” that includes “bending, climbing, crawling, reaching, twisting,” which reflects the risk factor of awkward posture.

The BLS definitions for these exposure event categories appear in Table VI-2. Note that musculoskeletal injuries and illnesses caused by acute events such as slips, trips, falls, being struck by objects, or by motor vehicle accidents are *excluded* from the data relied on in OSHA’s risk analysis (because they are not included in the coverage of the final rule (see paragraph (a) of the regulatory text)). The process used by OSHA to identify those injury and exposure event categories from which to select the BLS data represents the closest approximation possible from

the data available to OSHA of the MSDs that the final rule will actually cover.

The BLS injury and illness coding system also includes two exposure event categories that reflect exposure to vibration involving damage to the nerves or circulatory system (Ex. 26-1372). They include:

- Event code 05, rubbed or abraded by friction or pressure; this code includes injuries caused by rubbing or abrasion by “objects being handled,” and includes “superficial injuries such as blisters, scratches, or abrasions,” as well as those involving nerve or circulatory damage, and

- Event code 06, rubbed, abraded, or jarred by vibration, which includes injuries caused by vibration of mobile equipment or vehicles, as well as other machines or equipment.

**Table VI-2. Description of BLS Exposure Event Categories Corresponding to Workplace Risk Factors Associated with Work-Related Musculoskeletal Disorders**

BLS Code	Nature of Exposure Event	Description
21	Bodily reaction <sup>a</sup>	
210	Bodily reaction, unspecified	Codes in this major group apply to injuries or illnesses resulting from a single incident of free bodily motion which imposed stress or strain upon some part of the body. Generally, codes in this major group apply to the occurrence of strains, sprains, ruptures, nerve damage or other internal injuries
211	Bending, climbing, crawling, reaching, twisting	or illnesses resulting from the assumption of an unnatural position or from voluntary or involuntary motions induced by sudden noise, fright, or efforts to recover from slips or loss of balance (not resulting in falls). This major group includes cases involving musculoskeletal or internal injury or illness resulting from the execution of personal movements such as walking, climbing, bending, etc. when such movement in itself was the source of injury or illness. Group does not include falls.
212	Sudden reaction when surprised, frightened, startled	
213	Running--without other incident	
214	Sitting	
215	Slip, trip, loss of balance--without fall	
216	Standing	
217	Walking--without other incident	
	Bodily reaction, n.e.c.	

**Table VI-2. Description of BLS Exposure Event Categories Corresponding to Workplace Risk Factors Associated with Work-Related Musculoskeletal Disorders (Continued)**

BLS Code	Nature of Exposure Event	Description
22	Overexertion	Overexertion applies to cases, usually non-impact, in which the injury or illness resulted from excessive physical effort directed at an outside source of injury or illness. The physical effort may involve lifting, pulling, pushing, turning, welding, holding, carrying, or throwing the source of injury/illness. Free bodily motions that do not involve an outside source of injury or illness are classified either in major group 21, Bodily reaction, or in major group 23, Repetitive motion.
220	Overexertion, unspecified	
221	Overexertion in lifting	
222	Overexertion in pulling or pushing objects	
223	Overexertion in holding, carrying, turning, or welding objects	
224	Overexertion in throwing objects	
229	Overexertion, n.e.c.	
23	Repetitive motion	Repetitive motion applies when an injury or illness resulted from bodily motion which imposed stress or strain upon some part of the body due to a task's repetitive nature. Instances of carpal tunnel syndrome (CTS) from typing or any type of keyentry, including the use of calculators or nonscanning cash registers are coded 231. CTS resulting from cutting with a knife, repeated use of a power tool should be coded Repetitive use of tool (232). If an injury or illness resulted from prolonged vibration in long distance driving, the event should be coded in event group 061, Rubbed, abraded, or jarred by vehicle or mobile equipment vibration.
230	Repetitive motion, unspecified	
231	Typing or key entry	
232	Repetitive use of tools	
233	Repetitive placing, grasping, or moving objects, except tools	
239	Repetitive motion, n.e.c.	

<sup>a</sup> The subcategory of "Bending, climbing, crawling, reaching, twisting" is the only subcategory from the Bodily Reaction category used by OSHA to define MSDs.

Source: Occupational Injury and Illness Classification Manual, Bureau of Labor Statistics, December 1992 (Ex. 26-1372)

MSDs caused by segmental vibration are thus included with those caused by

whole-body vibration in both event categories, which makes it difficult to

separate out those vibration-induced injuries and illnesses related only to

segmental vibration, one of the risk factors covered by the standard. The BLS estimated that a total of 5,465 injuries related to exposure events classified under these two categories (excluding injuries involving the eyes) had occurred in 1996 (see BLS Table R32 for 1996, available at [http://www.bls.gov/oshc\\_d96.htm](http://www.bls.gov/oshc_d96.htm)). Because it is not possible to identify the number of injuries associated with segmental vibration, OSHA has included in its analysis only those MSDs related to the three event codes of overexertion, repetitive motion, and the subcategory of bodily reaction described above. The injury/illness and event codes used by OSHA in the Risk Assessment and Significance of Risk sections for the final rule are the same as those used to support these analyses of the proposed rule. OSHA's decision not to include vibration-induced injuries and illnesses in the universe of MSDs means that the risks estimated in the final Risk Assessment section, and the estimates in the Significance of Risk section, are understated.

OSHA received numerous comments on its selection of injury/illness and exposure event codes from those used in the BLS classification system. In particular, several commenters objected to OSHA's inclusion of injuries categorized as "sprains, sprains, and tears," because, in their view, such injuries reflect acute injury events, while OSHA's ergonomics program standard was intended to address injuries that arise from cumulative damage through long-term exposure to risk factors. These commenters include, among others, the Chamber of Commerce (Ex. 30-1722), the American Iron and Steel Institute (Exs. 30-3951, 32-206), Gibson, Dunn, & Crutcher on behalf of numerous clients (Exs. 500-197, 32-241), the National Coalition on Ergonomics (Ex. 32-368), the American Forest & Paper Association (Ex. 30-3865), the AEI-Brookings Joint Center (Ex. 30-3911), Edison Electric Institute (Ex. 32-300-1), the Center for Office Technology (Ex. 30-2208), Integrated Waste Services Association (Ex. 30-3853), Organization Resources Counselors (Ex. 30-3813), the American Meat Institute (Ex. 30-3677), Guilford Mills (Tr. pp. 11519-11520, 11566-11567), the Puerto Rico Manufacturers Association (Ex. 30-3348), and the National Paint and Coatings Association (Ex. 30-4340). In support of their views, these commenters point to the BLS's definition of "sprains, sprains, and tears," which appeared on Table VI-1 of the preamble to the proposal (64 FR 65928-65929) and reads as follows:

This nature group classifies cases of sprains and strains of muscles, joints, tendons, and ligaments. Diseases or disorders affecting the musculoskeletal system, including tendinitis and bursitis, which generally occur over time as a result of repetitive activity should be coded in Musculoskeletal System and Connective Tissue Diseases and Disorders, major group 17. (Ex. 26-1372)

Based on this definition, Gibson, Dunn, & Crutcher conclude that cases classified as sprains, strains, and tears represent single-incident traumatic injuries and "are not MSDs" (Ex. 500-197, p. I-166).

