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The Outcomes, Economics, and Ethics of the Workplace Wellness Industry

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-SYMPOSIUM-

THE OUTCOMES, ECONOMICS AND ETHICS OF THE WORKPLACE WELLNESS INDUSTRY

Al Lewis +++

Abstract

On its surface, who can argue with the concept of workplace wellness? How could there be anything wrong with corporations helping their employees reduce their risk of disease while saving money in the process?

What turns out to be wrong with the implied answer to this rhetorical question, as this essay will show, is that it is completely incorrect. Wellness programs have conferred no measurable benefit on the American workforce. Further, vendors routinely disregard clinical guidelines that are designed to avoid overtreatment, inappropriate doctor visits, and increasingly ubiquitous crash-dieting contests.

The economics follow the harms. Essentially every dollar companies spend on vendor-administered workplace-wellness programs is lost.² As a result, much of the wellness-vendor community has resorted to making demonstrably false claims about savings in order to maintain its revenue stream.³

These results—or lack thereof—might be acceptable if employees liked wellness programs. Certainly, employers spend money on programs without quantifiable benefits specifically because employees like them, such as holiday parties and field days. Wellness programs, however, are not

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Each company named in this article has been given multiple chances to rebut, clarify or retract, publicly or privately. All except Wellsteps declined. (Wellsteps' rebuttal is in the article.) In particular, the relevant employees of WatsonHealth (IBM), United Healthcare, McKesson, British Petroleum, and the Boise School District declined to respond to direct email requests to offer their viewpoints on the materials specific to their organizations.

Al Lewis, Part 3 of the Proof Wellness Doesn't Work, THEY SAID WHAT? (Nov. 5, 2015), https://theysaidwhat.net/2015/11/05/part-3-of-the-proof-wellness-doesnt-work/ (showing that there has been no reduction in hospital admissions and no net reduction in employer-paid costs for diseases or events associated with poor cardiometabolic health, such as heart attacks and diabetes-related events).

^{2.} Id.

^{3.} See ZOE CONSULTING, INc., *infra* note 197.

programs that employees like.⁴ Quite the contrary, to convince employees to participate in wellness programs, employers must threaten them with financial forfeitures, such as fines, foregone incentives, or even losing their health benefits, for refusing to submit to wellness programs.⁵ These forfeitures are a major source of what sponsoring organizations assert are savings.⁶

Wellness is the only segment of the three-trillion-dollar healthcare industry, other than childhood vaccinations, in which patients are effectively required to access healthcare services whether or not they want to do so. Employers are allowed to withhold or reclaim large sums of money from employees who refuse to submit to healthcare services, creating a moral hazard in which the programs that are most unappealing to employees are the most profitable for employers. It is also the only segment of the healthcare industry without oversight that mandates provider licensure, education, training, certification, or continuing education. Further, wellness programs are not required to comply with clinical guidelines.

Guidelines for wellness programs do exist, though. The United States Preventive Services Task Force ("USPSTF"), a panel of experts on preventive and evidence-based medicine, provides health-related recommendations based on peer-reviewed studies and issues guidelines for how to appropriately provide medical care to patients. The wellness industry should be subject to regulations that require vendors to disclose to employers if any components of their programs do not comply with the guidelines that the USPSTF promulgates, and to give employees the choice to opt out of non-compliant components without subjecting them to forfeitures. Otherwise, employees may not realize that these programs have the potential to be harmful. Requiring vendors to disclose to employers their non-adherence to clinical guidelines would help address

^{4.} See Natasha Singer, Health Plan Penalty Ends at Penn State, N.Y. TIMES (Sept. 18, 2013), http://www.nytimes.com/2013/09/19/business/after-uproar-penn-state-suspends-penalty-fee-in-wellness-plan.html.

^{5.} EEOC v. Flambeau, Inc., 131 F. Supp. 3d 849, 854 (2015).

See, e.g., Rahul K. Parikh, Do Workplace Wellness Programs Work?, L.A. TIMES (Sept. 15, 2013), http://articles.latimes.com/2013/sep/15/opinion/la-oe-parikhemployee-wellness-programs-20130912 (providing an example of a vendor that proposes this source of savings); Al Lewis, Bravo Wellness Offers "Savings" by Fining Employees, THEY SAID WHAT? (Jan. 9, 2015), https://theysaidwhat.net/2015/02/09/bravo-wellness-offers-savings-by-fining-employees/.

^{7.} See Wellness & Health Promotion Certification, NCQA, http://www.ncqa.org/programs/certification/whp-certification (last visited Apr. 1, 2017) (offering a non-governmental wellness promotion certification).

^{8.} Id.

About the USPSTF, U.S. PREVENTIVE SERVS. TASK FORCE (Oct. 2016), https://www.uspreventiveservicestaskforce.org/Page/Name/about-the-uspstf.

the industry's innumeracy, ethical lapses, and data falsification, as such disclosures would make employers more likely to question the vendors' highly controversial claims that their programs lead to health improvement and savings. ¹⁰ Absent regulations, a simple civil remedy could arise from vendors' failure to adhere to voluntary, minimal standards enumerated in the Employee Health and Wellness Program Code of Conduct. ¹¹

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I. Introduction

Workplace wellness can be divided into two distinct components for the purposes of this article—wellness done *for* employees and wellness done *to* employees. Wellness done for employees includes perks: better or locally sourced food in the cafeteria, subsidized gym memberships, unlimited vacation days, free physician house calls, and on-site clinics or

^{10.} See, e.g., Sharon Begley, Top Wellness Award Goes to Workplace Where Many Health Measures Got Worse, STATNEWS (Sept. 27, 2016), https://www.statnews.com/2016/09/27/workplace-wellness-award/.

^{11.} See The Employee Health and Wellness Program Code of Conduct, ETHICAL WELLNESS, www.ethicalwellness.org (last visited Apr. 1, 2017) [hereinafter Code of Conduct].

spas. ¹² These perks are often a significant part of employers' recruiting efforts. ¹³ Wellness done for employees does not include initiatives that require annual medical tests, fines, or penalties. Because wellness done for employees is voluntary, it creates no significant medico-legal or regulatory concerns. Wellness done *for* employees is not the subject of this article. Instead, the subject of this essay is the second, distinctly different, component: wellness done *to* employees. This type of wellness is not a perk, because employees forfeit an average of \$670 per year for refusing to submit to their employers' programs' requirements. ¹⁴

A. Health Risk Assessments

One component of wellness done *to* employees is the health risk assessment ("HRA"). Half of employers with two hundred or more workers require that their employees complete an HRA.¹⁵ HRAs ask questions about an employee's diet, lifestyle, drinking habits, and drug use and typically assess an employee's risk for future health problems.¹⁶ HRAs ask invasive questions, forcing employees to disclose private health information.¹⁷ They also often provide incorrect, unclear, or inappropriate information to employees. Cerner, a wellness provider, produces an HRA that illustrates the problems surrounding HRA use.¹⁸ Its HRA suggests, for example, that an employee with a pulse pressure of 20 mmHg "talk to [his] healthcare provider to discuss ways to reduce this risk."¹⁹ Realistically, however, this employee would exist only in intensive care, because a pulse pressure of 20 mmHg signals a serious cardiovascular event.²⁰ The author tested Cerner's HRA using a hypothetical light drinker who reports taking Ambien nightly;

- 12. Abigail Thorpe, *The 44 Healthiest Companies to Work for in America*, Greatist (Oct. 27, 2015), http://greatist.com/health/healthiest-companies.
- 13. See, e.g., The Daily Muse Editor, Healthy at Work: 7 Corporate Wellness Perks We Love, The Muse, https://www.themuse.com/advice/healthy-at-work-7-corporate-wellness-perks-we-love (last visited Apr. 1, 2017).
- Ed Emerman, Companies Are Spending More on Corporate Wellness Programs but Employees Are Leaving Millions on the Table, NAT'L BUS. GROUP ON HEALTH (Mar. 26, 2015), https://www.businessgrouphealth.org/pressroom/pressRelease.cfm?ID=252.
- 15. KAISER FAMILY FOUND., 2015 EMPLOYER HEALTH BENEFITS SURVEY 196 (2015).
- 16. Id. at 196-97.
- 17. See Singer, supra note 4.
- See, e.g., Workforce Health: Population health management for a healthy, happy and productive workplace, CERNER, https://www.cerner.com/solutions/employer (last visited Apr. 1, 2017).
- 19. Screenshot capturing this advice was on their brochure, which was discontinued following the observation that this advice was wrong. A screenshot of the original is available from the author.
- 20. Tansel Yildiran et al., Low Pulse Pressure as a Predictor of Death, 37 Texas Heart Inst. J. 284, 284 (2010) (nothing that a pulse pressure of less than 30-mmHg was a high predictor of death).

the results are shown in Figure 1. The HRA assessed his risk for chronic health issues as both "moderate" and "high." ²¹ Using both terms creates confusion. The HRA results do not clarify how a "wellness score" differs from a score assessing "risk for chronic health issues." It also fails to explain why regular, well-tolerated, prescribed use of a standard dose of Ambien creates "HIGH risk for chronic health issues," especially absent any other high-risk factors, since there is no clear or even suggested causal link between Ambien use and chronic health problems. ²²



Figure 1. The results from Cerner's risk assessment of a light drinker who takes Ambien nightly. It asserts that such a person's risk is both "HIGH" and "Moderate."

Finally, the Cerner HRA advises employees to reduce their consumption of both dietary cholesterol and saturated fat, ²³ advice that the Office of Disease Prevention and Health Promotion's dietary guidelines directly contradict. ²⁴ Though whether saturated fat poses a health risk is controversial, ²⁵ Cerner's HRA presents its recommendation as though it is undisputedly true that people should reduce the amount of saturated fat in their diets. Further, advising people to consume less fat causes them to

- 21. See Wellness Management, CERNER, http://www.cerner.com/solutions/employers/wellness_management/ taken from author's own results; results on file with Author).
- U.S. FOOD & DRUG ADMIN., HIGHLIGHTS OF PRESCRIBING INFORMATION (AMBIEN) (1992), available
 at
 https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019908s038lbl.pd
 f.
- 23. HRA screenshot recommending this diet is available upon request to author.
- 24. Jen Christensen, *New Dietary Guidelines Limit Sugar, Rethink Cholesterol*, CNN (Jan. 7, 2016, 4:46 PM), http://www.cnn.com/2016/01/07/health/2015-dietary-guidelines/; U.S. Dep't Health & Human Serv. & U.S. Dep't Agriculture, 2015-2020 DIETARY GUIDELINES FOR AMERICANS (8th ed. 2015).
- 25. See, Kathleen Doheny, Saturated Fats Not So Bad? Not So Fast, Critics of New Analysis Say, WebMD (Mar. 20, 2014), http://www.webmd.com/heart-disease/news/20140320/dietary-fats-q-a; NINA TEICHOLZ, THE BIG FAT SURPRISE: WHY BUTTER, CHEESE AND MEAT BELONG IN A HEALTHY DIET (2014).

substitute foods high in sugar, which increases the risk of diabetes.²⁶ As a result, Cerner's advice may actually increase risk, rather than reducing it.

HRAs also omit advice that they should include. For example, virtually no HRA advises a sixty-year-old employee with a history of chicken pox to discuss a shingles vaccine with a doctor.²⁷ Also, while HRAs place major emphasis on buckling seatbelts, virtually no HRA cautions against texting while driving.²⁸ In both situations, the hazard is real and avoidable, but the risk of the latter, though well-established, is not well-understood in the employee population.

