

National Coalition on Ergonomics

April 1, 2005

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Mr. Frank Frodyma
Acting Director
Directorate of Evaluation and Analysis
Occupational Safety and Health Administration
United States Department of Labor
200 Constitution Avenue, NW
Washington, DC 20310

Re: Information Quality Correction Request

Ergonomics Guidelines for Poultry Processing, Retail Grocery Stores,

and Nursing Homes

Dear Acting Director Frodyma:

On behalf of the National Coalition on Ergonomics ("NCE"), we are requesting corrective action with respect to information disseminated in three Occupational Safety and Health Administration ("OSHA") publications: Ergonomics for the Prevention of Musculoskeletal Disorders: Guidelines for Poultry Processing, issued on September 2, 2004 ("Poultry Guidelines"), Ergonomics for the Prevention of Musculoskeletal Disorders: Guidelines for Retail Grocery Stores, issued on May 28, 2004 ("Grocery Guidelines"), and Ergonomics for the Prevention of Musculoskeletal Disorders: Guidelines for Nursing Homes, issued on March 13, 2003 ("Nursing Home Guidelines") (collectively, "Guidelines"). This request is being filed pursuant to the procedures mandated by the Information Quality Act ("IQA"), Pub L. No. 106-554, App. C, § 515, as implemented by the Office of Management and Budget directive set forth at 67 Fed. Reg. 8452 (Feb. 22, 2002) and by the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor, promulgated at 67 Fed. Reg. 61669 (Oct. 1, 2002).

As originally conceived, the Guidelines were supposed to communicate "existing best practices" and "voluntary solutions" without the burden of shaping a "scientifically valid" ergonomics rule. Testimony of Elaine L. Chao before the Committee on Health, Education, Labor and Pensions, Apr. 18, 2002. NCE strongly supports this stated goal. There is a vital distinction, however, between "best practices" grounded in conventional practice and prescriptive remedies allegedly supported by scientific research. OSHA is entitled—and well-advised—to operate as a clearinghouse for ideas, communicating approaches that particular employers have found helpful. The agency runs afoul of the IQA, however, when it asserts that hard, verifiable scientific studies support these ideas.

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Statement of Interest

NCE is a broad based business coalition that is vitally concerned with OSHA's policy on ergonomics. NCE's membership, both within and outside the specific industries targeted in the Guidelines, have an important interest in this exercise. Despite the promise of "industry-specific" guidelines addressing "issues that may be unique to the industry or facility," http://www.osha.gov/ergonomics/FAOs-external.html, the Poultry, Grocery, and Nursing Home Guidelines have an indisputable impact on all of general industry. They all recommend a "systematic process," Poultry Guidelines at 3-a formal, seven-part program replicated in each document, which also is readily transferable to other industries. See Poultry Guidelines at 7-13 ("providing management support," "involving employees," "providing training," "identifying problems," "implementing solutions," "addressing reports of injuries," and "evaluating ergonomics efforts"); Nursing Home Guidelines at 6-8 (identical elements); Grocery Guidelines at 7-8, 11 (identical elements except that "evaluate ergonomics efforts" is labeled "evaluate progress"). The substance of these elements is largely identical; in fact, in many cases, large portions of text have been copied virtually verbatim, except for the insertion of "poultry processing," "retail grocery," or "nursing home" as applicable. Compare, e.g., Poultry Guidelines at 11 ("Addressing Reports of Injuries") with Grocery Guidelines at 8 and Nursing Home Guidelines at 7 (corresponding sections).

Not only are the Guidelines substantively identical, but there is also little meaningful difference between the Guidelines' cookie-cutter formula and the seven-part program that would have been mandated under the general industry ergonomics standard rejected by Congress. Compare 29 C.F.R § 1910.900(h) (rescinded "management leadership" requirement); 29 C.F.R § 1910.900(i) (rescinded "employee participation" requirement); 29 C.F.R § 1910.900(j) (rescinded "job hazard analysis" requirement); 29 C.F.R § 1910.900(k) (rescinded requirement to "reduce MSD hazards"); 29 C.F.R § 1910.900(p) (rescinded "MSD management" requirement); 29 C.F.R § 1910.900(t) (rescinded "training" requirement); 29 C.F.R § 1910.900(u) (rescinded requirement to "evaluate your ergonomics program").