To further support their view that strains, sprains, and tears reflect acute injury events and not cumulative trauma, Gibson, Dunn, & Crutcher note that most of the strain, sprain, and tear injuries described in OSHA's preliminary risk assessment were associated with overexertion, which is defined by the BLS as follows:

Overexertion applies to cases, usually non-impact, in which the injury or illness resulted from excessive physical effort directed at an outside source of injury or illness \* \* \* Free bodily motions that do not involve an outside source of injury or illness are classified either in major group 21, Bodily Reaction, or in major group 23, Repetitive Motion. (Ex. 26-1372)

Thus, Gibson, Dunn, and Crutcher argue that

Clearly, nothing in this definition suggests that overexertion injuries develop gradually over time. To the contrary, this definition expressly excludes injuries that result from repetitive motion. There is simply no evidence that sprains, strains, and tears associated with overexertion meet the definition of an MSD. (Ex. 500-197, p. I-167)

Similarly, the Chamber of Commerce stated: "It is not difficult to imagine that many, if not most of these injuries \* \* \* may well have occurred as the result of a single instantaneous event." (Ex. 30-1722)

Gibson, Dunn & Crutcher (Ex. 500-197), AISI (Exs. 32-206, 30-3951), the American Forest & Paper Association (Ex. 30-3865), the American Meat Institute (Ex. 30-3677), and the Hon. David M. McIntosh of the U.S. House of Representatives (Ex. 30-542) all objected to the inclusion of cases from BLS category 0972 (back pain, hurt back) in the universe of MSDs on the grounds that these are traumatic injuries as well. To support this position, Gibson, Dunn, & Crutcher pointed to OSHA's *Record Keeping Guidelines for Occupational Illnesses and Injuries*, commonly known as the "Blue Book." These guidelines instruct employers how to record occupational injuries and illnesses on their OSHA 200 logs.

Gibson, Dunn & Crutcher argued that, in the Blue Book, OSHA "concedes" that back cases should be categorized as injuries rather than illnesses. According to Gibson, Dunn and Crutcher (Ex. 500-197):

OSHA states that back cases are "injuries" that are "usually triggered by an instantaneous event" for purposes of OSHA 200 recording, [but] converts them into "illnesses" that develop "gradually over time" for purposes of its MSD statistics \* \* \* The bottom line is that OSHA has no reliable data regarding the causes of back pain and back injuries. OSHA allows employers to "generalize" about back pain for purposes of OSHA 200 recording precisely because its causes are often indeterminate.

OSHA has carefully considered these comments and finds them unpersuasive. It is necessary and appropriate to include these BLS categories to arrive at an accurate estimate of the risk posed by the biomechanical risk factors addressed in this standard.

First and foremost, OSHA is issuing its final ergonomics program standard because of substantial evidence that workers who are regularly exposed to biomechanical risk factors are at an increased risk of MSDs and the pain and disabilities associated with them. Whether these injuries and illnesses come about because of an acute event or because of pathology that develops over a longer term is not germane to the issue of whether workers who are regularly exposed need protection. The sole consideration is that increased exposure to biomechanical risk factors increases the risk to the worker. For example, a worker whose job involves heavy lifting on a regular basis is at an elevated risk of suffering a low back disorder. Such a disorder may arise either because repeated lifting is causing cumulative wear resulting in degenerative changes to the disc, or because the stress imposed on the spine during lifting can overcome the capacity of the disc to withstand compression, resulting in acute structural failure (see Section V.E on the health evidence for low-back disorders). Although a worker who lifts heavy loads infrequently may be at risk from acute failure, the worker who lifts frequently as part of their regular job is at greater risk via either mechanism.

Furthermore, there is substantial evidence in the record that many of the injuries coded as strains, sprains, and tears in fact develop gradually over time. Several commenters believed that it was appropriate for OSHA to include statistics on strains, sprains, and tears in its assessment of MSD risks. For example, the AFL-CIO, in their post-hearing brief, stated that

The industry is just plain wrong on this point [that back injuries are traumatic injuries]. The BLS survey is based on employer reports of injuries. To simplify recording, OSHA recording criteria specifically specify that back injuries, one major source of MSDs, should be recorded as injuries, even if they result from chronic exposure conditions. Disorders related to repeated trauma, including carpal tunnel syndrome are to be recorded as illnesses.

\* \* \* Thus, it is OSHA's recording criteria and BLSs coding rules and definitions that result in many MSDs, particularly back injuries, being classified as sprains, strains, and tears. This category includes injuries that may result from a single exposure and those that result from repeated activities. OSHA has limited the types of strains, sprains, and tears that are covered [in its risk assessment] to those \* \* \* associated with] exposures that are covered by the rule (e.g., overexertion, repetition). (Ex. 500-218, p. 13-14)

Testimony from Dr. Frank Mirer of the United Auto Workers, who is also a member of the BLS Labor Research Advisory Committee, explained why MSDs of the back are frequently recorded as sprains and strains:

You have to understand the reality of this BLS database, which is derived from [the] OSHA 101 form submitted by management medical departments to OSHA or to the BLS. Now when a worker goes up to the medical department \* \* \* all they know is they hurt. And most of them see a nurse and their disorder is just thrown into a bin. Back conditions are all injuries. They come as strain and sprain \* \* \*. [W]e have acute flare ups, just as a back injury is a chronic condition and has an acute flare up. So standard practice in the industry \* \* \* is [that] cases [considered to be] of ergo interest \* \* \* [include] sprain and strain injuries that are not accompanied by a fall or some other traumatic [event] \* \* \*. (Tr. 5896-5897)

When asked whether strains and sprains due to overexertion or repetition were likely to be related to the risk factors covered by the standard, both Dr. Rosecrance and Mr. Alexander agreed. Dr. Rosecrance testified that injuries classified as sprains or strains are appropriately considered MSDs, depending on the events leading to the injury:

\* \* \* I look at an MSD \* \* \* as a disorder affecting muscles, tendons, ligaments, bone, connective tissue. And certainly in my definition of MSD, a sprain would meet that because a sprain is a tear to a ligament \* \* \* [It] perhaps [might] be a traumatic one or from an acute injury like a slip or a trip \* \* \*. When we review, let's say, the OSHA 200 Log and there is a strain or sprain on there, I will ask \* \* \* what was the cause of that sprain or strain? Was the strain from repetitive use or was it a strain from an acute type of injury?

Some rulemaking participants provided evidence to the record documenting that back disorders were frequently recorded as strains and sprains without regard to the nature of the exposure or events associated with each case. For example, the post-hearing submission of the United Food and Commercial Workers Union (UFCW) (Ex. 500-133), which contained copies of OSHA-200 logs (Ex. 500-133-2), reported finding MSDs categorized as strains and sprains, back pain, hurt back, carpal tunnel syndrome, hernia, and disorders associated with repeated trauma. According to the UFCW, retail stores primarily categorized such MSDs as sprains and strains, back pain and hurt backs, and injuries, and seldom classified MSDs as illnesses. In contrast, the UFCW stated that meatpacking industry logs more often accurately record MSDs as illness, reflecting the greater experience this industry has in dealing with ergonomic issues. A review of OSHA 200 logs submitted by the Teamsters (Ex. 500-146) also shows that disorders that are clearly recognized as MSDs, such as carpal tunnel syndrome and tendinitis, are nevertheless often recorded by employers as injuries, which in turn would be described in the BLS statistics as strains and sprains.

Other rulemaking participants described the use of sprain and strain injury categories for ergonomic injuries in other injury classification systems. In describing the province of Victoria's (Australia) 1999 ergonomics regulation, which combined Victoria's earlier manual handling and occupational overuse syndrome (OOS) regulations, Mr. David C. Caple, Director, David Caple & Associates Pty Ltd., testified that both repetitive injuries and back injuries were combined under one generic sprain and strain category by that regulation (Tr. 2723-2724). The Ford Motor Company's injury classification system also combines strain and sprain injuries with cumulative trauma disorders and other disorders of interest to the company's ergonomics committee (Tr. 5826). When asked whether sprains and strains are included within the category of repetitive motion disorders under Oregon's workers' compensation law, Mr. Goodman replied that they are often classified in that category, depending on the events leading to the injury. He explained that Oregon's law defines an injury as "sudden and unexpected in onset"; thus, strains and sprains would be considered repetitive motion disorders if the onset was slow and insidious rather than sudden (Tr. 13694).