B. Biometric Screening

Another component of wellness done to employees is biometric screening. In some cases, to avoid a forfeiture, employees must attend a health fair at which their blood is drawn and they are given a lab report showing whether their cholesterol, glucose, or another blood value is out of the expected range.²⁹ Roughly half of employers with more than two hundred employees require employees to participate in these health fairs or screenings to avoid forfeiture. 30 Biometric screenings are not inherently problematic, and in fact would likely be beneficial if done according to the USPSTF's specifications. The USPSTF provides screening guidelines that are designed to balance the benefits of early detection with the potential harmful effects of false positives. 31 These guidelines state that the "optimal interval for screening is uncertain" for males over thirty-five and females over forty-five. Historically, the USPSTF guidelines recommended blood screenings every five years for people who are not at risk for heart disease or diabetes, and at more frequent intervals for people who are at risk for heart disease or diabetes ("at risk").32 For younger employees, the

- 26. See Kris Gunnars, 7 Ways the Low-Fat Diet Can Harm Your Health, AUTHORITY NUTRITION, https://authoritynutrition.com/7-ways-the-low-fat-diet-destroys-your-health/ (last visited Apr. 1, 2017) (listing ways in which reducing fat can adversely impact health).
- 27. The author, who has reviewed more than 50 HRAs, is unaware of any HRA advising a 60-year-old who had chicken pox to discuss a shingles vaccine with a doctor.
- 28. The author, who has reviewed more than 50 HRAs, is unaware of any HRA advising not to text while driving.
- L.V. Anderson, Workplace Wellness Programs are a Sham, SLATE (Sept. 2, 2016), http://www.slate.com/articles/health_and_science/the_ladder/2016/09/workpl ace_wellness_programs_are_a_sham.html.
- 30. Kaiser Family Found., supra note 15, at 198.
- See Published Recommendations, U.S. PREVENTIVE SERVS. TASK FORCE (Apr. 2017), https://www.uspreventiveservicestaskforce.org/BrowseRec/Index/browse-recommendations.
- 32. See Lipid Disorders in Adults (Cholesterol, Dyslipidemia): Screening, U.S. PREVENTIVE SERVS. TASK FORCE (Dec. 2014) [hereinafter Lipid Disorders in Adults], https://www.uspreventiveservicestaskforce.org/Page/Document/Recommendat ionStatementFinal/lipid-disorders-in-adults-cholesterol-dyslipidemia-screening.

guidelines have historically recommended blood screenings only for those who are at risk.³³ Many health-maintenance organizations recommend screening every four to six years or recommend screening intervals that depend on a person's risk for disease.³⁴ Vendors, however, routinely flout these guidelines and ignore risk and age considerations. Instead, they screen everyone annually.³⁵ Some vendors also screen for markers for which the USPSTF recommends against screening for, due to the potential harms arising from false positives.³⁶ Additionally, many wellness programs require an annual checkup,³⁷ though research overwhelmingly concludes that annual checkups are more likely to harm than benefit employees.³⁸

C. Weight-loss contests

Finally, there is the crash-dieting component. This component of wellness programs takes the form of biggest-loser contests or weight-loss challenges and involves weigh-ins over a short period of time.³⁹ Putting money at stake can encourage very unhealthy forms of cheating to ensure

- 33. USPSTF A and B Recommendations, U.S. PREVENTIVE SERV. TASK FORCE (June 2016), https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/ (listing optimal screening guidelines); see also Health Checkups: When you need them—and when you don't, Choosing Wisely, http://www.choosingwisely.org/patient-resources/health-checkups/ (last visited Apr. 1, 2017) (providing a lay version of USPSTF screening guidelines).
- 34. When to Have a Cholesterol Test Topic Overview, WEBMD, http://www.webmd.com/cholesterol-management/tc/when-to-have-a-cholesterol-test-topic-overview (last visited Apr. 1, 2017).
- 35. Bryce Williams, *The Big Wellness Question: To Test or not to Test*, EMP. BENEFIT NEWS (Feb. 1, 2016), http://www.benefitnews.com/opinion/wellness-wars-screening-for-risk-vs-over-testing.
- 36. Al Lewis, *Total Wellness Presents the Best Argument for Regulating the Wellness Industry*, They Said What? (Oct. 18, 2015), https://theysaidwhat.net/2015/10/18/total-wellness-presents-the-best-argument-for-wellness-industry-regulation/.
- 37. See, e.g., Wellness Program, New Orleans (Oct. 3, 2016, 1:39 PM), http://www.nola.gov/health-plan/wellness-program/; State Health Benefits Program Retiree Wellness Program Annual Physician Certification, Horizon Blue Cross Blue Shield of New Jersey, available at http://www.state.nj.us/treasury/pensions/pdf/hb/horizon-wellness-cert.pdf (last visited Apr. 1, 2017).
- Nadia Kounang, Do Annual Checkups Do More Harm than Good?, CNN (Oct. 15, 2015), http://www.cnn.com/2015/10/16/health/annual-physical-unnecessary/;
 Lasse T. Krogsbøll et al., General Health Checks in Adults for Reducing Morbidity and Mortality From Disease, 23 J. Am. MED. Assoc. 2489 (2013).
- See, e.g., Katerina, Corporate weight loss challenge, MY DIET & WEGHT [sic] Loss (May 18, 2015), http://mydiet-weightloss.blogspot.com/2015/05/corporate-weight-loss-challenge.html; Al Lewis, Wellness Corporate Solutions Gives Us a Dose of Much-Needed Criticism, They Said What? (Feb. 13, 2017), https://theysaidwhat.net/2015/02/13/wellness-corporate-solutions-gives-us-a-dose-of-much-needed-criticism/.

success in the short run,⁴⁰ while new research confirms the harms of repeated weight-cycling, or "yo-yo dieting," in the long run.⁴¹

II. The History of Wellness

Workplace wellness programs have existed for several decades. ⁴² As a result, most of the studies cited in recent literature that show favorable outcomes from workplace wellness programs are outdated. ⁴³ Wellness programs became much more prominent when Congress passed the Patient Protection and Affordable Care Act ("ACA"), which contains a wellness provision informally known as the Safeway Amendment that permits employers to make thirty percent of non-smokers' total healthcare premiums—and fifty percent of smokers' premiums—contingent on their adopting healthy behaviors or on outcomes such as weight loss and smoking cessation. ⁴⁴ Under the Safeway Amendment, non-adherent employees pay a much higher percentage of their premiums, while employers, ironically, save money on insurance in direct proportion to the number of employees either refusing to participate or, in the case of outcomes-based programs, who are unable to lose weight or stop smoking.

There is no formal legislative history that describes deliberations about the Safeway Amendment or documents introduced in support of or in opposition to it because Congress did not debate it.⁴⁵ There are two main economic explanations that the Safeway Amendments' supporters use to justify the ACA's support for workplace-wellness.

^{40.} See Biggest Loser Competition? Here's how to WIN!!, HEALTH STATUS, https://www.healthstatus.com/health_blog/body-fat-calculator-2/biggest-loser-competition-win/ (last visited Apr. 1, 2017); see, e.g., Al Lewis, Schlumberger's program confirms that in wellness, harming employees is the new black, THEY SAID WHAT? (Jan. 23, 2017), https://theysaidwhat.net/2017/01/23/schlumbergers-program-confirms-that-in-wellness-harming-employees-is-the-new-black/ (noting that Schlumberger and other energy companies charge as much as \$10,000 for a team of five).

^{41.} See Honor Whiteman, Yo-yo dieting may raise death risk for people with heart disease, Med. News Today (Apr. 6, 2017), http://www.medicalnewstoday.com/articles/316778.php.

^{42.} Michael Rucker, *The Interesting History of Workplace Wellness*, MICHAELRUCKER.COM (May 20, 2016), http://michaelrucker.com/workplace-wellness/the-history-of-workplace-wellness/.

^{43.} See, e.g., Baicker et al., Workplace Wellness Programs Can Generate Savings, 29 HEALTH AFF. 304, 311 (citing several studies that may be out of date).

^{44.} Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 Fed. Reg. 33159 (June 3, 2013) (to be codified at 45 C.F.R. pt. 146 and 147).

^{45.} See generally John Cannan, A Legislative History of the Affordable Care Act: How Legislative Procedure Shapes Legislative History, 105 L. LIBRARY J. 131 (2013).

A. Congress's Justification: Safeway's Wellness Program

Safeway's allegation that it reduced spending on healthcare by forty percent through its wellness program is the first justification for the ACA's wellness provision. Safeway's corporate wellness program was so prominent and unique that the ACA's wellness provision is referred to as the Safeway Amendment. No one appears to have challenged Safeway's reduced-spending claim in the media, even after the *Washington Post* revealed, two months prior to the ACA vote, that Safeway did not actually have a wellness program in place during the period in which this alleged reduction in corporate healthcare spending occurred. Nearly beauthcare spending to a program that did not exist.

B. Post-hoc Justification: The "Harvard Study"

The second justification for the ACA's support for wellness programs was a meta-analysis that three Harvard researchers completed ("Harvard Study")."⁴⁹ The Harvard Study claims to have found that wellness programs result in a 3.27-to-1 return-on-investment ("ROI") from reduced healthcare spending.⁵⁰ This study suffers from a number of problems, including an author's conflict of interest and underlying issues with the studies on which it relies. Despite its many problems, this study has become a touchstone for almost all wellness-vendor websites and has been cited over six hundred times in formal academic literature alone.⁵¹ In contrast, a subsequent *Health Affairs* study that showed that wellness programs do not result in savings received only fourteen citations and no mentions on any vendor website.⁵²

David Cutler, a Harvard professor and a co-author of the Harvard Study, was a healthcare adviser to President Obama during the push for the ACA's

- 49. Baicker et al., supra note 43, at 308-09.
- 50. Id. at 309.
- 51. See Id.

^{46.} Stephen A. Burd, *How Safeway Is Cutting Health-Care Costs*, WALL ST. J. (June 12, 2009), http://www.wsj.com/articles/SB124476804026308603.

^{47.} Chelsea Reynolds, Myths Surround Reform's 'Safeway Amendment', Ass'N OF HEALTHCARE JOURNALISTS (Jan. 20, 2010), http://healthjournalism.org/blog/2010/01/myth-surrounds-reforms-safeway-amendment/.

^{48.} David Hilzenrath, *Misleading Claims about Safeway Wellness Incentives Shape Health Care Bill*, WASH. POST (Jan. 20, 2010), http://www.washingtonpost.com/wp-dyn/content/article/2010/01/15/AR2010011503319.html.

^{52.} See Gautam Gowrisankaran et al., A Hospital System's Wellness Program Linked to Health Plan Enrollment Cut Hospitalizations but Not Overall Costs, 32 HEALTH AFF. 477 (2013) (finding that participation in a wellness program decreased hospitalizations but did not save employers).

passage.⁵³ After Cutler expressed support for the ACA as President Obama's adviser and after disclosing only his Harvard affiliation, he co-authored the Harvard Study, which provides economic support for the wellness provision of the ACA.⁵⁴ In the years following the Harvard Study's publication, both lead authors have consistently claimed that they are uninterested in the wellness industry and none of the authors has ever defended the study's findings.⁵⁵

Katherine Baicker, the study's other lead author, stated that readers should pay more attention to the study's limitations, ⁵⁶ and has wavered on the study's conclusion several times. ⁵⁷ For example, initially, she calculated savings attributed to wellness programs' successes to two significant digits, conveying certainty in the study's findings. ⁵⁸ After publication, however, she stated that it was "too early to tell" whether wellness programs work and that employers need to "experiment" on their employees. ⁵⁹ Later, she again qualified the Harvard Study's conclusion when she provided additional reasons why the study should not be taken at face value: ⁶⁰

- 1. the study cannot be generalized, especially to smaller employers, since the component studies were all based on very large employers;
- 2. only companies that believed that these programs would be successful would undertake them, creating self-selection bias; and

- 54. *Id*.
- 55. Paul Carroll, Editor's Note: A Step in the Evolution of ITL, INS. THOUGHT LEADERSHIP (Mar. 3, 2014), http://insurancethoughtleadership.com/editorsnotes/a-step-in-the-evolution-of-itl-2/#axzz2yawgiWgx.
- Frank Diamond, Wellness Debate Irrelevant for Insurers Eyeing the Market, MANAGED CARE (Feb. 2014), https://www.managedcaremag.com/archives/2014/2/wellness-debateirrelevant-insurers-eyeing-market.
- Shannon Mullen, Can Your Boss Fine You for Not Disclosing Your Weight?, MARKETPLACE (July 22, 2013), http://www.marketplace.org/2013/07/22/health-care/can-your-boss-fine-you-not-disclosing-your-weight/; Diamond, supra note 56; Julie Rovner, Wellness at Work Often Comes with Strings Attached, NPR (Dec. 11, 2014), http://www.npr.org/sections/health-shots/2014/12/09/369352885/wellness-at-work-often-comes-with-strings-attached.
- 58. Baicker et al., supra note 43, at 304 (calculating a 3.27-to-1 ROI; the two digits to the right of the decimal point are called "significant digits," which signifies the author's conclusion of accuracy to somewhere between 3.265-to-1 and 3.275-to-1).
- 59. Mullen, supra note 57.
- 60. Diamond, supra note 56.