Just as importantly, the Guidelines' common target is material handling and other supposed "risk factors." See Poultry Guidelines at 10; Grocery Guidelines at 8. Without grounding in data-driven medicine, the Guidelines broadly attack such activities, urging that they be "reduced" "minimized," or even "eliminated." See, e.g., Nursing Home Guidelines at 3, 7. The Guidelines rest on the counterintuitive proposition that physical activity is toxic. Conventional wisdom and sound medicine point unmistakably in the opposite direction, recognizing the benefits of physical activity in contexts ranging from geriatrics to sports medicine to surgical rehabilitation. The agency's contrarian medical philosophy, applicable to all employment contexts where physical labor is performed, is of special and profound concern to all of American industry. Indeed, the Nursing Home Guidelines make crystal clear their applicability to other "employers with similar work environments." Id. at 2.

Information in Question

The Guidelines are the first three in a series of documents promised under OSHA's "comprehensive approach" to ergonomics. After Congress rescinded OSHA's previous ergonomics standard, the agency settled upon this approach because of what it properly acknowledged as "scientific uncertainties" that stand in the way of renewed rulemaking. Testimony of Elaine L. Chao before the Committee on Health, Education, Labor and Pensions, Apr. 18, 2002. Guidelines are a key component of OSHA's commitment to address "musculoskeletal disorders" ("MSDs"). See Statement of John L. Henshaw to the National Ergonomic Conference, Las Vegas, Nevada, Dec. 11, 2002. Given their consequential import, we applaud the fact that each set of Guidelines was issued after a notice and comment period and stakeholder meetings at which interested members of the public could provide input. See 67 Fed. Reg. 55884 (Aug. 30, 2002) (request for comments and notice of stakeholder meeting on draft Nursing Home Guidelines); 68 Fed. Reg. 25068 (request for comments and notice of stakeholder meeting on draft Grocery Guidelines); 68 Fed. Reg. 33536 (June 4, 2003) (request for comments and notice of stakeholder meeting on draft Poultry Guidelines).

After correctly recognizing that the science was far too uncertain to justify the promulgation of a standard, the Guidelines pay only lip service to the scientific uncertainty surrounding ergonomics, briefly acknowledging that "[m]ore remains to be learned about the relationship between workplace activities and the development of MSDs." *Poultry Guidelines* at 3; *Grocery Guidelines* at 3; *Nursing Home Guidelines* at 2. The Guidelines completely ignore how much OSHA must "learn" about MSDs by making broad statements and instructions that are neither industry-specific nor scientifically or factually supported. In a document that is clearly "influential," *see infra* pp. 9-10, OSHA's weak disclaimer is insufficient to qualify or narrow the impact of its far-reaching and micromanaging Guidelines.

The following are but a few examples of the sweeping and scientifically unsupportable assertions that have a substantial impact on the regulatory community. These excerpts are illustrative of a much larger set of unsupported claims that permeate all of these documents. This request relates to the entirety of the three documents, and is not limited to the quoted passages.

Terminology

OSHA uses the term musculoskeletal disorders (MSD) to refer to a variety of injuries and illnesses, including:

Muscle strains and back injuries that occur from repeated use or overexertion:

- Tendinitis;
- Carpal tunnel syndrome;
- Rotator cuff injuries (a shoulder problem);

Epicondylitis (an elbow problem); and

• Trigger finger that occurs from repeated use of a single finger.

(Grocery Guidelines at 5; see also Poultry Guidelines at 5.)

MSDs include conditions such as low back pain, sciatica, rotator cuff injuries, epicondylitis, and carpal tunnel syndrome. (Nursing Home Guidelines at 2.)

MSDs include injury to the nerves, tendons, muscles, and supporting structures of the hands, wrists, elbows, shoulders, neck, and low back. (Poultry Guidelines at 5).

The shortcomings in OSHA's guidelines begin with the very term used to describe the subject matter. Repeated statements in the Guidelines, including the passages quoted above and other similar assertions throughout each document, suggest that "MSD" is an accepted and readily definable medical term. It is not.

Shortly after Congress' rescission of the former standard, the Secretary of Labor convened a set of public forums to consider multiple unanswered questions, the very first of which was the following:

What is an ergonomics injury? The Department of Labor is interested in establishing an accepted definition that the Occupational Safety and Health Administration, employers and their employees can understand and apply.