As described by the AFL-CIO submission and Dr. Frank Mirer's testimony, all back disorders are classified as injuries rather than illnesses, under OSHA's recordkeeping rules; as a result, back disorders are commonly classified as strains and sprains, regardless of whether the disorder arose from an acute, traumatic event or from cumulative damage caused by prolonged exposure to risk factors. Evidence in the record indicates that most cases of back pain arising from exposure to risk factors of the type covered by the final rule do not develop suddenly but are instead cases involving gradual onset, which makes it difficult to identify or relate the back pain to a single precipitating event. OSHA's witness, Dr. Stover Snook, testified that

I am of the view and most scientists are of the view that that is not typically how low back pain develops through traumatic things like playing football on a weekend. It usually develops gradually and insidiously, most of it, not all of it, but most of it does. (Tr. 884)

In a study of back braces, Walsh and Schwartz (Ex. 30-3857-7) also characterized the nature of work-related back disorders as being of gradual onset:

Most back injuries are not the result of a single traumatic incident but rather a compilation of minor traumatic events occurring during normal working conditions for reasons that are seldom obvious to the individual worker. Successive injuries result in more severe impairment and increase the probability of long-term disability \* \* \*. In fact, improper body mechanics and unhealthy work habits may take their toll on a daily basis. In recent years, there has evolved a body of evidence that suggests that the etiology of most but not all back pain is due to insidious and chronic deterioration of the intervertebral disc, facet joints, and ligaments in the back caused by biomechanical wear and tear. (Ex. 30-3857-7, p. 245)

OSHA's analysis of the biomechanical and pathological literature dealing with work-related back pain leads to conclusions that are consistent with these characterizations (see Section V, Health Effects).

Because back disorders are recorded as injuries, notwithstanding the mechanistic evidence described above that characterizes most back disorders as being of chronic onset, practicing ergonomists believe that it is important to investigate the underlying events associated with recorded cases of strain or sprain to determine whether the injury is related to excessive exposure to ergonomic risk factors. This practice was described in the testimony of Dr. John Rosecrance, Assistant Professor, University of Iowa and Mr. David Alexander, President of Auburn

Engineers, Inc. and reflects an understanding that the classification of back disorders as strains and sprains often does not mirror the true nature of these disorders.

OSHA's final risk assessment (like its proposed assessment) relies on statistics for strains and sprains that are associated only with overexertion (*i.e.*, lifting/lowering, pushing/pulling, holding/carrying), repetitive motion, and bodily reaction (*i.e.*, awkward postures). Thus, OSHA's treatment of the BLS data exclude strains and sprains that were determined by ergonomists or health care professionals to arise from accidents, such as slips or falls. Based on the evidence and testimony reviewed above, strains and sprain injuries captured by the BLS system and classified under these three exposure event codes properly reflect musculoskeletal disorders that arise as a result of exposure to the risk factors covered in the final rule. Further, as described below in part C of the risk assessment, OSHA has refined its analysis, based on data in the record, to estimate the number and incidence of MSDs occurring among those workers who are exposed to risk factors at levels that meet the final rule's screen; OSHA believes that this refinement will ensure that the Agency is accurately stating the risks posed to employees covered by the final rule.

The United Auto Workers (Ex. 32-185), argued that OSHA was underinclusive, not overinclusive, in its choice of the BLS categories that represent MSDs. In addition to the six categories chosen by OSHA, the UAW argued that OSHA should have included a substantial fraction of the injuries and illnesses categorized as "other" and "multiple injuries" as well. OSHA agrees that these injury categories contain MSDs that are relevant to OSHA's risk analysis. However, since data are not available to describe the proportion of the injuries classified under these categories that are, in fact, MSDs, the Agency has not included them in its revised risk assessment. This decision also means that the risks presented by OSHA in its Risk Assessment section and estimated in the Significance of Risk section are understated.

As explained by OSHA in its preliminary risk assessment for the proposed rule, risk estimates based on the BLS data understate the true risk of incurring a work-related MSD posed to

employees who are exposed to workplace risk factors that are associated with the development of MSDs, for several reasons. First, the BLS data include only those lost workday (LWD) cases that resulted in at least 1 day spent away from work, and thus do not capture either non-lost workday MSD cases nor MSD cases that resulted in the employee being temporarily reassigned to another job. Second, some LWD MSDs reported to the BLS by employers are likely to have been coded in BLS injury categories that are excluded from OSHA's categories of overexertion, repetition, and bodily reaction (bending, climbing, crawling, reaching, twisting); for example, injuries due to segmental vibration are included in BLS event categories other than those included by OSHA in its analysis, and, as pointed out by the UAW (Ex. 32-185), the non-specific BLS injury categories of "other" and "multiple injuries" are also likely to contain MSDs.

Finally, the incidence of MSDs reported by the BLS is the reported incidence of MSDs occurring among *all* workers in the industries surveyed (on a full-time-equivalent basis); that is, the incidence for each industry sector is calculated by BLS as the number of MSD cases reported in 1996 divided by the total number of full-time equivalent employees in that industry sector in 1996. Expressing the incidence in this way has the effect of diluting the estimated incidence of disorders that are actually occurring among exposed employees, *i.e.*, those who routinely are exposed to workplace risk factors that have been associated with the development of work-related MSDs. The risk to exposed employees is substantially higher than the risk reflected by the BLS estimates of MSD incidence, because most of the injuries reported to the BLS will in fact have occurred among that subset of workers whose jobs expose them to these risk factors (that is, if the incidence were calculated using the much smaller denominator that reflects the number of exposed employees, the resulting incidence estimate would be higher). Evidence that workers exposed to workplace risk factors are at substantially higher risk than other workers in their industry comes from the large data base of formal scientific studies of exposed worker populations that have demonstrated a positive relationship between exposure to

workplace risk factors and the relative risk of developing an MSD (see the Health Effects section of this preamble). These studies show that the prevalence of MSDs among exposed employees is often 2- or 3-fold higher, and can be as much as 10 to 20 times higher, as the prevalence among workers who are not so exposed.

In the next part of the Final Risk Assessment, OSHA presents two alternative approaches to quantifying risks posed to workers who are exposed to biomechanical risk factors on the job. The first approach is the same as that used in the Preliminary Risk Assessment presented in with the proposed rule. In that approach, OSHA's estimates of the risk are based on the numbers and incidence of MSDs reported by BLS (based on OSHA's definition of MSDs) by industry sector and by occupation. OSHA's second approach responds to a number of comments made in the record that the Agency's Preliminary Risk Assessment did not (1) properly subtract out MSD cases that occurred among employees who were not heavily exposed to physical risk factors, and (2) did not properly account for background risk (*i.e.*, that part of the risk that could not be attributed to workplace exposure or that occurs among the general population). To address these comments, the Agency was able to use data that became available in the record to more precisely characterize the MSD risk in the subset of employees who are the most heavily exposed to risk factors covered in the final rule, and to account for background risk. OSHA's underlying rationale is explained fully in part C below.

### C. Results

Table VI-3 provides the BLS estimates of the number of injuries and illnesses reported nationwide by employers for 1996, by nature of injury and type of workplace exposure, for all injury and exposure event categories determined by OSHA to represent the MSDs covered by the standard. Overall, OSHA estimates that there were a total of 647,344 lost workday MSDs that occurred in 1996, as derived from employer reports of thoseTable VI-3 here illnesses and injuries. These disorders represent about 34.4 percent of the 1.88 million LWD injuries and illnesses reported by employers in 1996 (BLS press release 97-453, 12/17/97).