^{53.} Biography: David M. Cutler, HARV. UNIV., https://scholar.harvard.edu/cutler/biocv (last visited Apr. 1, 2017).

3. only companies that believed that these programs worked for them would allow their results to be published, creating publication bias.

Baicker also admitted that "there are few studies with reliable data on both the costs and the benefits" of wellness. ⁶¹ She did not name any of the "few studies with reliable data," and the actual studies comprising this meta-analysis are mostly obsolete; the underlying studies were published during the twentieth century, an era in which preventable heart attacks were far more common than they are now. ⁶² Almost all were authored or co-authored by wellness vendors or consultants. ⁶³ None were published in journals that had ever previously published articles critical of wellness. ⁶⁴ It is therefore possible that wellness vendors' and consultants' involvement in the underlying studies created investigator bias or publication bias, potentially affecting the studies' validity. Most importantly, at least four component studies ⁶⁵ reached conclusions that could not pass peer review today because they are not supported—and are even arguably invalidated—by the evidence they present. ⁶⁶

The first study shows that people who were previously at high risk for chronic disease declined in risk more than low-risk people between the first measurement of risk and the follow-up measurement.⁶⁷ It shows, for

- 61. Rovner, supra note 57.
- 62. See Baicker et al., supra note 43, at Appendix, Table 1; Healthcare Cost and Utilization Project, U.S. DEP'T HEALTH & HUMAN SERV. (Feb. 2017) [hereinafter HCUP], http://hcupnet.ahrq.gov/HCUPnet.jsp?Id=45755C20A787AFBF&Form=DispTab&J S=Y&Action=%3E%3ENext%3E%3E&__inDispTab=Yes&_Results=Print&SortOpt= (noting that the number of heart attacks (diagnosis code: ICD-9 410) in the privately insured working age population has fallen from 226,000 in 1997 (the first year for which statistics are available) to 153,000 in 2013 (the last year for which statistics are available)).
- 63. See, e.g., Baicker et al., supra note 43, at Appendix (showing the first study in the appendix was co-authored by Ron Goetzel, the second was authored by Steve Aldana, CEO of Wellsteps (see infra note 164), the third was authored by Ron Ozminkowski, a senior executive in United Healthcare's wellness subsidiary).
- 64. A 10-year scan of database abstracts in *Journal of Occupational and Environmental Medicine* and *American Journal of Health Promotion* revealed only two, one of which appears to have been accidental. Siyan Baxter et al., *The Relationship between Return on Investment and Quality of Study Methodology in Workplace Health Promotion Programs*, 28 Am. J. Health Promot. 347 (July 2014) (showing a negative ROI from high-quality studies). *But see* Michael P. O'Donnell, *What is the ROI for Workplace Health Promotion? It Really Does Depend, and That's the Point*, 29 Am. J. Health Prom. V (2015) (explaining that Baxter et al.'s conclusion was not intended).
- 65. These four studies were examined because they did not require payment for access; the other twenty-four required payment for access.
- 66. See generally, supra notes 52-58.
- 67. Leiyu Shi, Health Promotion, Medical Care Use, and Costs in a Sample of Worksite Employees, 17 EVALUATION REV. 475 (1993).

example, that people with a lot of weight to lose lost more weight than people who had less weight or no weight to lose. People with high cholesterol were more likely to show declines in their cholesterol levels than people without high cholesterol.⁶⁸ The study attributed this decline in risk to the screening-and-coaching intervention, an intervention through which screeners hunt for risk factors and then refer employees with risk factors to coaches to help them reduce the risk factors.⁶⁹ The problem, however, with attributing the greater decline in risk factors among high-risk people to the intervention is that low-risk people cannot reduce risk, but high-risk people can. Smokers can stop smoking, but non-smokers cannot. Overweight people can lose weight, but thin people cannot or should not. The relatively greater decline in risk in a high-risk population when compared to against a low-risk population is called the natural flow of risk and would not be attributable to a wellness program.⁷⁰

The second study, published in 1998, put participants who were at risk for heart disease on a low-fat diet, which, at the time, was incorrectly considered a heart-healthy diet.⁷¹ There was no meaningful risk reduction.⁷² The study's authors claimed that the program produced immediate, substantial savings, though their dietary advice was flawed and despite a documented lack of meaningful reduction in risk.⁷³

The third study claimed savings that could not be attributable to the program—made up of an HRA and annual cholesterol screenings—it studied. The savings could not be attributed to HRAs or annual cholesterol screenings because HRAs and cholesterol screenings do not affect the categories of disease in which savings were claimed. The study claimed HRAs and annual cholesterol screenings had led to improvements in "diseases of the blood and blood-forming organs," including sideropenic dysphagia, lymphangioma, von Willebrand Disease, and cat-scratch fever. Answering questions and reducing cholesterol would not prevent any of those diseases.

- 68. Id.
- 69. Id.
- 70. DEE W. EDINGTON, UNIV. MICH. HEALTH MGMT. RESEARCH CTR., LOST PRODUCTIVITY: THE HIGH COST OF DOING NOTHING (2006), available at http://webcache.googleusercontent.com/search?q=cache:DGUr02kp1p0J:www.umich.edu/~hmrc/research/pdf/printableresearchslides.pdf+&cd=1&hl=en&ct=c lnk&gl=us.
- See generally James F. Fries & Dennis McShane, Reducing Need and Demand for Medical Services in High-risk Persons: A Health Education Approach, 169 WEST J. MED. 201 (1998).
- 72. Id.
- 73. Id
- 74. Shirley A. Musich et al., Effectiveness of health promotion programs in moderating medical costs in the USA, 15 HEALTH PROMOT. INT'L 5 (2000).
- 75. Id.

The fourth study showed twenty-nine percent savings for participants when compared to non-participants. ⁷⁶ Several natural experiments show that the participant-versus-non-participant study design is invalid. ⁷⁷ Further, it is not possible to save twenty-nine percent on healthcare spending through wellness because wellness-sensitive medical admissions ("WSMAs") represent only about two percent of total spending. ⁷⁸

Additionally, the Harvard Study has not been replicated. The single attempt to confirm the Harvard Study's findings, a study that the wellness trade journal conducted, concluded that randomized control trials ("RCTs") studying wellness programs show negative returns on investment, directly contradicting the Harvard Study's conclusion.⁷⁹

III. The Politics of Wellness

For several years after the ACA passed, it was difficult to determine who benefited from the provision allowing employers to tie employees' health behavior and health outcomes to their healthcare premiums, especially since the economics of wellness do not support forcing non-compliant employees to pay substantially more for health insurance. Few, if any, of the twenty-five types of hospital admissions on which employers spend the most in aggregate could be avoided through the methods wellness programs promote, including HRAs, biometric screenings, additional checkups, or crash-dieting contests.⁸⁰

Even including diseases that are not diagnosed through mass screenings, such as heart failure and asthma, only seven to eight percent of all admissions are theoretically avoidable through a wellness or disease-management program.⁸¹ Simple math suggests that only a small percentage

- 40 J. OCCUPATIONAL & ENVTL. MED. 341 (1998).
- Al Lewis, Do Wellness Outcomes Reports Systematically and Dramatically Overstate Savings?, AJMC.com (Jan. 24, 2017) [hereinafter Wellness Outcomes], http://www.ajmc.com/contributor/al-lewis-jd/2017/01/do-wellness-outcomesreports-systematically-and-dramatically-overstate-savings.
- 78. Goetzel et al., supra note 76.
- 79. Baxter et al., supra note 64.
- 80. HCUP, supra note 62; see also Al Lewis, Chronic Disease in the Workplace: Are We Fighting the Wrong Battle?, AMJC.com (Feb. 16, 2016), http://www.ajmc.com/contributor/al-lewis-jd/2016/02/chronic-disease-in-the-workplace-are-we-fighting-the-wrong-battle (providing a table derived from the Healthcare Cost and Utilization Project listing these top 25 types of hospital admissions for the employer-insured population).
- 81. This percentage is derived from the number of admissions for the diagnosis codes in Fries & McShane, *supra* note 71, divided by the total number of admissions for the privately insured population, for 2013 (last full year available). The data source is available from HCUP, *supra* note 62. See also HEALTH ENHANCEMENT RESEARCH ORG. & POPULATION HEALTH ALLIANCE, PROGRAM MEASUREMENT AND EVALUATION GUIDE: CORE

^{76.} Ron Z. Goetzel et al., Health Care Costs of Worksite Health Promotion Participants and Non-Participants,

of that seven percent could be avoided if wellness actually worked, especially given employees' low rate of participation in wellness programs. Be Wellness proponent and industry leader Ron Goetzel, who directs Watson Health's wellness-consulting arm, has acknowledged that only one to two percent of risk, and therefore only one to two percent of that seven to eight percent of admissions and emergency-room visits, can be avoided after two to three years. The cost of avoiding that small percentage, as will be shown below, would overwhelm any savings from the avoided healthcare spending.

By process of elimination, the only economic justification remaining for wellness is the money that the Safeway Amendment permits employers to withhold. It essentially allows employers to take money from employees who refuse to submit to wellness or cannot lose sufficient weight in the form of forfeitures. Employees from lower socioeconomic strata are disproportionately the victims of this forfeiture. ⁸⁴

Because it takes two to three years for behavior changes to translate into risk reduction, even according to Goetzel, penalties are the only way to generate immediate cost savings.⁸⁵ This fact is not well-publicized. Bravo Wellness, the only vendor that has ever advertised penalties as source of savings on their website, removed the reference from their website following exposure of this reference by the author.⁸⁶

The political force behind the Safeway Amendment and the transfer of wealth from employees to employers via forfeitures was unclear for several years. But starting in 2013, the Business Roundtable ("BRT"), a public-policy group made up of high-level executives from major American corporations, ⁸⁷ began to publicly support wellness programs. ⁸⁸ In 2013, the

METRICS FOR EMPLOYEE HEALTH MANAGEMENT 22-23 (2015) (concurring that only seven to eight percent of all admissions are theoretically avoidable through a wellness or disease-management program).

- 82. See Soeren Mattke et al., RAND Corp., Workplace Wellness Programs Study: Final Report 8 (2013) (Reporting that "fewer than half" of employees complete the screening and HRAs, and of those completers invited into a wellness program, roughly 20% participate.).
- 83. Mark Taylor, *Do Workplace Wellness Programs Work?*, CHICAGO TRIBUNE (July 19, 2016, 8:41 AM), http://www.chicagotribune.com/lifestyles/health/sc-wellness-programs-health-0720-20160718-story.html.
- 84. Jill R. Horwitz et al., Wellness Incentives in The Workplace: Cost Savings Through Cost Shifting to Unhealthy Workers, 32 HEALTH AFF. 468 (2013).
- 85. Taylor, supra note 83.
- 86. See The Bravo Difference, Bravo Wellness (accessed July 10, 2016) (on file with author).
- 87. More Than Leaders: Leadership, Business Round Table, http://businessroundtable.org/about (last visited Apr. 1, 2017).
- 88. See Gary Loveman, Business Roundtable, Letter to the President on Pending Wellness Rule (May 2, 2013); See Sharon Begley, US CEOs Threaten to Pull Tacit Obamacare Support over "Wellness" Spat, Reuters (Nov. 29, 2014),

BRT lobbied for more corporate discretion over the rules governing the forfeitures and less oversight from the Equal Employment Opportunity Commission ("EEOC"). ⁸⁹ In 2014, the BRT lobbied President Obama directly, threatening to withdraw its support for the ACA if it constrained corporate control over forfeitures. ⁹⁰ In 2015, the BRT threatened to push for an Act of Congress to enshrine the ACA's wellness provisions if the EEOC continued to represent employees against wellness-program overreach. ⁹¹ The BRT also prevailed upon the Senate Health, Education, Labor, and Pensions Committee to hold a hearing about wellness programs called "Employer Wellness Programs: Better Health Outcomes and Lower Costs." ⁹² As the hearing title implies, the Senate did not invite skeptics of wellness programs' outcomes and savings claims to testify at this hearing. ⁹³

The BRT's counterparts at the United States Chamber of Commerce are also major supporters of wellness programs, as their 2016 report, *Winning with Wellness*, demonstrates.⁹⁴ This report includes quotations that misrepresent the views of the original authors. For example, RAND, a nonprofit public-policy consulting organization, stated that

[e]mployee participation in lifestyle management aspects of workplace wellness programs does not reduce healthcare utilization or cost regardless of whether we focus on higher-risk employees or those who are more engaged in the program. ⁹⁵

The United States Chamber of Commerce interpreted RAND's statement to mean: "There is solid evidence to be optimistic." ⁹⁶

The Chamber of Commerce report also quoted RAND as finding a "reduction of \$30 in healthcare costs per member per month, after seven years of continuous participation in either the lifestyle- or disease-

http://www.reuters.com/article/us-usa-healthcare-wellness-exclusive-idUSKCN0JD0AC20141129; Preserving Employee Wellness Programs Act, S. 620, 114th Cong. (2015).