66 Fed. Reg. 31,694 (June 12, 2001). OSHA, however, was not able to identify an accepted definition. On two occasions, the agency delayed implementation of a recordkeeping regulation that would have required separate recording of MSDs because "the agency has not yet decided on the correct approach for dealing with the Part 1904 MSD definition." 67 Fed. Reg. 77,166 (Dec. 17, 2002). The agency ultimately withdrew the proposal without drawing a conclusion, and it has yet to revisit the issue. 68 Fed. Reg. 38,601 (June 30, 2003).

OSHA's inability to settle upon a definition reflects scientific reality, while its MSD laundry list in the Guidelines is mere pretense. During the forums, the president of the American Society of Safety Engineers, M.E. Greer, noted that "at least 200 different definitions" are available; see also http://www.osha.gov/SLTC/ergonomics/faqs.html (providing no specific definition in the "comprehensive policy" announcement because "there are a wide variety of opinions on how the Agency should define an ergonomic injury"). In its legislatively-mandated report to Congress in January 2001, for example, the National Academy of Sciences ("NAS") defined a musculoskeletal "disorder" to include "an alteration in an individual's usual sense of wellness or ability to function," which "may or may not be associated with well-recognized anatomic, physiologic, or psychiatric pathology." National Research Council, NAS, Musculoskeletal Disorders and the Workplace: Low Back and Upper Extremities ("NAS Report") 36 (2001). Others define MSD in a manner that presumes the anatomic pathology that NAS found lacking. See 65 Fed. Reg. 68853 (definition from rejected standard).

Both the Poultry Guidelines and the Nursing Home Guidelines cite the NAS Report to support the assertion that MSDs involve specific "injury" to identified parts of the body. Poultry Guidelines at 5; see also Nursing Home Guidelines at 5. This is incorrect. NAS was careful to contrast "injury"—primarily a "biological event representing the impact of an environmental alteration on the individual," NAS Report at 23, with "pain syndromes" typically associated with MSDs, which often "do not satisfy rigorous diagnostic criteria for well-defined clinical entities," id. at 25. This explains NAS' definition of MSDs as "alterations . . . of wellness" rather than objective injury. Id. at 36. To cite NAS in support of the latter definition is a misrepresentation of that report.

The National Institute for Occupational Safety and Health ("NIOSH") has lamented the disagreement concerning terminology, stating that "[w]ork-related MSDs are defined differently in different studies," with a "scarcity of objective measures" or "standardized criteria." NIOSH, Musculoskeletal Disorders and Workplace Factors ("NIOSH Report"), at 1-7 (1997). Because of this uncertainty, research results typically have focused on subjective "symptoms, rather than diagnoses," which "should not be equated with causation or prevention of specific pathologic entities (e.g., diagnoses)." American College of Occupational and Environmental Medicine ("ACOEM"), Occupational Medicine Practice Guidelines 2 (2d ed. 2004).

Against this backdrop of confusion and disagreement, it is completely inappropriate to unequivocally state that MSDs "include" certain conditions, which in many cases are themselves ill-defined. It is even more inappropriate to miscite the underlying sources. OSHA's inclusion of a matter-of-fact, categorical "definition," even after it was unable to settle upon a recordkeeping definition over more than two years, undermines the credibility of the Guidelines.

Claims Concerning Causation

Manual lifting and other tasks involving the repositioning of residents are associated with an increased risk of pain and injury to caregivers, particularly to the back. (Nursing Home Guidelines at 4.)

Whether certain work activities put an employee at risk of injury depends on the duration (how long), frequency (how often), and magnitude (how intense) of the employee's exposure to the risk factors in the activity. For example, performing cashier work for an extended period of time without a break has been associated with increased hand and wrist problems and could contribute to back and lower limb problems. (Grocery Guidelines at 8.) (citations omitted)

[W]hen an employee develops carpal tunnel syndrome, the employer needs to look at the hand and forearm activity required for the job and the amount of time spent doing the activity. If an employee develops carpal tunnel syndrome, and his or her job requires frequent hand activity, or forceful or sustained awkward hand motions, then the problem may be work-related. If the job requires very little hand or arm activity then the disorder may not be work-related. (Grocery Guidelines at 5-6; Poultry Guidelines at 5-6.)