TABLE VI-3.—ESTIMATES OF THE NUMBER OF LOST WORKDAY MUSCULOSKELETAL DISORDERS (MSDs) IN 1996, BY NATURE OF INJURY AND TYPE OF WORKPLACE EXPOSURE

Nature of injury	BLS Code	Type of workplace exposure					Subtotal
		Total for all exposures	Overexertion	Repetition	Subtotal (O and R)	Bodily Reaction <sup>a</sup>	
Total for all lost workday injuries			526,594	73,796	600,390	79,475	679,865
Musculoskeletal Disorders:							
Sprains, Strains, Tears	021	819,658	424,290	12,872	437,162	66,068	503,230
Back Pain, Hurt Back	0972	52,046	28,046	861	28,907	4,646	33,553
Soreness, Hurt, except back	0973	73,542	17,984	5,811	23,795	2,896	26,691
Carpal tunnel syndrome	1241	29,937		29,809	29,809		29,809
Hernia	153	29,624	25,819	322	26,141	670	26,811
Musculoskeletal and connective system diseases and disorders	17	35,238	7,761	18,278	26,039	1,211	27,250
Total Number of MSDs		1,040,045	503,900	67,953	571,853	75,491	647,344

<sup>a</sup>Data from BLS included only those injuries reported to have been associated with "Bending, climbing, crawling, reaching, twisting." Source: BLS-reported estimates for BLS nature-of-injury codes 021, 0972, 0973, 1241, 153, and 17, and for BLS exposure events of overexertion, repetition, and bodily reaction (1996).

For 1998, the BLS estimated that there were 592,500 MSDs that occurred throughout U.S. industry, representing an 8.5-percent decline from 1996 ("Lost-Worktime Injuries and Illnesses: Characteristics and Resulting Time Away From Work, 1998," U.S. Bureau of Labor Statistics, available at <http://www.bls.gov/news.release/osh2.nr0.htm>). This decline is consistent with the pattern seen from 1992–1996, when both MSD and overall injury rates declined. For the final risk assessment, OSHA has continued to use 1996 BLS data in order to be consistent with the economic analysis, which uses 1996 as a base year throughout. For example, 1996 is the base year from which data are used to estimate numbers of establishments and employees, revenues, profits, and costs associated with the final rule.

About 66 percent of the estimated number of MSDs reported to the BLS in 1996 were categorized by BLS coders as "sprains, strains, and tears" due to overexertion. As discussed in part B above, OSHA received many comments on the use of BLS data on injuries classified by the BLS as sprains, strains, and tears; these commenters objected to including these injuries in the risk assessment on the grounds that injuries classified as strains, sprains, and tears reflect acute injuries that cannot be considered MSDs. Based on the

evidence and testimony presented in part B above, however, OSHA has determined that it is appropriate to include strains, sprains, and tears that are associated with the exposure events of overexertion, repetitive motion, and bodily reaction in the universe of relevant MSDs because these injuries arise from exposure to relevant risk factors. Furthermore, OSHA believes that, when MSDs result from exposure to the biomechanical risk factors covered in the final rule, it is not important to make any distinction between whether those injuries arose from acute or chronic events. The purpose of the standard is to reduce the risk of MSDs resulting from exposure to risk factors, regardless of the duration of the exposure preceding to those injuries and illnesses.

As further evidence of the appropriateness of including strain, sprain, and tear injuries in the risk assessment, OSHA presented BLS data in the preliminary risk assessment that provides additional information on the nature of the injuries and the exposure events associated with those injuries [64 FR 65931]; these data are reproduced in Table VI-4. For this analysis, OSHA obtained from the BLS a breakout of the estimated number of injuries, by body part and by type of overexertion event. This breakout appears in Table VI-4 and shows that about 89 percent of these

sprain, strain, and tear injuries (379,615) are comprised of injuries due to lifting/lowering, pushing/pulling, holding/carrying, or throwing, all of which are activities involving force. For the remaining 11 percent of the BLS-coded sprain, strain, and tear injuries, the exact nature of the overexertion exposure was either not reported by the employer or did not fall into any other exposure classification under the BLS system. Of the 379,615 injuries for which the nature of the overexertion exposure was reported, the majority (88 percent) affected body parts that are consistent with the kinds of injuries addressed by the final standard, such as the upper extremities, neck and shoulder, lower extremities, and back. Fifty-two percent of these injuries represent back injuries due to lifting or lowering. Only a small proportion (12 percent) of sprain, strain, and tear injuries reported by the BLS in 1996 affected body parts that are not relevant to MSDs. Therefore, OSHA is confident that the vast majority of BLS-coded sprain, strain, and tear injuries are appropriately included in the estimated number of MSDs for 1996, and that the judgment of the OSHA expert panel in selecting appropriate BLS injury and event categories for Table VI-4 here the risk analysis is confirmed by this additional breakout and review of the BLS data.

**Table VI-4. Number and Percentage of All BLS-Reported Sprain, Strain, and Tear Injuries That are Work-Related Musculoskeletal Disorders (i.e., Caused by Overexertion), by Body Part and Nature of Exposure, 1996**

Body Part Affected	Type of Overexertion Exposure							Total excluding NEC and Unspecified
	Lifting/ Lowering	Pushing/ Pulling	Holding/ Carrying	Throwing	Unspecified	Not Elsewhere Classified (NEC)		
Shoulder	20,728	8,639	6,895	395	2,277	2,177	36,657	
Back	174,107	33,805	35,358	888	15,625	9,811	244,158	
Neck	4,844	1,984	1,812	--	810	720	8,640	
Arm	7,012	2,717	2,451	66	751	807	12,246	
Wrist	6,567	2,608	2,787	--	712	866	11,962	
Hand	1,417	443	403	--	210	87	2,263	
Finger, fingernails	849	496	319	--	133	205	1,664	
Upper extremities, nec	--	59	--	--	--	--	59	
Upper extremities, unspecified	--	--	--	--	--	--	0	
Multiple upper extremities	1,085	308	342	--	326	142	1,735	
Legs	6,074	4,195	2,426	--	743	969	12,695	
Ankles	829	717	320	--	126	460	1,866	
Foot	236	382	36	--	65	48	654	
Toes	--	16	--	--	--	--	16	
Lower extremities, unspecified	--	--	--	--	--	--	0	
Lower extremities, nec	37	--	--	--	--	--	37	
Multiple lower extremities	218	61	--	--	--	--	279	
Total all Work-Related MSDs	224,003	56,430	53,149	1,349	21,778	16,292	334,931	
Total for Other Body Parts	29,698	8,030	6,843	113	3,304	2,749	44,684	
Total Sprains, Strains, Tears	253,701	64,460	59,992	1,462	25,082	19,041	379,615	
Percent of Injuries Representing Work-Related MSDs	88	88	89	92	87	86	88	

The data summarized above have been broken out by the BLS both by

industry sector and by occupation code. In addition, the BLS provided OSHA

with estimates of the incidence of MSDs, as defined above by injury type

and cause, for each 2-digit SIC. As explained above, the BLS-calculated incidence estimates are based on the incidence among all employees (full-time equivalents) in each industry sector, and therefore understate the true incidence of work-related MSDs occurring among workers who are highly exposed to workplace risk factors, *i.e.*, exposed in jobs that meet the standard's action trigger. Nevertheless, OSHA believes that these incidence estimates are useful for characterizing industry-specific MSD risks and for comparing the extent of the problem between industry sectors covered by the ergonomics program standard. Table VI-5 provides estimates of the number and incidence of LWD MSDs in each general industry 2-digit SIC group for which the BLS provided data. Industries having the highest incidence of MSDs include the following:

Air transportation (36.6 cases/1,000 workers);  
 Local and suburban transit (14.7 cases/1,000);  
 Motor freight transportation and warehousing (14.4 cases/1,000);  
 Health services (13.8 cases/1,000);  
 Transportation equipment (13.4 cases/1,000); and  
 Food and kindred products (12.2 cases/1,000).  
 Table VI-6 provides estimates of the number and incidence of LWD MSDs by occupation code for the 75 occupations having the highest estimated annual incidence of employer-reported MSDs. Because the BLS does not provide incidence estimates by occupation, OSHA calculated the incidence using employment estimates from the Bureau of the Census Employment and Earnings (1996). Occupations having the highest incidence include:

Driver—sales workers (42.4 cases/1,000 workers);  
 Machine feeders and offbearers (34.6 cases/1,000);  
 Public transportation attendants (32.1 cases/1,000);  
 Nursing aides, orderlies, and attendants (31.6 cases/1,000);  
 Punching and stamping machine operators (30.4 cases/1,000 workers);  
 Laborers, except construction (29.1 cases/1,000);  
 Sawing machine operators (18.9 cases/1,000);  
 Furnace, kiln, and oven operators, except food (18.0 cases/1,000);  
 Grinding, abrading, polishing machine operators (17.9 cases/1,000);  
 Health aides, except nurses (16.9 cases/1,000); and  
 Licensed practical nurses (16.5 cases/1,000).

**Table VI-5. Estimated Number of Lost Workday MSDs in 1996 and Annual Incidence per 1,000 Workers, by 2-Digit SIC**

Two Digit SIC	Industry Sector	Estimated Number of LWD MSDs	Incidence per 1,000 Workers
45	Transportation by air	34,150.0	36.580
41	Local and suburban transit and interurban highway passenger transportation	4,617.3	14.671
42	Motor freight transportation and warehousing	23,800.1	14.438
80	Health services	103,478.7	13.847
37	Transportation equipment	24,524.0	13.420
20	Food and kindred products	20,540.1	12.242
24	Lumber and wood products, exc. furniture	9,228.5	12.166
34	Fabricated metal, exc. machinery & transportation equipment	17,751.1	12.121
33	Primary metals	8,940.0	12.099
30	Rubber and misc. plastics	11,982.7	12.069
25	Furniture and fixtures	5,892.1	11.741
32	Stone, clay, glass, concrete products	6,316.4	11.444
53	General merchandise stores	22,395.6	11.152
52	Building materials, hardware, garden supply, mobile home dealers	8,621.9	10.699
54	Food stores	25,268.9	10.191
44	Water transportation	1,537.1	9.959
51	Wholesale trade-nondurable goods	24,768.4	9.792
31	Leather and leather products	856.4	9.226
39	Misc. manufacturing industries	3,375.8	8.997
21	Tobacco products	322.9	8.308
70	Hotels, rooming houses, camps, other lodging	11,241.0	8.216
35	Industrial and commercial machinery & computer equipment	17,124.5	7.946
23	Apparel and other finished products made from fabric	6,379.6	7.869
83	Social services	13,755.1	7.483
50	Wholesale trade - durable goods	26,782.1	7.235
57	Home Furniture, Furnishings, And Equipment Stores	6,016.1	7.136
26	Paper and allied products	4,865.2	6.921
07	Agricultural Services	5,187.8	6.861
27	Printing, publishing, and allied industries	9,195.3	6.547
36	Electronic and other electrical, exc. computer equipment	10,782.5	6.506
76	Miscellaneous Repair Services	2,274.4	6.506
49	Electric, Gas, And Sanitary Services	5,712.1	6.478
79	Amusement And Recreation Services	5,805.4	5.857
22	Textile mill products	3,483.4	5.626
59	Miscellaneous Retail	10,043.2	4.857
65	Real Estate	5,882.8	5.113
09	Fishing, Hunting, and Trapping	49.5	4.951
55	Automotive dealers and gasoline service stations	10,347.3	4.847
38	Measuring, analyzing, and controlling instruments; photo, medical, optical; watches, clocks	4,036.9	4.785
75	Automotive Repair, Services, And Parking	4,347.9	4.422
48	Communications	5,708.2	4.398
72	Personal Services	3,527.2	3.865
73	Business services	16,706.8	3.564
28	Chemicals and allied products	3,641.2	3.507
47	Transportation Services	1,263.1	3.262
13	Oil and Gas Extraction	1,075.7	3.170
56	Apparel And Accessory Stores	2,439.1	3.132
29	Petroleum refining and related industries	432.1	2.956
58	Eating and drinking places	14,457.5	2.830
86	Membership Organizations	1,838.5	2.745
82	Educational Services	2,926.6	2.681
87	Engineering, Accounting, Research, Management, And Related Services	5,653.6	2.114
63	Insurance Carriers	2,659.1	2.068
67	Holding And Other Investment Offices	297.6	1.579
81	Legal Services	1,264.4	1.524
60	Depository Institutions	2,487.7	1.355
61	Non-depository Credit Institutions	399.3	0.810
64	Insurance Agents, Brokers, And Service	472.2	0.733
62	Security And Commodity Brokers, Dealers, Exchanges, And Services	276.7	0.533

Source: Estimates provided by BLS (Ex. 26-1413) for disorders classified by injury types and exposure events shown in Table VI-3.

**Table VI-6. Estimated Number of Lost Workday MSDs in 1996 and Annual Incidence per 1,000 Workers, by Occupation Code, Ranked by Incidence**

Occupation	Estimated Number of LWD MSDs	Median Number of Days Away From Work	Number of Employees in 1996 (000)	Incidence per 1,000 Workers
806	Driver-sales workers (8218)	7	156	42.4
878	Machine feeders and offbearers (8725)	10	70	34.6
463	Public transportation attendants (5257)	9	95	32.1
447	Nursing aides, orderlies, and attendants (5236)	5	1,850	31.6
706	Punching and stamping press machine operators (7314, 7317, 7514, 7517)	6	89	30.4
889	Laborers, except construction (8769)	6	1,334	29.1
727	Sawing machine operators (7433, 7633)	5	78	18.9
766	Furnace, kiln, and oven operators, except food (7675)	7	65	18.0
709	Grinding, abrading, buffing, and polishing machine operators (7322, 7324, 7522)	7	125	17.9
446	Health aides, except nursing (5233)	4	336	16.9
207	Licensed practical nurses (366)	5	395	16.5
785	Assemblers (772, 774)	9	1,271	16.2
804	Truck drivers (8212-8214)	8	3,019	16.0
719	Molding and casting machine operators (7315, 7342, 7515, 7542)	7	110	16.0
869	Construction laborers (871)	7	809	15.3
364	Traffic, shipping, and receiving clerks (4753)	6	616	15.0
368	Weighers, measurers, checkers, and samplers (4756, 4757)	8	55	14.9
756	Mixing and blending machine operators (7664)	5	108	14.7
449	Maids and housemen (5242, 5249)	6	683	14.3
888	Hand packers and packagers (8761)	10	279	13.7
783	Welders and cutters (7332, 7532, 7714)	6	605	13.2
754	Packaging and filling machine operators (7462, 7662)	8	393	13.1
686	Butchers and meat cutters (6871)	8	242	12.9
206	Radiologic technicians (365)	3	135	12.8
757	Separating, filtering, and clarifying machine operators (7476, 7666, 7676)	8	57	12.7
877	Stock handlers and baggers (8724)	5	1,106	12.2
544	Millwrights (6178)	15	89	11.3
799	Graders and sorters, except agricultural (785)	8	169	11.1
529	Telephone installers and repairers (6158)	9	176	11.1
769	Slicing and cutting machine operators (7478, 7678)	5	179	11.0
365	Stock and inventory clerks (4754)	8	497	11.0
748	Laundering and dry cleaning machine operators (6855, 7658)	5	202	10.9
507	Bus, truck, and stationary engine mechanics (6112)	5	336	10.8
593	Insulation workers (6465)	12	54	10.5
683	Electrical and electronic equipment assemblers (6867)	7	325	10.4
444	Miscellaneous food preparation occupations (5219)	11	664	10.3
523	Electronic repairers, communications and industrial equipment (6151, 6153, 615)	8	1,600.1	9.6