- 89. See LOVEMAN, supra note 88.
- 90. Begley, supra note 88.
- 91. Preserving Employee Wellness Programs Act, S. 620, 114th Cong. (2015).
- 92. Employer Wellness Programs: Better Health Outcomes and Lower Costs: Before the Health, Education, Labor and Pensions Committee, 114TH CONG. (Jan. 29, 2015), available at https://www.help.senate.gov/hearings/employer-wellness-programs-better-health-outcomes-and-lower-costs.
- 93. See John Gizzi, Senate Health Panel Leaving Out Obamacare Opponents, NEWSMAX (Jan. 28, 2015), http://www.newsmax.com/US/senate-health-panel-obamacare/2015/01/28/id/621367/ (last visited Nov. 15, 2016).
- 94. U.S. CHAMBER OF COMMERCE, WINNING WITH WELLNESS (2016).
- 95. SOEREN MATTKE ET AL., RAND CORP., WORKPLACE WELLNESS PROGRAMS: SERVICES OFFERED, PARTICIPATION, AND INCENTIVES, at xvi (2014).
- 96. U.S. Chamber of Commerce, *supra* note 94, at 17.

management program."⁹⁷ It fails to acknowledge, however, that the RAND report qualified this finding by emphasizing that the thirty-dollar reduction was an average of two very different figures for two very different programs, and that when considering the cost of wellness programs without disease-management programs, lifestyle-management programs increased costs by about three dollars for every dollar saved.⁹⁸

In 2017, the American Benefits Council ("ABC") joined this group, and actively lobbied for H.R. 1313, the newer version of the Preserving Employee Wellness Programs Act. As will be described, this version would allow employers to collect DNA from employees and their dependents, including children, as part of workplace wellness.⁹⁹

As the above examples demonstrate, supporters of wellness programs are almost exclusively organizations and individuals that profit from them. On the other hand, unaffiliated economists and members of the media who have opined on wellness programs almost uniformly disparage them. RAND's conclusions, the *New York Times*-affiliated The Incidental Economist wrote: "We've said it before, many times and in many ways: workplace wellness programs don't save money." A *Los Angeles Times* business columnist called wellness a "scam" in 2014 and repeated this word, in the context of H.R. 1313 in March 2017.

- 97. Id. at 16.
- 98. John P. Caloyeras et al., Managing Manifest Diseases, But Not Health Risks, Saved PepsiCo Money Over Seven Years, 33 HEALTH AFF. 124, 128 (2014).
- 99. Andie Burjek, New Wellness Bill HR 1313 Gets Flak for Genetic Privacy Concerns, Workforce (Mar. 20, 2017), http://www.workforce.com/2017/03/20/new-wellness-bill-gets-flack-for-genetic-privacy-concerns/.
- 100. HEALTH ENHANCEMENT RESEARCH ORG. & POPULATION HEALTH ALLIANCE, PROGRAM MEASUREMENT AND EVALUATION GUIDE: CORE METRICS FOR EMPLOYEE HEALTH MANAGEMENT 3-4 (2015) [hereinafter HERO Guide].
- 101. See, e.g., Al Lewis & Vik Khanna, The Ten Worst Wellness Programs and What They Do to Harm Employees, Health Care Blog (Dec. 4, 2015), http://thehealthcareblog.com/blog/2015/12/04/the-ten-worst-wellness-programs-and-what-they-do-to-harm-employees/; Anderson, supra note 29; Judith Feder & Samuel R. Bagenstos, Beware: 'Wellness'' May be Hazardous to Your Health, Huffington Post (May 11, 2015), http://www.huffingtonpost.com/judith-feder/corporate-wellness-programs_b_6846350.html.
- 102. Austin Frakt, *Workplace wellness programs don't save money*, INCIDENTAL ECONOMIST (Dec. 2, 2014, 6:00 AM), http://theincidentaleconomist.com/wordpress/workplace-wellness-programs-dont-save-money/.
- 103. See Michael Hiltzik, Why 'wellness' program scams cost employers and harm employees, L.A. TIMES (Dec. 2, 2014), http://www.latimes.com/business/hiltzik/la-fi-mh-how-wellness-programs-cost-employers-and-harm-employees-20141202-column.html.
- 104. Michael Hiltzik, This Republican bill would let your employer demand access to your genetic information, L.A. TIMES (Mar. 14, 2017),

researcher wrote in *Harvard Business Review* that "in [their] quest to increase employee wellness . . . organizations are often unwittingly making things worse." ¹⁰⁵

As mentioned, RAND concludes that wellness loses more than three dollars for every dollar spent. At a conference on wellness at Case Western Reserve University in 2016, RAND's Soeren Mattke offered impromptu advice for his own employer, which still offers a wellness program: "RAND, to my chagrin, still has a wellness program. I keep telling them give me the \$150 [in vendor fees], that would make me a lot . . . happier . . . and [more] motivated, if you just give me the money and do away with the silly program." While wellness vendors presumably profit from wellness programs and forfeitures from non-participants, wellness done to employees has been a failure in outcomes, economics, and clinical impact. These three areas in which they fail have also created an environment in which major ethical lapses are necessary in order to sustain the industry revenue stream.

IV. The Proven Failure of Wellness: Outcomes, Economics, Clinical Impact, and Ethics

In a typical scientific debate, advocates of opposing viewpoints offer equally opposing scientific proofs based on their own investigations and their own data sets and then challenge the other side's data. In this debate, however, a proof that wellness programs fail need not rely on its own data set or on challenging industry data. Instead, the data the wellness industry provides in support of its programs invariably invalidates itself when read closely. 107

Rather than using a debatable scientific level of proof, most wellness programs' data can be invalidated using a dispositive mathematical level of proof. The difference, to use a legal analogy, is that a scientific level of proof would go to the jury, whereas a mathematical level of proof can be decided in summary judgment. Even assuming that the data the wellness industry

http://www.latimes.com/business/hiltzik/la-fi-hiltzik-wellness-genome-20170313-story.html.

Emma Seppala, Good Bosses Create More Wellness than Wellness Plans Do, HARV.
 Bus. Rev. (Apr. 8, 2016), https://hbr.org/2016/04/good-bosses-create-more-wellness-than-wellness-plans-do.

^{106.} CASE WESTERN RESERVE UNIV. Sch. of LAW, Corporate Wellness Programs: Are they Hazardous to Well-Being? (1), YOUTUBE, at 25:30 (Apr. 19, 2016), https://www.youtube.com/watch?v=PPyBZcDFeKM.

^{107.} See, e.g., Al Lewis & Vik Khanna, British Petroleum's Wellness Program is Spewing Invalidity, Health Care Blog (July 10, 2013), http://thehealthcareblog.com/blog/2013/07/10/british-petroleums-wellness-program-is-spewing-invalidity/; Bruce Shutan, Wellness ROI Comes Under Fire, EMPLOYEE BENEFIT NEWS (Jan. 8, 2016), http://www.benefitnews.com/news/wellness-roi-comes-under-fire; Begley, supra note 10.

provides is correct, the conclusion is clear: wellness programs lose money for employers. Three data sets, directly or indirectly ¹⁰⁸ attributable to the wellness industry, are used in this proof.

A. The Healthcare Cost and Utilization Project

The first data set that proves wellness loses money is a database sponsored by the Agency for Healthcare Research and Quality ("AHRQ") called the Healthcare Cost and Utilization Project ("HCUP"). 109 HCUP tracks hospital admissions over time using diagnosis codes. It is the "largest set of all-payer healthcare databases that are publicly available." 110 HCUP's drawback is that, as of this writing, it is four years out of date. However, for 2014, 2015, and 2016, the Disease Management Purchasing Consortium ("DPMC") used a similar methodology on a much smaller sample size to track admissions, yielding a continuation of the same trend lines. 111

B. Everett Koop Award Applications

The second data set comes from applications for the C. Everett Koop Award ("Koop"), an award given to "exemplary" wellness programs. The Health Project awards the Koop to wellness programs it identifies as "exemplary health promotion and disease prevention programs." ¹¹² It is fair, then, to cite the Koop-winning programs as representative of the most effective programs that the industry offers. Applications for this award contain a number of admissions against interest by prominent wellness-industry executives and vendors. These statements are not issues of fact because the executives made these statements and have not retracted them.

C. The HERO Program Metric and Evaluation Guide

The third data set is the largest wellness-industry trade organization, the Health Enhancement Research Organization ("HERO"). In 2015, HERO published the *Program Metric and Evaluation Guide* ("HERO Guide" or "Guide"). The Guide's acknowledgments page lists twenty-five

- 108. The Healthcare Cost and Utilization Project database is compiled for the government by Watson Health, which also advocates wellness. There is no allegation that the data is biased in favor of wellness as a result of this provenance, but rather that there is no reason to think the data would be biased against wellness.
- 109. See generally HCUP, supra note 62.
- 110. See Id.
- 111. See, e.g., Providence Health Plan, VALIDATION INST., http://www.validationinstitute.com/validated-organizations/#providence-health-plans (last visited Apr. 1, 2017) (noting Providence Health Plan's event rate trend through 2015).
- 112. See generally C. Everett Koop National Health Awards, Health Project, www.thehealthproject.com (last visited Apr. 1, 2017).
- 113. HERO Guide, supra note 100.

collaborators, four endorsers, six members of the steering committee, and seventeen "subject-matter experts." HERO describes those who collaborated on the Guide as "among the most credible and conscientious scientists and practitioners working in corporate wellness today." The first chapter of the HERO Guide states that it represents "two years and countless hours of research and discussions by more than 60 members of both organizations and many outside experts." The word "consensus" appears fifteen times in the Guide's eighty-nine pages. Based on these credentials, it appears that the HERO Guide indeed represents the wellness-industry leaders' consensus, as it claims to do.

1. Outcomes: The Failure of Wellness to Reduce Wellness-Sensitive Medical Admissions

Wellness-sensitive medical admissions ("WSMAs") include heart attacks, diabetes-related health events, and other admissions that are, at least in part, reasonably attributable to poor lifestyle choices. The Guide states that "WSMAs are the most important metric for determining program success" in that a good wellness program should reduce WSMAs. Researchers in *Health Affairs*, 119 the Validation Institute, 120 and the field's only outcomes-measurement textbook, *Why Nobody Believes the Numbers: Distinguishing Fact from Fiction in Population Health Management*, 121 also use WSMAs to track outcomes and would agree that a good wellness program should reduce them.