Excessive exposure to these risk factors [force, repetition, and awkward postures] can result in a variety of disorders in affected workers. (Nursing Home Guidelines at 4.)

Excessive exposure to these risk factors [repetition, force, awkward and static postures and vibration] can lead to MSDs. (Poultry Guidelines at 5.)

Jobs and tasks that have multiple risk factors have a higher probability of causing MSDs. (Poultry Guidelines at 10.)

These statements, and other similar assertions throughout the Guidelines, misstate the current state of knowledge concerning the causative link between "risk factors" and "injuries" or "disorders." Just as the Secretary recognized the scientific uncertainty surrounding these speculations when they were part of a standard, so the IQA demands such recognition in the use of promulgated Guidelines.

NAS began its executive summary by noting the ongoing "debate concerning sources of risk, mechanisms of injury, and the potential for intervention strategies to reduce these risks." *NAS Report* at 1-2. Indeed, in the specific context of carpal tunnel syndrome, prominently identified in the Grocery Guidelines as a work-related consequence of hand activities, the NAS expressly disclaimed any causal connection:

The report does not state that interventions prevent carpal tunnel syndrome or, indeed, any other upper-extremity disorder. The emphasis, rather, is on amelioration of symptoms, which is the end point in the relevant literature.

Id. at 459.

Others have echoed these concerns. For example, the ACOEM, described by OSHA as "the world's largest occupational medical society," 65 Fed. Reg. 68293 (Nov. 14, 2000), included the following observations in the latest edition of *Occupational Medicine Practice Guidelines*, released earlier this year:

The current scientific literature about potentially work-related musculoskeletal disorders (WRMSDs)... is notable for a lack of studies that temporally and quantitatively define causal associations of work exposures. There are very few prospective studies; most are cross-sectional and case-control studies, which do not allow determination of temporal association. Other information is derived from physiology laboratory measurements rather than clinical observation in real-world situations.

Further, almost all available studies either define exposure to work-related factors qualitatively or use job title as a proxy. . . . Thus, at present, <u>risk factors</u> that have been found to be associated with or predictive of certain WRMSDs and other syndromes <u>have not necessarily been found to be causal</u> for these entities. Due to the absence of certainty regarding causality and the lack of quantitative exposure-response data, most recommendations for the prevention of WRMSDs will be qualitative. While practitioners must make good-faith efforts to prevent these

complaints, these assumptions should not extend to opinions about causation for benefits or medicolegal purposes.

ACOEM, Occupational Medicine Practice Guidelines 2-3 (2d ed. 2004) (emphasis added).

Findings such as these, from respected members of the scientific and medical communities, were an important factor in Congress' decision to rescind the ergonomics standard that had been issued in 2000. In its regulatory preamble, OSHA had advanced a "significant risk" justification remarkably similar to statements featured in the Guidelines—except that its citation of literature was far more extensive:

Th[e] evidence strongly supports . . . a positive relationship between work-related musculoskeletal disorders and employee exposure to workplace risk factors.

65 Fed. Reg. 68263 (Nov. 14, 2000). During floor debate, however, Senator George Voinovich disputed this conclusion:

Ergonomics remains an uncertain science. While a recently completed National Academy of Science study reveals that musculoskeletal disorders are a problem in the workplace, much remains to be learned about the causation and potential remedies associated with repetitive-motion injuries.

147 Cong. Rec. S1865 (daily ed. Mar. 6, 2001). Similarly, Rep. Greg Ganske, a doctor himself, made the following statement during House debate:

[W]e believe that OSHA's new ergonomics rules are not founded on "a substantial body of evidence." We agree with the National Research Council that we need a much better understanding of the mechanisms that underlie the relationships between the causal factors and outcomes.

147 Cong. Rec. H687 (daily ed. Mar. 7, 2001). In the wake of Congress' decision, the Secretary of Labor herself acknowledged the "lack of consensus within the scientific and medical communities" concerning the adequacy of research supporting the critical link between physical ergonomic "risk factors" and injuries. Letter from Secretary of Labor Elaine L. Chao to Senator Edward Kennedy, June 24, 2002.