Table VI-6. Estimated Number of Lost Workday MSDs in 1996 and Annual Incidence per 1,000 Workers, by Occupation Code, Ranked by Incidence (continued)

Occupation	Estimated Number of LWD MSDs	Median Number of Days Away From Work	Number of Employees in 1996 (000)	Incidence per 1,000 Workers
759	1,901.2	5	200	9.5
563	1,539.8	10	162	9.5
318	2,869.8	7	304	9.4
516	1,433.5	14	156	9.2
566	923.9	12	103	9.0
885	1,510.0	9	169	8.9
577	1,102.3	9	126	8.7
668	511.8	7	59	8.7
585	4,742.4	11	555	8.5
439	2,063.2	6	257	8.0
573	1,317.0	6	168	7.8
567	8,872.2	7	1,220	7.3
268	1,814.6	6	254	7.1
689	925.2	7	131	7.1
595	1,389.2	7	197	7.1
856	3,580.6	7	512	7.0
865	801.2	5	115	7.0
453	15,278.0	6	2,205	6.9
95	13,595.2	4	1,986	6.8
344	710.1	10	104	6.8
588	543.1	10	80	6.8
653	844.0	5	126	6.7
797	380.9	25	57	6.7
744	3,971.1	9	595	6.7
637	3,193.3	10	491	6.5
103	766.4	5	118	6.5
356	1,198.4	6	188	6.4
796	3,404.2	6	538	6.3
518	3,407.5	8	540	6.3
738	351.3	9	56	6.3
508	835.4	8	137	6.1
734	1,908.2	9	315	6.1
488	379.1	6	63	6.0
448	992.9	5	166	6.0
657	460.8	9	79	5.8
274	8,616.0	7	1,499	5.7
486	4,981.4	5	875	5.7

Source: Estimates of number of work-related disorders provided by BLS (Ex. 26-1413) for disorders classified by injury types and exposure events shown in Table VII-3. Annual Incidence calculated by OSHA based on 1996 employment data from Employment and Earnings (U.S. Bureau of Census, 1996).

Of the Census Employment and Earnings (1996). Occupations having the highest incidence include:

- Driver—sales workers (42.2 cases/1,000 workers);
- Machine feeders and offbearers (34.6 cases/1,000);
- Public transportation attendants (32.1 cases/1,000);
- Nursing aides, orderlies, and attendants (31.6 cases/1,000);
- Punching and stamping machine operators (30.4 cases/1,000 workers);
- Laborers, except construction (29.1 cases/1,000);
- Sawing machine operators (18.9 cases/1,000);
- Furnace, kiln, and oven operators, except food (18.0 cases/1,000);
- Grinding, abrading, polishing machine operators (17.9 cases/1,000);
- Health aides, except nurses (16.9 cases/1,000); and
- Licensed practical nurses (16.5 cases/1,000).

Of the 225 occupations for which BLS provided estimates of the numbers of employer-reported MSDs and total employment, the annual incidence of MSDs was 1 LWD case or more per 1,000 workers per year for 178 (79 percent) of the occupations. The data described above reflect the annual incidence of MSDs estimated to have occurred in 1996 within general industry sectors and within occupations within this sector.

Past risk assessments conducted by OSHA in other health standards rulemakings have typically estimated the lifetime risk to workers based on the assumption that they are exposed to the hazard in question for a full 45-year working lifetime. These past risk assessments dealt primarily with chronic, fatal diseases such as cancer. Unlike the impairments of health caused by many other OSHA-regulated hazards, however, MSDs are not fatal, although they are often debilitating. Moreover, a worker can experience more than one work-related MSD over a working lifetime. As a result, the lifetime risk associated with exposure to risk factors on the job can be expressed in a number of ways. One way of doing this is to define lifetime risk as the probability that a worker will experience at least one work-related musculoskeletal disorder during his or her working lifetime (45 years). This probability is calculated as  $1-(p)^{45}$  where  $p$  is the probability that a worker will not experience a work-related MSD in any given year (*i.e.*,  $p$  is one minus the estimated MSD incidence for 1996

in the industry sector of interest).<sup>1</sup> For example, the estimated incidence of MSDs in 1996 for SIC 80, Health Services, is 13.847 lost workday cases per 1,000 workers. The probability that a worker in SIC 80 will not experience an MSD in any given year is calculated as  $1-0.013847$ , or 0.9862 (almost 99 percent). Over 45 years, the probability that a worker will never experience a work-related MSD is  $(.9862)^{45}$ , or 0.534 (*i.e.*, 53 percent). Therefore, the probability that a worker in SIC 80 will experience at least one work-related MSD is  $1-0.534$ , or 0.466 (*i.e.*, 466 per 1,000 workers).

Alternatively, lifetime risk could be defined as the expected number of work-related MSDs an employee entering an industry will experience over a working lifetime in that industry. Unlike a probability, the expected value in such cases can exceed 1. (That is why, in the table below, one industry is identified in which an individual who works for 45 years can expect to experience, on average, more than one work-related MSD during that time.) The expected value represents the experience of the “average” individual, a measure that reflects the aggregate experience of many individuals.

Both approaches<sup>1</sup> taken by OSHA to estimate lifetime risk assume that the risk to a worker is independent from one year to the next, *i.e.*, that a worker's injury experience in any one year does not modify his or her risk in any subsequent year. Although this is a reasonable assumption for the purpose of estimating an average lifetime risk, it is likely to be the case that the risk will be higher for workers who have had an MSD and continue to be exposed since musculoskeletal tissue has already been damaged. Among workers who have not experienced symptoms of an MSD, the risk to any individual worker in subsequent years depends on the amount of tissue damage sustained from exposure to risk factors and that worker's individual ability to repair or resist continued injury to the point of

<sup>1</sup> OSHA used two simplifying assumptions when calculating the probability of experiencing no work-related MSDs in a working lifetime: (1) Employment in an industry was used as a surrogate for exposure to ergonomic hazards in that industry. (2) The probability of experiencing a work-related MSD in any given industry was treated as if it were identical for workers in that industry who had never previously experienced a work-related MSD and those who had previously experienced a work-related MSD.

<sup>1</sup> In written comments (Ex.32-185-3), the UAW expressed a strong preference for estimating the lifetime risk as the probability that a worker will experience at least one MSD in a working lifetime rather than as an estimate of the lifetime risk expressed as the expected number of MSDs a worker will experience in a working lifetime.

experiencing an MSD. In addition, OSHA's approach also assumes that each worker within a given industry sector (defined by 2-digit SIC) has the same risk. For the same reasons as discussed above, a relatively small number of workers will, in fact, experience injury rates far in excess of the average, while a comparatively large number will experience injury rates below the average. At this time, data are not available that would allow OSHA to determine the lifetime MSD risks for subpopulations of workers within each industry sector, *i.e.*, those subpopulations with higher than average or lower than average risks, respectively.

Another meaning or interpretation of expected value may be more intuitive: The expected value is the total number of MSDs that may be expected to occur in a cohort of 1000 workers all of whom enter an industry sector at the same time and all of whom work for 45 years in the industry. The expected value of the number of MSDs occurring among these 1,000 workers over 45 years of employment is calculated as the annual MSD incidence multiplied by 45. For example, the estimated incidence of work-related MSDs in 1996 for SIC 80 (Health Services) is 13.847 cases per 1,000 workers, or a frequency of 0.01387. The expected value of the number of work-related MSDs predicted to occur among those 1,000 workers over 45 years is estimated to be  $(0.01387*45)$ , or 0.623 (623 per 1,000 workers).