Using the HCUP database that the AHRQ compiles, Figure 2 tracks all admissions data for the privately insured population, such that it captures the entire population exposed to workplace wellness programs, estimated

- 114. Id. at 3.
- 115. Unsolicited letter from HERO Board of Directors, to selected members of the media, who can be identified to interested parties following the consummation of a non-disclosure agreement (Dec. 1, 2015) (on file with Author); Al Lewis, HERO's Paul Terry, Ron Goetzel, Seth Serxner Admit to Fabricating Data, THEY SAID WHAT? (Apr. 12, 2016) [hereinafter HERO Data Fabrication], https://theysaidwhat.net/2016/04/12/hero-finally-forced-to-reveal-poison-penletter-they-circulated-to-the-media/ (providing excerpts correspondence from HERO to Harvard Business Review).
- 116. HERO Guide, supra note 100, at 3.
- 117. See generally Id.
- 118. Id. at 22-23.
- 119. Gautam Gowrisankaran et al., A Hospital System's Wellness Program Linked to Health Plan Enrollment Cut Hospitalizations but Not Overall Costs, 32 HEALTH AFF. 477 (Mar. 2013).
- 120. See generally Validating Performance in Healthcare, Validation Inst., www.validationinstitute.com (last visited Apr. 1, 2017).
- 121. ALFRED LEWIS, WHY NOBODY BELIEVES THE NUMBERS: DISTINGUISHING FACT FROM FICTION IN POPULATION HEALTH MANAGEMENT (2012).

at sixty-six million people. ¹²² There are roughly 154 million people covered in the category HCUP calls the "privately insured" population. ¹²³ The figure tracks the privately insured population against the remaining United States population over the thirteen-year period during which the wellness industry has grown dramatically. The figure also tracks the rate of WSMAs listed in the HERO Guide—hypertension, stroke, heart attack and diabetes—against the admissions rate for everything else. ¹²⁴

If wellness works, the rate of these targeted WSMAs should be decreasing in the population exposed to wellness programs, even though many insured people lack access to them, at a rate higher than their decrease in the reference population. If wellness works, there should be separation between the two population trend lines. If the privately insured population trends flat, the reference population would increase significantly, or if the reference population trends flat, the privately insured population rate would decrease significantly. Instead, both lines trend flat, meaning that applying workplace wellness to the privately insured

^{122.} Karen Pollitz & Matthew Rae, *Workplace Wellness Programs Characteristics and Requirements*, Kaiser Family Found. (Jan. 4, 2016), http://kff.org/private-insurance/issue-brief/workplace-wellness-programs-characteristics-and-requirements/.

^{123.} Health Insurance Coverage of the Total Population, KAISER FAMILY FOUND., http://kff.org/other/state-indicator/total-population/ (last visited Apr. 1, 2017).

^{124.} The specific ICD9s are: hypertension and stroke, ICD-9 401 to 405, 430 to 438; heart attacks, 410; diabetes, 250.

population had no discernable impact between 2001 and 2013. This trend has continued since 2013. 125

Wellness-sensitive medical admissions ("WSMAs") as percentage of total admissions ("totals") (privately insured WSMAs/totals vs. all other WSMAs/totals)

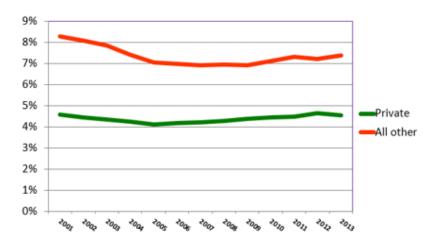


Figure 2. There has been no decrease in WMSAs among those with access to wellness programs.

Wellness supporters could argue that wellness programs are successful but affect too few employees to influence the overall trend line since only forty-two percent of employees have access to wellness programs. That argument, however, meets an insurmountable mathematical hurdle. All employers combined spend only \$11.3 billion on WSMAs. ¹²⁶ This means that only \$4.8 billion—forty-two percent of employer spending on WSMAs—spent on WSMAs are spent on people with access to wellness programs. If the industry size were \$4.8 billion or less, it would be possible to break even if wellness programs did a perfect job. However, the industry size is estimated at seven billion dollars. ¹²⁷ Thus, savings are impossible, no matter what the degree of inflection in the trend line. That the trend line shows no inflection compounds the mathematical impossibility of savings. This creates an argument in the alternative: wellness cannot save money, mathematically speaking, and even if it could, it hasn't.

The HERO Guide acknowledges that wellness programs lose money, but describes far more modest losses than the math dictates. The HERO Guide

^{125.} The continuation of this trend since 2013 is based on data compiled by and available upon request from the author.

^{126.} HERO Guide, *supra* note 100, at 23 (calculated using the HERO Guide's estimate of \$22,500 per admission).

^{127.} IBISWORLD, CORPORATE WELLNESS SERVICES IN THE US: MARKET RESEARCH REPORT (2015).

states that vendor fees for a wellness program are, on average, \$1.50 per employee per month ("PEPM"), or about eighteen dollars per year. ¹²⁸ A simple division of the seven-billion-dollar industry by the sixty-six million affected employees, however, yields vendor fees averaging almost six times HERO's vastly understated \$1.50 PEPM—or eighteen-dollar per employee per year—figure.

The HERO Guide lists savings as ninety-nine cents PEPM, resulting in approximately \$11.88 in savings per employee every year. ¹²⁹ Even if employers did save approximately \$11.88 per employee, their wellness programs would lose approximately six dollars per employee per year. In correspondence circulated to members of the media and not intended for publication, HERO's board claims that, in creating the Guide, they "fabricated" these numbers for the purpose of providing an example. ¹³⁰ Publicly, Goetzel, a member of HERO's board, stated that "[t]hose numbers are wildly off... every number in that chapter has nothing to do with reality." ¹³¹

The chapter's author, however, disputes the HERO board's and Goetzel's claim that the numbers were fabricated. He argues that, quite the contrary, the data is real and several board members, including Goetzel, reviewed it prior to publication. ¹³² Reconciling the example's data with the HCUP database, which shows almost total consistency between the HERO sample and the population, provides further evidence for the author's claim that the data is not "wildly off" but rather real, and a representative sample of the privately insured American workforce. ¹³³

Fabricated or not, to reconcile the example's costs with their estimated program savings, HERO's board argues that the example program's estimated costs were not intended to be compared to the estimated

^{128.} HERO Guide, supra note 100, at 15.

^{129.} Id. at 23.

^{130.} HERO Data Fabrication, *supra* note 115.

^{131.} Al Lewis & Ron Goetzel, The Great Debate, Population Health Alliance (Oct. 12, 2016), https://ccavoice.wordpress.com/?s=debate (providing a recording of a debate between Al Lewis and Ron Goetzel, at minute 1:17); Al Lewis, And the Envelope Please: The Best Outcomes Evaluator in Wellness Is . . . *, They Said What? (Jan. 30, 2017), https://theysaidwhat.net/2017/01/30/and-the-envelope-pleasethe-best-outcomes-evaluator-in-wellness-is/ (providing a summary of The Great Debate); see also Al Lewis, Ron Goetzel proves, definitively, that screening loses money . . . and lots it, THEY SAID WHAT? (Feb. 2017), of https://theysaidwhat.net/2017/02/07/ron-goetzel-proves-definitively-thatscreening-loses-money-and-lots-of-it/ (providing an analysis of Goetzel's most recent admission against interest that he made in Ron Goetzel et al., Workplace Programs, Policies, And Environmental Supports To Prevent Cardiovascular Disease, 36 HEALTH AFF. 229 (2017)).

^{132.} Lewis, supra note 131.

^{133.} HCUP, supra note 62.

savings described in the same chapter.¹³⁴ This departs from the norm; typically, costs and savings are compared to determine a program's cost-effectiveness. To argue that costs are not supposed to be compared to benefits appears specious.

2. Economics: Wellness Programs Lose More than a Dollar for Each Dollar Spent

There are two pieces of evidence that show that wellness programs actually cause healthcare spending to increase above and beyond vendor fees themselves. The first is an admission against interest that HERO made. The HERO Guide lists eleven elements of cost that increase due to wellness. Along with direct costs, like fees and incentives, and indirect costs, like employee time and legal review, a third category, "tangential" costs, includes "employee morale and company reputation." 135 The candor of this third category reflects the number of high-profile cases in which wellness programs damaged one or both, such as those introduced at Penn State, 136 CVS, 137 and Honeywell. 138 Some of these tangential costs cannot be translated into dollars. The list also omits important and substantial costs that increase as a result of wellness programs. For example, the Guide does not mention consulting fees for vendor selection and program evaluation, though they can be quantified and may be substantial. Consulting fees, along with the remaining eleven direct and indirect cost items mentioned above, are also excluded from the Guide's later cost calculations. The Guide includes only vendor fees, estimated at \$1.50 PEPM, in its program-cost calculation. 139

That above-described private correspondence from the HERO board complained that a mathematical analysis conducted using the allegedly fabricated data should have used real data. Substituting Goetzel's "real data" suggests that there are approximately \$100 to \$150 in costs per year for each employee, rather than \$1.50 PEPM, or eighteen dollars per

- 134. Id. at 22.
- 135. Id. at 10.
- 136. Singer, supra note 4.
- 137. Jillian Berman & Hunter Stuart, CVS Sued Over Controversial Wellness Program, HUFFINGTON POST (Mar. 20, 2014), http://www.huffingtonpost.com/2014/03/20/cvs-healthscreening_n_4986861.html.
- 138. Reed Abelson, *Wellness Programs Use Carrots and, Increasingly, Sticks*, N.Y. TIMES (Jan. 24, 2016), https://www.nytimes.com/2016/01/25/business/employeewellness-programs-use-carrots-and-increasingly-sticks.html.
- 139. HERO Guide, supra note 100, at 22.
- 140. HERO Data Fabrication, supra note 115.
- 141. WELLSOURCE, INC., HOW MUCH DOES A GOOD WELLNESS PROGRAM COST? (2011), available at http://wellsource.com/wp-content/uploads/2015/08/How_Much_Should_a_Wellness_Program_Cost.pdf.

year. ¹⁴² His data, therefore, actually dramatically increases the losses from approximately six dollars per employee per year to eighty-eight dollars to \$138 per employee per year, even before the other elements of direct and indirect cost are included. ¹⁴³

Vendor fees and direct and indirect costs are administrative costs, not costs paid directly in insurance claims. The cost of utilizing other services, however, also increases, according to HERO. The Guide states:

It is important to recognize that [wellness programs] should increase the use of certain services, such as preventive and screening services, certain chronic medications, and outpatient visits. It is even possible to see a rise in [emergency room] and urgent care visits."¹⁴⁴

These healthcare expenses that HERO acknowledges and describes are excluded from the savings calculation. These added expenses could easily dwarf the ninety-nine cent PEPM savings before even considering the vendor fees. HERO's own statements, therefore, project losses from wellness programs exceeding the wellness vendors' fees.

Connecticut's wellness program, for example, bears out the prediction that wellness programs lose money. The results from its program, published in 2016, show an increase in Connecticut's healthcare spending. 145 The state administrator, Kevin Lembo, contends that immediate cost increases in preventive services would eventually lead to cost decreases. 146 He did not provide any factual support for this contention. 147 The speculation is further suspect because Connecticut's preventive care schedule conflicts with the USPSTF's guidelines. He also failed to provide any explanation for why he believes that flouting accepted guidelines for appropriate preventive care will lead to eventual cost decreases.

1. The Wellness Industry's Admissions Against Interest

Every investigation conducted by investigators who are not connected to the wellness industry shows losses. As Connecticut's program demonstrates, even investigations that were conducted by parties supporting wellness programs show losses. The only investigations that

^{142.} WELCOA, *The Cost of Wellness: A WELCOA Expert Interview With Dr. Ron Goetzel* (July 21, 2010), https://www.scribd.com/document/34732477/The-Cost-of-Wellness-A-WELCOA-Expert-Interview-With-Dr-Ron-Goetzel.

^{143.} HERO Data Fabrication, supra note 115.

^{144.} HERO Guide, supra note 100, at 22.

^{145.} Richard A. Hirth et al., Connecticut's Value-Based Insurance Plan Increased the Use of Targeted Services And Medication Adherence, 35 HEALTH AFF. 637 (2016).

^{146.} Arielle Levin Becker, Study: State Employee Wellness Plan Increased Use of Preventive Services, CTMIRROR (Apr. 5, 2016), http://ctmirror.org/2016/04/05/study-state-employee-wellness-plan-increased-use-of-preventive-care/.