When viewed against the backdrop of categorical statements concerning the effect of physical work factors, vague disclaimers about how "much remains to be learned" suggest that the core principles are settled and all that remains is research on the details. That is simply not the case, as NAS, the ACOEM, and other experts have found. It is precisely the kind of science-based caveats articulated by the NAS and ACOEM, *supra* pp. 6-7, that industry has sought to incorporate into the Guidelines. See Docket No. GE2002-1, Ex. 4-36 (comments of the National Association of Manufacturers on the Draft Nursing

NAS and ACOEM are not opposed to ergonomics; indeed, they recognize its many practical applications in the workplace. This makes their acknowledgements of scientific uncertainty all the more compelling. NCE is simply asking OSHA to follow the lead of NAS and ACOEM by ensuring that the Guidelines conform to the limitations of scientific knowledge. The IQA requires no less of the agency.

Home Guidelines); Docket No. GE2003-1, Ex. 3-16 (comments of the U.S. Chamber of Commerce on the Draft Grocery Guidelines); Docket No. GE2003-2, Ex. 3-5 (comments of the National Association of Manufacturers on the Draft Poultry Guidelines). OSHA's rejection of any statement as to the scientific limits of ergonomics renders these Guidelines inconsistent with peer-reviewed scientific studies and in clear violation of the IQA.

Claims Concerning Remedial Measures

This section describes storewide ergonomic principles on safe work practices employees can follow to reduce their risk of injury. Employers should train employees to use these techniques and design stores to make it easy to do so. (Grocery Guidelines at 13.)

Using postures other than those recommended will generally waste energy and motion as well as potentially raise the risk of injury. (Grocery Guidelines at 15.)

Effective solutions usually involve workplace modifications that eliminate hazards and improve the work environment. These changes usually include the use of equipment, work practices, or both. (Nursing Home Guidelines at 7.)

Poultry processors can usually meet this goal [of reducing work-related MSDs] by changing work methods, equipment, or workstations. (Poultry Guidelines at 6.)

Working outside [preferred] work zones results in non-neutral postures that may increase the risk of injury. (Grocery Guidelines at 16.)

The number and severity of injuries resulting from physical demands in nursing homes—and associated costs—can be substantially reduced [through an ergonomics process]. (Nursing Home Guidelines at 6.)

OSHA's continuing reliance on "equipment" and "work practices" as a panacea for reducing the "risk of injury" is unsupported by the science. NAS, among others, has rejected the notion that employers can effectively address MSDs through simple physical modifications of the workplace. "Interventions" such as equipment and work practices, according to NAS, may influence "pain reports" and result in the "amelioration of symptoms," but NAS was unwilling to find that such measures could prevent "specifically defined disorders." *Id.* at 459.

The Guidelines, like the now-rejected standard, see 65 Fed. Reg. 68598-744 (Nov. 14, 2000), rest their effectiveness claims upon anecdotal evidence. These reports have none of the methodological protections of scientific studies, creating textbook examples of biases such as "Hawthorne effect." See generally Examination of Selected References Supporting OSHA's Proposed Ergonomics Program, OSHA Docket No. S-777, Ex. No. 32-241-3-7. Although unverified, unscientific "success story" claims are commonplace, the effectiveness of comprehensive workplace modifications has not been demonstrated in a single well-designed trial. See, e.g., Linton, SJ, van Tulder, MW, Preventative

Interventions for Back and Neck Problems: What Is the Evidence?, Spine 2001 26:778-787 (Apr. 1, 2001); Lincoln, et al., Interventions for the Primary Prevention of Work-Related Carpal Tunnel Syndrome, American J. of Preventative Medicine, 18 (4 Supp.) 37-50 (2000).

Nature of the Complaint

The IQA requires agencies to ensure and maximize the "quality, objectivity, utility, and integrity of information . . . disseminated by the agency." IQA § 515(b)(2)(A). It also authorizes affected parties to "seek and obtain correction of information maintained and disseminated by the agency that does not comply." *Id.*, § 515(b)(2)(B). The Poultry, Grocery, and Nursing Home Guidelines fall far short of IQA compliance.

The core "quality" principles of the IQA are "objectivity," "utility," and "integrity." Id. § 515(b)(2)(A); see also 67 Fed. Reg. at 8459. The most exacting standards arise from the "objectivity" principle, which requires, among other things, that information be accurate, clear, complete, and unbiased, with sources clearly identified so that their reliability can be assessed by the public. Id.