Table VI-7 presents OSHA's estimates of the lifetime risk of experiencing work-related MSDs, by industry sector. Based on the probability approach, the estimated probability of experiencing at least one work-related MSD during a working lifetime ranges from 24 per 1,000 to 813 per 1,000, depending on the industry sector. Based on the expected value approach, the expected number of work-related MSDs that will occur in a cohort of workers all entering an industry at the same time ranges from 24 per 1,000 to 1646 per 1,000, since this approach recognizes that it is possible for a worker to experience more than one work-related MSD in a working lifetime.

Several rulemaking participants criticized OSHA's preliminary risk assessment on the grounds that the Agency's risk estimates made no allowance or correction for background risk. These participants (see, for example, Exs. 32-206, 500-223, Tr. pp.10248-9, Exs. 30-3865, 30-3356, 32-368, 30-4185, 30-3813, 30-1722, 500-221) argued that MSD risks for specific industries and occupations based on

BLS data should be compared to the background rate of MSD risk in the general population to calculate the excess risk associated with work. Some of these stakeholders asserted that, because OSHA has not done so, the Agency's estimates here represent only the average MSD risk posed to a worker in a particular industry or occupation by exposure to "all of life's activities." OSHA does not agree; the BLS data reflect only cases that employers have deemed to be work-related. It would be inappropriate to adjust the MSD rates estimated on the basis of the BLS data by subtracting from these rates the MSD rates that have been reported in the

general population. When excess risk is calculated by comparing a population of concern (in this case the employed population) to a reference population (*e.g.*, the general population), the proper approach is to compare the *total* incidence in the population of concern to the *total* incidence in the reference population (see Rothman and Greenland, Ex. 38-240). That is, to estimate the excess risk of MSDs among workers using the approach suggested by these commenters, one must have data that describes the incidence of all MSDs, both work-and non-work-related, in the working population. Assuming that the MSD rate for the general

population is the non-work-related rate, and then subtracting this rate from the BLS-based rate, would yield estimates of the work-related, or excess, risk to workers only if the BLS data truly represented all MSDs occurring among workers (both on the job and off the job). This is clearly not the case, since the BLS data are designed only to capture those injuries that are work-related; the BLS system does not capture those MSDs that occur among workers that are unrelated to work. Therefore, adjusting the BLS data by subtracting out MSD rates for the general population would not yield meaningful estimates of the excess MSD risk to workers.

Table VI-7. Estimated Risk of Developing a Work-Related MSDs Over a 45-Year Working Lifetime, by 2-Digit SIC

Two Digit SIC	Industry Sector	Estimated Incidence per 1,000 Workers	Expected Number of MSDs per 1,000 Workers During a Working Lifetime	Number of Workers per 1,000 Estimated to Have at Least One MSD During a Working Lifetime
45	Transportation by air	36.580	1,646	813
41	Local and suburban transit and interurban highway passenger transportation	14.671	660	486
42	Motor freight transportation and warehousing	14.438	650	480
80	Health services	13.847	623	466
37	Transportation equipment	13.420	604	456
20	Food and kindred products	12.242	551	426
24	Lumber and wood products, exc. furniture	12.166	547	424
34	Fabricated metal, exc. machinery & transportation equipment	12.121	545	422
33	Primary metals	12.099	544	422
30	Rubber and misc. plastics	12.069	543	421
25	Furniture and fixtures	11.741	528	412
32	Stone, clay, glass, concrete products	11.444	515	404
53	General merchandise stores	11.152	502	396
52	Building materials, hardware, garden supply, mobile home dealers	10.699	481	384
54	Food stores	10.191	459	369
44	Water transportation	9.959	448	363
51	Wholesale trade-nondurable goods	9.792	441	358
31	Leather and leather products	9.226	415	341
39	Misc. manufacturing industries	8.997	405	334
21	Tobacco products	8.308	374	313
70	Hotels, rooming houses, camps, other lodging	8.216	370	310
35	Industrial and commercial machinery & computer equipment	7.946	358	302
23	Apparel and other finished products made from fabric	7.869	354	299
83	Social services	7.483	337	287
50	Wholesale trade - durable goods	7.235	326	279
57	Home Furniture, Furnishings, And Equipment Stores	7.136	321	275
26	Paper and allied products	6.921	311	268
07	Agricultural Services	6.861	309	266
27	Printing, publishing, and allied industries	6.547	295	256
36	Electronic and other electrical, exc. computer equipment	6.506	293	255
76	Miscellaneous Repair Services	6.506	293	255
49	Electric, Gas, And Sanitary Services	6.478	292	254
79	Amusement And Recreation Services	5.857	264	232
22	Textile mill products	5.626	253	224
59	Miscellaneous Retail	4.857	219	197
65	Real Estate	5.113	230	206
09	Fishing, Hunting, and Trapping	4.951	223	200
55	Automotive dealers and gasoline service stations	4.847	218	196
38	Measuring, analyzing, and controlling instruments; photo, medical, optical; watches, clocks	4.785	215	194
75	Automotive Repair, Services, And Parking	4.422	199	181
48	Communications	4.398	198	180
72	Personal Services	3.865	174	160
73	Business services	3.564	160	148
28	Chemicals and allied products	3.507	158	146
47	Transportation Services	3.262	147	137
13	Oil and Gas Extraction	3.170	143	133
56	Apparel And Accessory Stores	3.132	141	132
29	Petroleum refining and related industries	2.956	133	125
58	Eating and drinking places	2.830	127	120
86	Membership Organizations	2.745	124	116
82	Educational Services	2.681	121	114
87	Engineering, Accounting, Research, Management, And Related Services	2.114	95	91
63	Insurance Carriers	2.068	93	89
67	Holding And Other Investment Offices	1.579	71	69
81	Legal Services	1.524	69	66
60	Depository Institutions	1.355	61	59
61	Non-depository Credit Institutions	0.810	36	36
64	Insurance Agents, Brokers, And Service	0.733	33	32
62	Security And Commodity Brokers, Dealers, Exchanges, And Services	0.533	24	24

Source: Estimated Incidence of MSDs provided by BLS for disorders classified by injury and exposure events shown in Table VI-5. Lifetime risk estimates calculated by OSHA using methods described in the text.

Some commenters (see, e.g., Ex. 30-3813, Tr. 4102-4108, Exs. 30-3356, 30-46-28, 30-4564, 30-3865, 30-4185, 30-3368, 30-1897) argued that, despite screening out some of the background risk, the BLS data are still overinclusive.

They pointed out that under the applicable OSHA and BLS guidelines, a case is considered "work-related" if an event or exposure in the workplace made *any* contribution to the injury or illness, regardless of the extent of that contribution. For example, Frank White of ORC testified that

ORC [and others] question OSHA's ability to make quantitative determinations of workplace risks based on data that do not allow OSHA to differentiate between the respective contributions of workplace and non-workplace factors. In the face of OSHA's own acknowledgment of the special difficulties associated with establishing MSD causation compared "to more traditional workplace exposures and disorders," the use of data that inherently include conditions caused by both work and non-work exposures to determine workplace risk is unacceptable. The result, once again, is an overreaching by OSHA—this time in its estimation of the true workplace risk—that has the effect of permeating, and effectively invalidating, the entire proposal. (Tr. 4102)

OSHA interprets Mr. White's comment as saying that, although strictly non-work-related MSDs are not captured by the BLS system, some proportion of cases in the system nevertheless represent MSDs that occur among workers who are not regularly exposed to risk factors, or whose exposures arise from tasks that are not "core elements" of the job (using the language contained in the proposed rule). In other words, although there may be some contribution from work to these cases, exposure to risk factors on the job are no greater than those encountered during non-work activities.