^{147.} Id.

show savings, however, are the investigations conducted by wellness supporters. Those, upon closer examination, self-invalidate, and as such could be considered "admissions against interest"—the publication of data that undermines the industry's own position. The sample reviewed for this article is extensive and includes peer-reviewed and Koop-winning programs. As extensive as it is, it is just a sample—there are at least fifty other vendors reporting substantial savings based on data that self-invalidates. ¹⁴⁸

HealthiestYou reported a greater reduction in emergency-room visits than there were emergency-room visits to reduce. 149 Wellsteps reported that costs decreased for its client, the Boise School District, but also admitted elsewhere in the report that costs increased. 150 Wellnet reported a reduction in undetected-claims cost that was a large multiple of total healthcare claims cost, 151 but there is no such thing as "undetected claims" cost." Staywell reported that it saved British Petroleum ("BP") one hundred times more than its own study says is possible 152 and won a Koop Award in 2014 for its report. 153 As is the case with most other Koop winners, both Staywell—BP's vendor—and Mercer—BP's consulting firm—were represented on the awards committee, 154 and as an award sponsor. 155 US Corporate Wellness reported substantial savings on people whose health did not improve¹⁵⁶ and separately reported that participants in their wellness program were "230% less likely" to miss work than non-

- 148. The self-invalidation arithmetic for all fifty is available at www.theysaidwhat.net. For examples of independent analyses questioning wellness economics see Frakt, supra note 102; Begley, supra note 10.
- 149. Following the exposure of this fact, HealthiestYou removed any evidence of it from their website. However, this statistic can be found by going to visit www.theysaidwhat.net and entering "HealthiestYou" into the search function.
- 150. WELLSTEPS, THREE YEARS OF WORKSITE WELLNESS: A ZERO TREND CASE STUDY, available at https://www.wellsteps.com/files/three_years_of_wellness.pdf (last visited Apr. 1, 2017).
- 151. WELLNET, *Healthcare Case Studies 2011*, SLIDESHARE, at slide 4 (Apr. 26, 2011), http://www.slideshare.net/WellNet123/wellnet-healthcare-case-studies-2011.
- 152. Amanda McGrory-Dixon, Prevention Necessary for Reducing Health Care Costs, BENEFITSPRO (Nov. 22, 2012), http://www.benefitspro.com/2012/11/22/prevention-necessary-for-reducing-health-care-cost; Lewis & Khanna, supra note 107.
- 153. See generally BP America, HEALTH PROJECT, http://thehealthproject.com/winner/bp-america/ (last visited Apr. 1, 2017).
- 154. See Board of Directors, HEALTH PROJECT, http://thehealthproject.com/about-us/board-of-directors/ (last visited Apr. 1, 2017).
- 155. See 2016-2017 Sponsors, HEALTH PROJECT, http://thehealthproject.com/sponsors/ (last visited Apr. 1, 2017).
- 156. Al Lewis, *US Corporate Wellness Saves Money on People Who Don't Cost Money*, They Said What? (July 30, 2014), https://theysaidwhat.net/2014/07/30/210/.

participants.¹⁵⁷ This claim was removed from their website after it was observed to be mathematically impossible.¹⁵⁸

The industry's own trade association, HERO, was not the only wellness promotion organization to show losses. The industry's own trade publication, the *American Journal of Health Promotion* ("AJHP"), did the same. An attempt to confirm the Harvard Study's findings showed savings, but only in low-quality studies. ¹⁵⁹ The AJHP's meta-analysis found that "randomized control trials . . . exhibited negative ROI." ¹⁶⁰

The former editor of AJHP, Michael O'Donnell, acknowledged as much. In addition to graciously conceding that this author is "not an idiot" and is "close to being accurate," O'Donnell stated that "90% to 95% of programs fail." Goetzel joins him in this opinion, indicating that "there is a group of about 100 employers whose programs have really smart ingredients . . . but thousands of others still don't do wellness right and are not getting good health outcomes." He did not mention any of these one hundred employers by name, making it impossible to verify this claim. For the last seven years, no peer-reviewed article in a major journal has found that wellness programs lead to substantial risk reduction. Even award-winning programs achieve only low-single-digit percentage reductions in risk factors, excluding dropouts and non-participants.

By contrast, breaking even would require a very substantial reduction in risk. Mike Tinney, the CEO of Fitness Interactive Experience, acknowledges that finding an ROI in wellness requires a "leap of faith," and that breaking even on wellness is possible only with a fifty percent reduction in heart attacks, ¹⁶³ which would be twenty-five to fifty times the typical one-percent to two-percent risk reduction that Goetzel claims is achievable over a multiyear period. ¹⁶⁴

- 157. Id.
- 158. The case study has been removed from the website but can be found in: US CORPORATE WELLNESS, Wellness Program Case Study: The Children's Hospital, DISEASE MANAGEMENT, available at http://www.dismgmt.com/sites/default/files/tch_case_study.pdf (last visited Apr. 1, 2017).
- 159. Baxter et al., supra note 64.
- 160. *Id.* at 347 (However, "[f]inancial returns become increasingly positive across quasi-experimental, nonexperimental, and modeled studies.").
- 161. Michael O'Donnell, *Does Workplace Health Promotion Work or Not? Are You Sure You Really Want to Know the Truth?*, 28 Am. J. Health Promotion iv (2013).
- 162. Begley, supra note 10.
- 163. Mike Tinney, Belief in Wellness Savings May Require Leap of Faith, but They're Real, CFO (June 3, 2015), http://ww2.cfo.com/health-benefits/2015/06/belief-wellness-savings-may-require-leap-faith-theyre-real/#comment-857278.
- 164. Taylor, supra note 83.

2. Wellness Industry's Methodologies for Measuring Savings Self-Invalidate

The wellness industry relies overwhelmingly on two methodologies to show savings. The first is comparing participants, excluding dropouts, to non-participants. The second is pointing out reductions in risk factors for employees at high risk for disease. ¹⁶⁵ Both methodologies self-invalidate based on wellness vendors' own studies, confirming that both methodologies show savings where none exist.

The Food and Drug Administration ("FDA") does not allow participant-versus-non-participant comparison studies. Instead, in order to equalize subjects' motivations to participate, they divide would-be participants into study and control groups. ¹⁶⁶ By contrast, wellness industry participant-versus-non-participant studies do not count or track dropouts or acknowledge that counting dropouts could change results. While no data is tallied on dropouts because a study cannot follow up with them, it appears likely that people drop out because they are failing rather than because they are succeeding, an assumption with which HERO concurs. ¹⁶⁷ It seems even likelier that dropouts occur due to participants' failures to achieve results if participants who succeed and complete the program receive a monetary reward, as is usually the case in wellness programs.

As a result, the investigations that wellness advocates conduct appear to show savings because the participation effect—active participants' motivations as compared to motivations of non-participants and dropouts—is not isolated from the program effect—the impact of the actual intervention.

What if these two effects could be isolated? What if there were situations in which:

^{165.} See Al Lewis, How the 2016 Koop Award Raises Lying to an Art Form, They Said What? (Sept. 28, 2016), https://theysaidwhat.net/2016/09/28/this-mornings-koop-award-raising-lying-to-an-art-form/ (Comparing comments made by Wellsteps' CEO, Steve Aldana, regarding employees with high risk factors in One of the Nation's Best Wellness Programs, WellSteps (July 15, 2016), https://www.wellsteps.com/blog/2016/07/15/koop-award/, to comments made by Mr. Aldana in Begley, supra note 10. The former credits the program with the reduction while the latter acknowledges the "regression to the mean" that causes outliers as a group to tend towards the average over time).

^{166.} Suzanne White Junod, *FDA and Clinical Drug Trials: A Short History*, U.S. FOOD & DRUG ADMIN. (Apr. 11, 2016), http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm304485.htm

^{167.} HERO Guide, *supra* note 100, at 17 ("For example, sometimes savings due to lifestyle risk reduction is calculated on the 20% of the population that supplied appropriate data. It's assumed that the other 80% didn't change but if some of the people who didn't supply risk factor data worsened, and people who got worse were less likely to report their data, that model would overestimate savings.").

- 1. Participants were separated from non-participants, but not offered a program in which to participate?
- 2. A program gave demonstrably bad advice, the advice was taken, and participants still showed savings?
- 3. A controlled experiment tested participation impact against program impact?

The wellness industry uses studies like the ones described above to justify its programs. Each study is peer-reviewed or Koop Award-winning, and wellness supporters conducted all of them, eliminating investigator bias. 168

Eastman Chemical's wellness program, operated by Health Fitness Corporation, follows the first scenario; its study showed savings without offering a program in which employees could participate. 169 The figure below, a major part of Eastman Chemical and Health Fitness Corporation's Koop-winning application, clearly claims that it saved money on healthcare before it even began offering its program. 170 Their application claimed the program was saving \$359 per year per employee before the program actually started. 171

^{168.} See Wellness Outcomes, supra note 77 (providing a more detailed analysis of the invalidity of the participants-vs-non-participants study design).

^{169.} See generally Eastman Chemical, HEALTH PROJECT. http://thehealthproject.com/winner/eastman-chemical-healthe-connections/ (last visited Apr. 1, 2017).

^{170.} Id. (providing this figure in the 2011 Koop Award Application; to view, select "Evaluation Documentation" and scroll to the end, the graph appears without the x-axis, which was removed altogether in December 2014, as explained in the "Erratum" statement).

^{171.} Wellness Outcomes, supra note 77 (showing \$2432 vs. \$2073, the 2006 comparison of participants vs. non-participants).

Health Fitness Corporation/Eastman Chemical ROI analysis from Koop Committee Submission



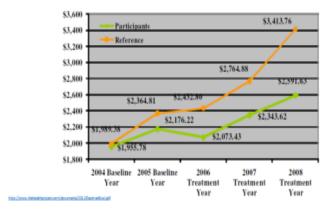


Figure 3. Eastman Chemical/Health Fitness Corporation Participants versus Non-Participants display, with original axis labeling¹⁷²

In 2014, after The Incidental Economist critiqued the study in *Health Affairs*, the Koop committee removed the x-axis from the award application.¹⁷³ Absent the original screenshot, the alteration of the chart would have prevented readers from seeing it in its original form. Whereas the original version clearly shows separation absent a program in the initial two years, the revised version, lacking the x-axis, makes it impossible for readers to realize that the alleged savings occurred before the program even began. Goetzel then wrote in *Health Affairs* that the "original is online and subject to review,"¹⁷⁴ when, in fact, only the revised version was available for review.¹⁷⁵

- 172. This screenshot was taken from the 2011 application for the Koop Award from Eastman Chemical and Health Fitness Corporation from www.thehealthproject.com, before it was altered in December 2014.
- 173. Eastman Chemical Evaluation Documentation, HEALTH PROJECT, http://thehealthproject.com/wp-content/uploads/2015/05/EastmanEval.pdf (last visited Apr. 1, 2017).
- 174. Ron Goetzel, *The Value of Workplace Health Promotion (Wellness) Programs*, HEALTH AFF. BLOG (Dec. 22, 2014), http://healthaffairs.org/blog/2014/12/22/the-value-of-workplace-health-promotion-wellness-programs/.
- 175. Al Lewis et al., Workplace Wellness Produces No Savings, HEALTH AFF. BLOG (Nov. 25, 2014), http://healthaffairs.org/blog/2014/11/25/workplace-wellness-produces-no-savings/ (providing the original version); Eastman Chemical Evaluation Documentation, supra note 173 (showing the later version with the x-

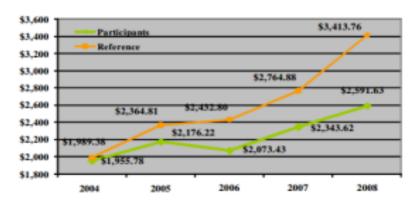


Figure 6. ROI Analysis Summary Results

Figure 4. Screenshot of the Eastman Chemical/Health Fitness Corporation Koop Award application display following the 2014 removal of the axis labels, taken in 2015.

Regardless of the x-axis, by the end of the 2008, Eastman Chemical reported that savings for program participants exceeded nine hundred dollars per year, but its application for the Koop reports revealed that average participant's risk declined only 0.17 on a scale of zero to five—about three percent—excluding dropouts. ¹⁷⁶ A three percent decline in risk would lead one to expect, at maximum, a three percent decline in wellness-sensitive medical admissions. Rounding for simplicity, a three percent decline in two percent of spending yields roughly a 0.06 percent decline in total healthcare spending by 2008, not twenty-four percent, as the chart above claims. This is a four hundred-fold overstatement of the likely result. None of the Koop committee members, nor Eastman Chemical or Health Fitness Corporation, attempted to explain the discrepancy. ¹⁷⁷

This example, though it is award-winning and peer-reviewed, clearly overstated its wellness program's impact on savings. It is one of many award-winning and peer-reviewed wellness programs that attributes substantial savings to very small reductions in risk factors. Wellness

axis removed); Lewis & Goetzel, *supra* note 130 (showing the juxtaposed version in Part 4 of *The Great Debate*, at 40:50)

^{176.} Eastman Chemical Evaluation Documentation, supra note 173, at Section D.

^{177.} Eastman Chemical, supra note 168 (showing the 2014 acknowledgement of the 2012 exposition of the error was posted in an "Erratum").