The IQA, moreover, imposes particularly high standards upon the dissemination of "influential" information. "Influential' means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." 67 Fed. Reg. at 8460; DOL Guidelines at 15. The Poultry, Grocery, and Nursing Home Guidelines indisputably constitute "influential" information for IQA purposes. OSHA's own website describes the guidelines as a "major component of OSHA's four-pronged approach to ergonomics," http://www.osha.gov/SLTC/ergonomics/guidelines.html, intended to "reduce injuries and illnesses related to MSDs," http://www.osha.gov/SLTC/ergonomics/faqs.html. The noticeand-comment and stakeholder meeting process employed for all three documents speaks volumes about the importance of the guidelines and their intended impact on the private sector. See OSHA Protocol for Developing Industry-Specific and Task-Specific Ergonomics Guidelines (http://www.osha.gov/SLTC/ergonomics/protocol.html). Influential releases of information are subject to "stricter quality standards," 67 Fed. Reg. at 8455, including "a high degree of transparency," id. at 8460, and a more exacting level of "quality control and review," DOL Guidelines at 5.

In the specific context of "analysis of risks to human health, safety, or the environment," the objectivity requirement must be satisfied by "adopt[ing] or adapt[ing]" following standards set forth in the Safe Drinking Water Act Amendments of 1996:

- (3) Risk assessment, management, and communication. -
 - (A) Use of science in decisionmaking. In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use -

- (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and
- (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).
- (B) Public information. In carrying out this section, the Administrator shall ensure that the presentation of information on public health effects is comprehensive, informative, and understandable. The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable -
 - (i) each population addressed by any estimate of public health effects;
 - (ii) the expected risk or central estimate of risk for the specific populations;
 - (iii) each appropriate upper-bound or lower-bound estimate of risk;
 - (iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and
 - (v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.

42 U.S.C. 300g-1(b)(3)(A) & (B) (incorporated by reference in 67 Fed. Reg. at 8459). The Department of Labor chose to "adapt" these principles, committing, among other things, to "use... the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor ("DOL Guidelines") at 15 (Oct. 1, 2002).

The Guidelines fall woefully short of OSHA's obligations under the IQA. Indeed, they are not "objective" at all. Although the guidelines address a contentious subject on which, by the agency's own admission, there is a "lack of consensus," *supra* pp. 7-8, they present only one side of the debate—the side that postulates physical workplace factors as the cause of "injuries." They do so, moreover, with almost no reference to scientific research at all, much less "the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." *DOL Guidelines* at 15.

With respect to retail grocery operations, for example, the entirety of the "scientific" research relating to physical factors consists of one citation to the NIOSH Report and two individual articles: an eleven-year-old, unpublished, non-peer reviewed paper on hand and wrist "disorders" allegedly attributable to checkout scanners,² and a fifteen-year-old article tabulating questionnaire responses from supermarket cashiers.³ OSHA provides no specific citation from the 590-page NIOSH report to support the supposed conclusion that risk of injury depends on the "duration," "frequency," and "magnitude" of exposure to "risk factors," and a thorough search of that document reveals no such passage. NIOSH did state, however, that it was taking only "a first step in assessing the work-relatedness of MSDs," which did not include "quantitative risk estimates" that would have related measures of exposure to levels of risk; these were "beyond the purpose and scope of this document." NIOSH Report at 1-14. As for the two individual studies, neither had sufficient prominence or indicia of reliability to even qualify for consideration in NIOSH's subsequent, purportedly "comprehensive" review of the literature. Both employ an observational, cross-sectional research design that is incapable of supporting the "temporal association" conclusions that OSHA seeks to draw from them. See ACOEM, Occupational Medicine Practice Guidelines 2 (2d ed. 2004).

OSHA never considered more recent published research that raises serious questions about the connection between repetitive work activities and hand and wrist disorders such as carpal tunnel syndrome. See, e.g., Stevens, J., et al., The Frequency of Carpal Tunnel Syndrome in Computer Users at a Medical Facility, Neurology 2001; 56:1568-1570; Anderson J., et al., Computer Use and Carpal Tunnel Syndrome, JAMA 2003; 289: 2963-2969.⁴ Nor did it take into account the consensus of the 2001 National Academy of Sciences report, which conceded that ergonomic interventions have not been shown to "prevent carpal tunnel syndrome or, indeed, any other upper-extremity disorder." NAS Report at 459.