In this risk assessment for the final ergonomics program standard, OSHA has relied on BLS injury and illness data in much the same way it does when evaluating the risks associated with safety hazards. Because the statistics relied upon by OSHA reflect work-related injuries and illnesses reported by employers and determined by OSHA to have been associated with exposure to the risk factors addressed by the final rule, there is no "background" number of injuries and illnesses in the OSHA data in the sense that BLS data are capturing non-work-related injuries. In other words, the total number of MSDs that occur in the workforce are either work-related or non-work-related; BLS counts the first and the second represents background. Thus, OSHA does not agree with these commenters that it is necessary to adjust the BLS data *per se* to account for such background risk.

However, OSHA does recognize that some fraction of the number of MSDs estimated from the BLS data represents injuries and illnesses occurring among

employees in jobs that would not be covered by the OSHA standard. That is, some of the MSDs being captured by the BLS's annual survey reflect injuries to workers who are not in jobs that meet the action trigger, *e.g.*, those who may be exposed to risk factors only infrequently or those whose exposures were not of sufficient duration. OSHA does not intend the final ergonomics program standard to apply to these kinds of jobs. Instead, OSHA intends the standard to apply to those jobs where MSDs have occurred and the employee's exposure to risk factors was of sufficient duration, magnitude, and frequency to have contributed to the injury. This concept is reflected in the final rule in the form of the Basic Screening Tool, which explicitly identifies those exposure conditions that must be present on the job, along with an employee's report of an MSD incident, before the employer is obligated to implement the program. Employers have no obligation to establish an ergonomics program under the final rule if employees are not exposed to risk factors at least at the level(s) reflected in the Basic Screening Tool. Thus, OSHA adjusted, as an alternate analysis, its estimates of risk based on the BLS data to include only that portion of the risk that will be addressed by an ergonomics program developed under the final rule, *i.e.*, that portion of the risk that is occurring among employees who are exposed to risk factors at least to the extent reflected in the final rule's screening tool. OSHA is thus estimating the risk of MSDs occurring among employees who would be covered in an ergonomics program, *i.e.*, those who are more highly exposed to biomechanical risk factors.

As explained by OSHA above, the BLS-reported incidence of MSDs reflects the number of MSDs reported per 1,000 full-time equivalent workers employed in industry. This incidence figure distributes the MSDs evenly across all workers in an industry sector or occupation. However, as demonstrated by the scientific evidence presented in the Health Effects section (Section V), OSHA has determined that the work-related risk of MSDs increases with the intensity and/or duration of exposure. Because of this, MSDs are not, in fact, evenly distributed across all workers, but are concentrated among the proportion of workers who are the more highly exposed to biomechanical risk factors. Thus, the incidence of MSDs among the more highly exposed workers is greater than that among the lesser-exposed workers; this has been shown in the almost 200 epidemiological

studies reviewed in the Health Effects section. It is for this reason that OSHA believes that the risk estimates presented in the first analysis above, which relied on the BLS-reported incidence estimates by industry and occupation, understate the true risk among the workers who are more highly exposed to physical risk factors (while overstating it for workers who are not highly exposed to risk factors).

OSHA's second approach to estimating work-related MSD risks takes account of this risk differential between more highly exposed (*i.e.*, higher-risk) workers and lesser-exposed (*i.e.*, lesser-risk) workers to estimate more precisely the risk among those workers who would most benefit from an ergonomics program. In addition, the risk among the higher-risk workers is estimated in two forms. One assumes that all of the risk among the higher-risk workers can be attributed to their exposure to biomechanical risk factors, *i.e.*, all of the risk is work-related. OSHA believes this is reasonable because the data used to make these estimates are the BLS data, which represents MSDs reported by employers to be work-related. The second form assumes that, despite the fact that the data derive from reports of work-related injuries, only part of the risk can be attributed to workplace exposure to physical risk factors because of the presence of some "background" risk among the higher-risk workers. This background risk represents MSDs that are not work-related and are attributed to some unknown non-work exposure to risk factors. OSHA believes that making such an adjustment to the estimated risk among higher-risk workers leads to an overly conservative estimate of risk among workers whose jobs will be screened in under the final rule; however, the Agency is nevertheless making this adjustment in response to addresses the concerns of those commenters who argued that OSHA should take account of the "background" incidence of MSDs.

The first step in OSHA's second approach to estimating work-related MSD risks is to estimate the incidence of MSDs for higher-risk and for lesser-risk workers. OSHA considers the higher-risk workers to be those workers who are exposed to risk factors at levels that meet the final rule's basic screening tool; all other workers are considered lower-risk in the sense that they are exposed to risk factors at levels below the final rule's screen.

To accomplish this analysis, OSHA relied on data contained in the record from Washington State's industry-wide survey of workplace exposure to

physical risk factors (Ex. 500–41–118); details of this survey are presented in Chapter 3 (Benefits Assessment) of the Final Economic Analysis. Data from this survey were used to estimate the percentage of employees in each major industry group who are exposed to risk factors that at least meet the level of a “caution zone” job under Washington State’s ergonomics standard. The kinds and durations of risk factor exposures contained in Washington State’s definition of a “caution zone” job are similar to those contained in OSHA’s Basic Screening Tool, *e.g.*, generally 2 or more hours per shift of exposure to repetitive motions, awkward postures, contact stress, or segmental vibration, or 4 or more hours per shift of keyboarding activity. Both tools also use the same lifting weight and frequency-of-lift criteria to screen jobs for force associated with manual handling. Because of the similarities between OSHA’s screening tool and the Washington State criteria, OSHA believes it reasonable that use of the Washington State survey data on workplace exposures to biomechanical risk factors will yield reasonable estimates of the numbers of workers who are exposed to risk factors at the levels that meet the action trigger of the final rule. OSHA has used these data,

along with data derived from the epidemiology studies reviewed in the Health Effects section (Section V of the final rule’s preamble), to estimate the number and incidence of MSDs occurring annually among employees who are exposed to risk factors at levels meeting the action trigger in the final rule. OSHA’s Final Economic Analysis contains a detailed description of the Washington State survey data and OSHA’s use of these data to estimate the percentage of workers in each covered industry sector who are exposed to risk factors at levels that meet the final rule’s action trigger.

OSHA’s approach to estimating the excess risk of MSDs among exposed workers is summarized in Table VI–8. From the Washington State survey data, OSHA estimated the percentage of employees who are exposed to risk factors that meet the final rule’s screen criteria (Column D of Table VI–8) in each 2-digit industry sector, as well as the number of higher-risk workers (Column E).

To estimate the incidence of MSDs separately for higher-risk as compared with lower-risk workers, OSHA assumes that the annual incidence of MSDs among the higher-risk workers is three times that of low-risk workers. The justification for this assumption can be found in the many epidemiology studies

reviewed in the Health Effects section of this preamble (Section V). These studies compared the prevalence or incidence of MSDs among workers who are regularly exposed to the risk factors addressed by the final rule with the prevalence or incidence among the referent (or less-exposed) worker populations. Typically, these epidemiological studies report observed differences in these rates as ratios (such as odds ratios, incidence ratios, prevalence ratios, or other relative risk measures). A compilation of the risk measures identified in these studies appears in the form of estimated median and mean risk ratios in Table VI–9, separated by part of body. As the table shows, median risk ratios for back disorders, neck and shoulder disorders, and upper extremity disorders are 1.85, 2.7 to 3.3, and 2.8 to 6.6, respectively. Mean values for back disorders, neck and shoulder disorders, and upper extremity disorders are 2.4, 4.5 to 5.2, and 4.4 to 12.6, respectively. Based on these values, OSHA finds that, in general, employees who are regularly exposed to the risk factors covered by the final rule are at three times higher risk or, put another way, will experience a 3-fold higher incidence of MSDs than is the case for workers who are not so exposed.