^{178.} A further demonstration of this point: as this article was going to press, Health Fitness Corporation published a case study showing \$586 in savings for employees who gained 9 ounces less than the control group, which translates to a savings of roughly \$1041 per pound of weight not gained. New Research Demonstrates Participation in Coaching Moves the Needle, Business Wire (Feb. 7, 2017), http://www.businesswire.com/news/home/20170207006047/en/Research-Demonstrates-Participation-Coaching-Moves-Needle.

affects only a small number of WSMAs, and therefore can only affect a small percentage of all healthcare spending. 179

Another study, conducted by Stanford researchers, alleged that it reduced costs by \$397 per participant in the first six months of participation in a program that involved placing participants on a low-fat diet.¹⁸⁰ The study attributes its substantial savings to its participants consuming less fat and more carbohydrates, which is the opposite of what most dietary experts currently recommend.¹⁸¹ Because participant risk factors declined only 2.2 percent, the advice provided was demonstrably incorrect, and the program could not have had such a short-term impact even if the advice it provided had been correct, the only factor that could explain this otherwise-inexplicable result is that participants will always outperform non-participants. What they ate or did not eat over twenty-six weeks could have had no meaningful bearing on this outcome. Despite its obvious invalidity, this study was selected for inclusion in Harvard Study described above, tainting the overall 3.27-to-1 ROI result.¹⁸²

A study of Aetna's wellness program showed that there was no change in the study group's risk factors, but still showed a reduction in cost of \$1464 the program's first year. This study divided a cohort of healthy Aetna employees into three groups: the control group and two study groups. The study groups were a participant group including only those who were invited to participate in the study and accepted the invitation, and a non-participant group including only those who were invited to participate in the study and declined the invitation. 184

This study design contrasted results that an RCT generated with the results the wellness industry's preferred participants-versus-non-participants design generates. The RCT—the gold standard in the field of statistics—showed that Aetna's wellness program had no discernable,

- 179. HERO Guide, *supra* note 100, at 23 (Stating between 2.62 and 3.14 WSMAs/ 1000 members out of a total of roughly 40 all-cause admissions, excluding birth-related events; roughly a third of so-called WSMAs are respiratory or heart failure-related—these are not found through screens. That leaves between about 1.4 and 2.1 admissions/1000 to be theoretically avoidable through screening.).
- 180. See Fries & McShane, supra note 71.
- 181. *Id.*; see also Kris Gunnars, 23 Studies on Low-Carb and Low-Fat Diets: Time to Retire the Fad, Authority Nutrition, https://authoritynutrition.com/23-studies-on-low-carb-and-low-fat-diets/ (last visited Apr. 1, 2017).
- 182. See Baicker et al., supra note 43.
- See Gregory Steinberg et al., Reducing Metabolic Syndrome Risk Using a Personalized Wellness Program, 57 J. OCCUPATIONAL & ENVTL. MED. 1269, 1270 (2015).
- 184. Id.
- 185. See Random Controlled Trials (RCTs), ARIZ. DEP'T EDU., https://cms.azed.gov/home/GetDocumentFile?id=589894d91130c10cbc242e42 (last visited Apr. 1, 2017); see also Wellness Outcomes, supra note 77.

clinically significant differential impact on health indicators between the study and control groups. 186

Nor should there have been any difference between the study and control groups. The cohort was designed to include only subjects who had not been diagnosed with a major chronic disease. Participants were selected either because they had metabolic syndrome or were at risk for developing metabolic syndrome, a condition that puts patients at risk for diabetes or heart attack. In other words, part of the cohort was at risk only for being at risk for having a disease, but not actually at risk for having a disease. None of the study group actually had heart disease or diabetes.

A sudden reduction in costs by \$1464 per participant, as the Aetna study's authors claim occurred, would require a reduction in sudden events, such as heart attacks. However, the baseline heart-attack rate was already zero—people who had experienced heart attacks were excluded from the study because they had already been diagnosed with heart disease. ¹⁸⁹ Thus, it would be impossible to save money by reducing the heart-attack rate.

With the impossibility of reducing the heart-attack rate and the questionable theory behind getting employees to lose weight, it was no surprise that the study showed exactly the opposite of what its sponsors had hoped to show: their program had no impact on its participants' wellness. The comparison between the control and study groups showed trivial relative changes in risk factors that were statistically insignificant. 190

Though there was no statistically significant change in risk factors between the two groups, the subset of participants in the invited group allegedly saved \$1464 as compared to the non-participants. Because there was no overall difference between the study and control groups' performances, only participation bias could explain the discrepancy between the two results. The investigators, who work for Aetna—which markets this wellness program—did not acknowledge the RCT results and instead highlighted the participants-versus-non-participants result. They knew or should have known this result was implausible, given the short time frame, the RCT results, and that the subjects were at low risk. 192 The

^{186.} Al Lewis, *Genetic Testing: The New Frontier of Wellness Madness*, HEALTH CARE BLOG (Dec. 16, 2015), http://thehealthcareblog.com/blog/2015/12/16/genetic-testing-the-new-frontier-of-wellness-madness/; Steinberg et al., *supra* note 183.

^{187.} Lewis, supra note 186.

^{188.} Steinberg et al., *supra* note 183, at 1269 (noting that metabolic syndrome is "a constellation of five risk factors An individual with at least three . . . qualifies as having [metabolic syndrome]." Study participants were selected if they had at least two.).

^{189.} See generally Id. (omitting the heart attack rate as a factor).

^{190.} Id. at 1273, Table 3; see also Lewis, supra note 186.

^{191.} Steinberg et al., *supra* note 183, at Table 4 (noting \$312 per month for participants vs. \$434 per month for non-participants, or \$1464 per year).

^{192.} Id.

decision to suppress their own study drew a rebuke from Mattke, who wrote: "I congratulate the authors on planning to subject their intervention to such a rigorous analysis, but wish they had actually applied this rigor to the analysis." ¹⁹³

Additionally, a member of the editorial advisory board of the journal in which this study appeared wrote:

I have long been on the Editorial Board of the *Journal of Occupational* and *Environmental Medicine*. However, I was not involved in the peer review or Editorial decisions regarding the Aetna study. If I had been, the issues Al Lewis is raising would have been considered, if not determinative. ¹⁹⁴

Wellness providers also take credit for the natural flow of risk. Suppose one hundred coins are heads up on the table. If you flip them, about fifty will land tails-up. Likewise, a hypothetical company offering a program to flip heads to tails would generally show a fifty percent success rate if all the coins were heads to begin with. To be fair, that program should also count tails flipping to heads. No one would believe a result that counted only heads flipping to tails and not the reverse and then claimed credit for a fifty percent reduction in heads. In the wellness industry, however, as the Wellsteps example showed, it is quite common for wellness vendors to count only high-risk participants who reduce risk factors, but not low-risk participants whose risk factors increase. Por example, vendors will count people who lose weight but not people who gain weight, or will count

^{193.} See Soeren Mattke, Comment on Steinberg et al: Reducing Metabolic Syndrome Risk Using a Personalized Wellness Program, 58 J. OF OCCUPATIONAL & ENVTL. MED. e114, e114 (2016).

^{194.} See Nortin Hadler, Comment to Al Lewis, in Genetic Testing: The New Frontier of Wellness Madness, HEALTH CARE BLOG (Dec. 16, 2015), http://thehealthcareblog.com/blog/2015/12/16/genetic-testing-the-new-frontier-of-wellness-madness/.

^{195.} See, e.g., Al Lewis, ShapeUp Falls Down Trying To Do Math For Highmark, THEY SAID WHAT? (July 23, 2014), https://theysaidwhat.net/2014/07/23/shapeup001/ (Noting that 163 people out of roughly 11,000 participants were reported to have reduced their BMI classification from obese to overweight or overweight to normal weight, but none of the 11,000 were disclosed to have gained weight. Highmark fired ShapeUp for failure to perform.); Steve Twedt, Are Worker Wellness Plans Best for Business?, PITTSBURGH POST-GAZETTE (Mar. 3, 2015, 12:00 http://www.post-gazette.com/business/healthcarebusiness/2015/03/03/Worker-wellness-plans-called-into-question-but-othersdefend-it/stories/201503030025; Leonard L. Berry et al., What's the Hard Return Wellness Programs?, HARV. https://hbr.org/2010/12/whats-the-hard-return-on-employee-wellnessprograms ("Of those classified as high risk when the study started (according to body fat, blood pressure, anxiety, and other measures), 57% were converted to low-risk status by the end of the six-month program.").

^{196.} Lewis, supra note 195.

people who stop smoking but not people who resume or begin. In reality, people's risk factors are almost equally likely to increase as decrease. 197

An instructive example from Interactive Health and its evaluators, Zoe Consulting, shows the natural flow of risk clearly, with only a 5.3 percent net reduction in risk factors, excluding dropouts and non-participants. ¹⁹⁸ The study asserted that the wellness program resulted in eight-figure savings, even though only 278 more people reduced risk than increased it out of the 22,500 people studied. ¹⁹⁹ A subsequent version of report from which this instructive example was extracted now omits the table, as well as any acknowledgement of the one-percent net favorable risk migration or explanation how such a trivial risk reduction could support the eight-figure savings claims. In percentages, Interactive Health is now claiming that this evaluation, with its one-percent reduction in risk, generated a twenty-percent cost savings. ²⁰⁰

Wellsteps, too, only tracks improvements in people with the "worst health behaviors." This is essentially the same thing as only counting heads-to-tails, and an excellent example of a vendor taking credit for regression to the mean. Originally, Wellsteps attributed these "dramatic improvements" in Figure 5 to the "program impact." For example, the number of alcoholic drinks that people with the "worst health behaviors" self-reported that they imbibed fell from 1.31 per day to 1.10 per day, a change for which Wellsteps took credit. It is also worth noting that self-reporting is generally unreliable, 203 and that the 691 respondents in this chart equal the 691 who admitted to drinking alcohol at all, meaning that Wellsteps considers any alcohol consumption a "worst health behavior." Further, 691 is only about twenty-three percent of the total number of

EDINGTON, supra note 70, at 10; EDINGTON ASSOC., NATURAL FLOW: BY RISK STATUS 2 (Apr. 5, 2016), available at https://www.uschamber.com/sites/default/files/dr._dee_edington.pdf.

^{198.} ZOE CONSULTING, INC., INTERACTIVE HEALTH WORKSITE WELLNESS PROGRAM LOWERS MEDICAL COSTS AND INCREASES PRODUCTIVITY 9 (last viewed Apr. 1, 2017) (on file with author).

^{199.} See Interactive Health& Zoe Consulting, Inc., Proof Positive: Study Demonstrates Interactive Health Outcomes-Based Wellness Program Lowers Medical Costs and Increases Productivity 5, http://interactivehealthinc.com/wp-content/uploads/2014/06/Claim-Study-Research-Summary-Interactive-Health.pdf (last visited Apr. 1, 2017).

^{200.} Interactive Health Honors Employers with Top Workplace Wellness Programs, PR NEWSWIRE (Apr. 11, 2017), http://www.prnewswire.com/news-releases/interactive-health-honors-employers-with-top-workplace-wellness-programs-300437763.html.

^{201.} WellSteps, supra note 150, at 3.

^{202.} Aldana, supra note 165.

^{203.} Rob Hoskin, The Dangers of Self-Report, Science Brainwaves (Mar. 3, 2012), http://www.sciencebrainwaves.com/the-dangers-of-self-report/.

employees. Since roughly seventy percent of adults drink alcohol,²⁰⁴ it is likely that roughly forty-seven percent simply lied and Wellsteps did not notice, or noticed but did not disclose it.

Health Behavior	Berelles	Vers 1	Year 2*
<2 days of exercise/week, n=502	Baseline 1.46 days	2.29 days	2.47 days (+69%)
<2 days or exercise/week, n=302	Two days	2.29 uays	2.47 days (403%)
<60 minutes/week, n=373	18.79 min	113.20 min	134.71 min (+617%)
<3 daily servings fruits/veggies, n=426	2.46 servings	3.48 servings	3.63 servings (+47%
<3 days of restful sleep/week, n=407	2.23 days	3.17 days	3.36 days (+51%)
Smokers (days per week, n=77)**	4.35 days	5.43 days	4.27 days (-1.6%)
annuers foots her week (I-77)	4.55 days	3.43 0075	4.2. nays (-1.0%)
Alcohol Use (drinks/day, n=691)	1.31 drinks	1.16 drinks	1.10 drinks (-16%)

Table 2. Improvements in Health Behaviors Among Those With the Worst Health Behaviors

Figure 5. Wellsteps' table displaying the downward flow of risk.