The Poultry Guidelines and Nursing Home Guidelines also limit their review almost exclusively to the NIOSH Report and the NAS Report. The NIOSH Report is cited for the sweeping proposition that "[e]xcessive exposure to . . . risk factors can result in a variety of disorders in affected workers," Poultry Guidelines at 5; Nursing Home Guidelines at 4, without any discussion of the research basis, qualifications, disclaimers, or other scientific considerations underlying that statement. Having been found inadequate to establish "significant risk" for purposes of a standard, the NIOSH Report certainly cannot

Kennedy, S. et al., 1992. "Prevalence of muscle-tendon and nerve compression disorders in the hand and wrist of a working population of grocery cashiers using laser scanners," Occupational and Environmental Disease Research Unit, University of British Columbia.

³ Ryan, G.A. "The prevalence of musculo-skeletal symptoms in supermarket workers," Ergonomics, 1989, Vol. 32, No. 4, 359-371.

⁴ The preeminent journals publishing this peer-reviewed research—JAMA and Neurology, among others—are far more authoritative than non-medical periodicals such as Ergonomics or unpublished, non-peer reviewed papers. OSHA's decision to rely upon the latter in the Guidelines, but not the former, cannot be defended under the IQA's quality standards.

support such a categorical claim in these documents. The NAS Report, on the other hand, is cited primarily for the purported definition of "MSD." Nursing Home Guidelines at 5. The citation is indisputably erroneous. See supra p. 5. NAS is also invoked in the Poultry Guidelines for the proposition that "[c]old temperatures in combination with [other] risk factors" are a heightened risk factor. Poultry Guidelines at 5. The NAS Report, however, only mentions a handful of low-quality cross sectional studies and calls for the inclusion of such "combinations" as "priorities for future studies" using more definitive "prospective" methodologies. NAS Report at 104.

The Poultry and Nursing Home Guidelines each cite only one individual scientific journal publication. In the Nursing Home Guidelines, the article is an unpublished non-peer reviewed study prepared by an industrial engineer with no medical background, which does not rely on any observation, identification, or diagnosis of "injuries" by qualified medical professionals.⁵ In the Poultry Guidelines, the only individual article is a 14-year-old review of conservative non-surgical treatment approaches for carpal tunnel syndrome, which reveals nothing about the causes of these conditions or how they may be prevented.⁶

OSHA has ignored very important recent developments in each of these industries. The Nursing Home Guidelines, for example, do not even mention a far more rigorous, randomized controlled trial which found that "[m]usculoskeletal injury rates were not significantly altered" by the mechanical devices and no-lift techniques advocated by OSHA. A. Yassi, J.E. Cooper, R.B. Tate, S. Gerlach, M. Muir, J. Trottier & K. Massey, "A Randomized Controlled Trial to Prevent Patient Lift and Transfer Injuries of Health Care Workers," Spine 26(16):1739-46 (2001). OSHA's abandonment of sound science becomes particularly apparent in its treatment of this study, for the article was cited in the draft Guidelines for a proposition it did not support. When the error was pointed out to OSHA during the public comment period, Docket No. GE2002-1, Ex. 4-36, at 6-7, the agency responded not by correcting its mistake, but rather by retaining the recommendation in its final document but removing all supporting references. Compare Nursing Home Guidelines at 19 with Draft Nursing Home Guidelines at 34. Sleight of hand is no substitute for rigorous scientific objectivity.

Relief Requested

NCE does not oppose OSHA's guidelines initiative; to the contrary, it strongly supports OSHA's decision to rely on voluntary guidelines in lieu of a standard. OSHA can provide a valuable service if it circulates accurate and appropriately qualified information on methods employers might adopt to enhance employee comfort, reduce fatigue, and improve efficiency. Perhaps, in some as yet unknown fashion, these best practices may

⁵ Garg, A. 1999. Long-Term Effectiveness of "Zero-Lift Program" in Seven Nursing Homes and One Hospital. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, Cincinnati, OH. August. Contract No. U60/CCU512089-02.

⁶ Kaplan, S.J. Glickel, S.Z. Eaton, R.G. Predictive Factors in the Non-Surgical Treatment of Carpal Tunnel Syndrome. The Journal of Hand Surgery. February, 1990. Vol. 15-B, No. 1.

have a positive impact on pathoanatomic injury or at least complaints and symptoms related to the performance of physical labor. OSHA's purported goals are hindered rather than helped, however, if the Guidelines are divorced from scientific support, thereby overselling their impact on presumptively hazardous employee working conditions.

Anecdotal "success stories" may appear to support investments in expensive ergonomics programs that emphasize mechanical devices and attempts to "eliminate" manual lifting. Broader experience, however, does not bear out claims that such investments will pay off in injury rate reductions. See, e.g., OSHA Docket No. S-777, Ex. 32-185-3, at 3-1 (data submitted by the United Auto Workers, showing that injury rates in the automobile industry have more than tripled since ergonomics programs were first instituted in the late 1980s). The very latest research findings, employing more rigorous study methodologies including randomized controlled trials, are showing that these traditional approaches are not effective in reducing injuries. See, e.g., A. Yassi et al., supra p. 13. 7

Unrealistic expectations created by the Guidelines, moreover, may have serious negative consequences. Employees will be encouraged to medicalize sensations of discomfort—and to inappropriately blame work tasks or equipment—resulting in unnecessary disability, diminution or interruption of income, and other consequences that ergonomic controls will be unable to cure. See OSHA Docket No. S-777, Ex. 32-241-3-7 (testimony of Arthur J. Barsky, M.D., Harvard University). Employers also may feel compelled to divert limited resources from important safety and health initiatives or other productive, employee-friendly purposes to formal ergonomics programs that will not achieve their intended purpose.

It is essential, therefore, for OSHA to revise the Poultry, Grocery, and Nursing Home Guidelines to appropriately and prominently acknowledge scientific uncertainty. The IQA demands no less. Theories, anecdotes, and suggested interventions can still be presented, but these must be accompanied with unambiguous disclaimers that clearly communicate the uncertain state of the science. Given current research, the agency can do little more than encourage the examination of these best practices, which may ameliorate discomfort, make the job less exerting, and, according to the NAS definition of "MSD," promote a sense of well-being. To oversell these guidelines as a means of eliminating the risk factors for anatomic injury is to misrepresent and ignore peer-reviewed, evidence-

The zeal of the ergonomics advocates who often generate or circulate "success stories" can lead to major distortions of fact. The Draft Grocery Guidelines, for example, claimed that Lucky Stores had "reduced injuries by 55% by implementing a proactive safety program in which ergonomics was a primary component." Draft Grocery Guidelines at 5. The supporting exhibit, however, was a brief 1992 newsletter article describing a general "safety program," which the employer credited for reducing "accident frequency" by 55 percent. Notwithstanding the reduction in "accidents," the article revealed that "since implementation of the program, workers compensation claims at Lucky for cumulative trauma disorders have doubled." Docket No. GE2003-1, Ex. 2-5: Although this specific example was removed from the final Grocery Guidelines after it was brought to OSHA's attention in comments from NCE members, it illustrates the danger inherent in any anecdotes gathered from sources such as press accounts, e.g., Grocery Guidelines at 12 n.13, or employer emails, id at 6 n. 5. Such citations are the antithesis of the IQA's "objectivity," "integrity," and "quality" requirements.

based science, which the IQA demands before these guidelines can be disseminated in their present form.

Detailed, constructive suggestions as to how OSHA may bring the Guidelines into compliance with the IQA were submitted during the public comment periods for all three documents. See Docket No. GE2002-1, Ex. 4-36 (comments of the National Association of Manufacturers on the Draft Nursing Home Guidelines); Docket No. GE2003-1, Ex. 3-16 (comments of the U.S. Chamber of Commerce on the Draft Grocery Guidelines); Docket No. GE2003-2, Ex. 3-5 (comments of the National Association of Manufacturers on the Draft Poultry Guidelines). Although the IQA does not mandate the precise language suggested by these commenters, it does require OSHA to fully and honestly disclose scientific uncertainty in a manner similar to these suggestions.

NCE, therefore, respectfully urges OSHA to withdraw and reconsider the Poultry, Grocery, and Nursing Home Guidelines, including appropriate acknowledgements of scientific uncertainty sufficient to bring them into compliance with the IQA.

Sincerely,

(Name removed)

Co-Chair National Coalition on Ergonomics

(Name removed)



Co-Chair National Coalition on Ergonomics

cc: Dr. John D. Graham

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(Names and signatures have been removed in order to protect the privacy of the individuals submitting the complaint.)