In a subsequent exposé by STATNews' Sharon Begley about Wellsteps' wellness program, Wellsteps' Chief Executive Officer, Steve Aldana, acknowledged that cherry-picking only those employees with the "worst health behaviors" was invalid, stating:

In just one year, many employees will move from one [risk] group to the other even though they did not participate in any wellness programs or any intervention whatsoever. [That movement] reflects changes in health risks that occur naturally, even though your program didn't do anything. ²⁰⁵

Even peer-reviewed wellness studies will use a cohort comprised mostly of people with few risk factors as a control for high-risk participants, taking advantage of the fact that the latter will benefit from regression to the mean. For example, one study declared that it "compared the reductions in cost and health risk of a health education program aimed at high-risk persons with a similar program addressed to all risk levels." Since most people are at low risk, even in the absence of a program, high-risk subjects' risk levels will fall farther than low-risk subjects' risk levels simply because they have farther to fall, regardless of the intervention. Or, to wrap up the coin analogy, one-hundred heads will likely decline by fifty, to fifty heads and fifty tails, while sixty heads and forty tails will also likely flip to fifty

^{204.} Alcohol Facts and Statistics, NAT'L INST. ON ALCOHOL ABUSE & ALCOHOLISM (Feb. 2017), https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/alcohol-facts-and-statistics (showing seventy percent of adults have had alcohol in the last year).

^{205.} Begley, supra note 10.

^{206.} Fries & McShane, supra note 71.

heads and fifty tails, declining only by ten. Comparing their respective reductions ignores the built-in bias of having farther to fall.

3. The Clinical Impact of Wellness Programs

Losses might be acceptable if these programs improved employee health status. One could then optimistically infer that someday costs might fall a little, assuming the health-status improvements are maintained. That assumes, however, that health status improves in the first place. Aetna's program, for example, did not improve the study group's health indicators, despite a five-hundred-dollar cost per participant.²⁰⁷

Even Koop-winning programs achieve, at best, only single-digit reductions in risk factors, and the two most recent award examples achieved none. The 2015 winner was McKesson. Even though they excluded dropouts and non-participants, employees did not improve in objective biometric testing. Description of the companion of the com

	Risk Factor	Members		Increased to Elevated Risk	Stayed at Elevated Risk	Decreased to Low Risk	Significance Indicator
Biometric	BMI	19,377	25%	6.5%	64%	5.4%	1
	Cholesterol	19,439	51%	13.1%	25%	10.5%	1
	SBP	19,390	40%	15.6%	28%	16.7%	4
	DBP	19,391	57%	12.6%	14%	17.1%	4
	Glucose	19,378	73%	8.8%	11%	6.9%	1
	Cotinine	14,607	87%	1.5%	9%	1.6%	

Figure 6. McKesson risk factor changes as reported in its Koop Award application, highlighting increases to elevated risk in red and decreases to low risk in green.

In the McKesson program, body-mass index ("BMI"), cholesterol, and glucose all worsened. Systolic and diastolic blood pressure improved slightly, as did cotinine, an objective marker of tobacco use. The increased-to-elevated-risk and decreased-to-low-risk columns both sum to fifty-eight percent, meaning there was no net change in risk. Despite the program's failure to improve risk on balance, McKesson nonetheless alleged substantial savings. McKesson even hired a graduate student to

^{207.} Steinberg et al., supra note 183.

^{208.} Al Lewis, Albert Einstein Meets the C. Everett Koop Wellness Award, THEY SAID WHAT? (Dec. 2, 2015) [hereinafter Albert Einstein Meets Koop], https://theysaidwhat.net/2015/12/02/albert-einstein-meets-the-c-everett-koop-wellness-award/.

^{209.} McKesson Corp., 2015 C. Everett Koop National Health Award for Excellence in Health Improvement and Cost Savings (2015), available at http://thehealthproject.com/wp-content/uploads/2015/09/McKesson_Koop-Award-Application-2015.pdf .

^{210.} Id.

^{211.} Id.

^{212.} Shutan, supra note 107.

claim the program had led to savings and to explain how weight could increase and decrease at the same time. ²¹³ The wellness industry claims that reducing risk generates savings. If, as with McKesson, it turns out that risk did not decline, one must conclude that the savings were fabricated.

McKesson is not alone in winning a Koop while accomplishing no meaningful risk reduction. ²¹⁴ The table below includes a list of the winners from previous years, together with their risk reduction. To give the programs the benefit of the doubt, risk-reduction percentages include self-reported risk reduction, as in the Wellsteps example above, in which all the responses were self-reported. Self-reported risk reduction is almost always greater than biometric risk reduction. This is not just because people are observed to lie on these surveys, as with Wellsteps. Often, employees can only procure the best coverage options if they say they have completed certain tasks or changed health behaviors. ²¹⁵

To further confer the benefit of the doubt, in each case below the risk reduction among active participants, excluding dropouts, is spread across the entire population.

Year	Winner	Risk Reduction (including self-reported)
2016	Wellsteps/Boise School Dist.	Risk factors increased. ²¹⁶
2015	McKesson	1%
2014	British Petroleum	3%
2012	Nebraska state employees	1%
2011	Eastman Chemical	2%
2010	Pfizer	2%

Figure 7. Table describing company-wide risk reduction in Koop-winning programs. ²¹⁷

In addition to the best programs' failures to make meaningful reductions in risk factors, another data point that shows the wellness industry in its most favorable light is the single reported instance of a

214. Albert Einstein Meets Koop, supra note 208.

^{213.} Id.

^{215.} Fred Golstein, *Update to: The Dodo Bird and Employee Wellness Programs – The Phone Call*, AH! ACCOUNTABLE HEALTH (Nov. 6, 2016), https://accountablehealth.wordpress.com/2016/05/05/the-dodo-bird-and-employee-wellness-programs-the-phone-call/.

^{216.} Begley, supra note 10; Al Lewis, Protecting Employees from Harmful Wellness Vendors: A Wake-Up Call, Am. J. OF MANAGED CARE (Oct. 10, 2016), http://www.ajmc.com/contributor/al-lewis-jd/2016/10/protecting-employees-from-harmful-vendored-wellness-programs-a-wake-up-call.

^{217.} The 2013 winner is excluded due to conflict-of-interest; this list of winners and risk reduction figures are drawn from www.thehealthproject.com. See the years and the respective applications. The summary can be found at *Albert Einstein Meets Koop, supra* note 208.

wellness company employing a wellness program for its own employees. ²¹⁸ Both investigator bias and self-selection bias suggest that there would be a favorable outcome. The wellness company in question, however, Vitality Group, reported both an increase in BMI and a deterioration in its employees' eating habits in response to its wellness program for its parent corporation, Discovery Health. ²¹⁹ If a wellness company cannot reduce its own employees' weight, it would be unreasonable to expect it to reduce other companies' employees' weights. Just as failing to achieve financial savings might be acceptable if employee health improved, failure to improve employees' health might be acceptable if there were not also a good chance that it will cause harm to employees.

Since 1998, Congress has authorized the USPSTF to determine the value of preventive-care screenings.²²⁰ It assigns grades to common screening tests. An A or a B means that the benefits of undergoing the screening exceed the harms. A D means that the test should not be done because the harms it can cause exceed the potential benefits. In addition to scoring the tests themselves, the USPSTF proposes the frequency at which people should undergo many tests to prevent over-screening. It may not seem logical that too much prevention is bad, but it is.²²¹

The harms of over-medicalization, and over-screening in particular, are well-documented. The harms and shortcomings of over-screening include:

- 1. false positives, causing people to seek unnecessary and possibly harmful follow-up medical care;²²³
- 2. false negatives, causing people to become complacent if they experience unexplained symptoms;²²⁴
- 218. Ike Swetlitz, Should Companies Publicly Report Employees' Weight and Stress Levels?, STATNEWS (Jan. 22, 2016), https://www.statnews.com/2016/01/22/publicizing-employee-health-data/.
- 219. *Id.*; Al Lewis, *Vitality's Glass House: Their Own Wellness Program Fails Their Own Employees*, They SAID WHAT? (Jan. 2, 2016), https://theysaidwhat.net/2016/01/22/vitalitys-glass-house-their-own-wellness-program-fails-their-own-employees/.
- 220. See About the USPSTF, U.S. PREVENTIVE SERVS. TASK FORCE (Oct. 2016), https://www.uspreventiveservicestaskforce.org/Page/Name/about-the-uspstf.
- 221. See generally Alan Cassels, Seeking Sickness: Medical Screening and the Misguided Hunt for Disease (2012).
- 222. See e.g., id.; H. GILBERT WELCH ET AL., OVER-DIAGNOSED: MAKING PEOPLE SICK IN THE PURSUIT OF HEALTH (2012); OTIS WEBB BRAWLEY, HOW WE DO HARM: A DOCTOR BREAKS RANKS ABOUT BEING SICK (2012).
- 223. See, e.g., WELCH ET AL., supra note 222, at 45-60.
- 224. *Id.* at 80. ("[M]ammograms miss about one-quarter of cancers destined to appear during the following year.").

- 3. the possibility of missing the most-aggressive and fastest-growing tumors that grow between screening sessions but catching those slow-growing or otherwise clinically insignificant tumors which may not do harm;²²⁵
- 4. failure to acknowledge that many cancers discovered during screening are better left undetected because they will do no harm; ²²⁶
- 5. findings that are not the focus of the screens, called incidentalomas, that are likely clinically insignificant;²²⁷
- 6. the harms of screening itself, such as radiation, or physical harm, as in colonoscopies. ²²⁸

Though not specifically confined to wellness, false-positive arithmetic is also worth an example. Excluding people already diagnosed with coronary-artery disease or who already know they are at high risk, maybe one in one-thousand employees will suffer a heart attack this year. Assume that there is a magical blood test that can determine who will suffer a heart attack this year with ninety-percent accuracy. If an employee tests positive, his odds of a false positive are not ten percent as would be expected if a test is ninety-percent accurate. Instead, despite the test's magical accuracy, about one hundred out of one thousand employees will test positive, but only one will have a heart attack. Meanwhile, the other ninety-nine employees that tested positive will undergo unnecessary follow-up tests, drugs, and procedures.²²⁹ While patients could be expected not to understand this, even doctors appear to vary greatly in their understanding of false-positive arithmetic.²³⁰

If doctors—following many years of college, medical school, and supervised training—cannot understand these harms and this arithmetic, it

- 225. *Id.* ("There are two reasons why this happens: one is that the image (or the radiologist looking at the image) fails to detect a cancer that is there: the other is that the cancer wasn't there at the time of the test but started growing soon after. Unfortunately, the second explanation is a marker for a more deadly cancer, because it indicates a fast-growing cancer.").
- 226. *Id.* at 53 ("It used to be we thought all cancers progressed . . . but we are learning this assumption is wrong.").
- 227. Id. at 90.
- 228. Cheryl Clark, *Colonoscopy Complications Occur at Surprisingly High Rate*, MedPage Today (Feb. 16, 2016) http://www.medpagetoday.com/gastroenterology/generalgastroenterology/562 04.
- 229. Evan Horowitz, *Why Don't Screening Tests Seem to Help Against Cancer*, BOSTON GLOBE (Feb. 26, 2015), https://www.bostonglobe.com/metro/2015/02/26/oftenscreening-tests-don-help-against-cancer/gvaZGAE3yuMrcEOIzpg7IM/story.html.
- 230. Gerd Gigerenzer & Adrian Edwards, Simple Tools for Understanding Risk: From Innumeracy to Insight, 327 BRITISH MED. J. 741, 741 (2003).

seems unlikely that wellness vendors could do better, especially since the industry lacks any requirements whatsoever for education, training, testing, licensure, compliance, and ethics. Because of their failure to understand basic false-positive arithmetic, vendors almost unanimously support annual screening, believing that more prevention is better and that biometric screening is the answer. ²³¹ They also earn revenue for additional screenings, ²³² creating a moral hazard.

For example, Nebraska's wellness-program sponsors waived all age restrictions for preventive screenings²³³ in order to encourage more employees to get screenings.²³⁴ They wrote that their screening coverage was "greater than guidelines."²³⁵ The waiver reflects Nebraska's—or its vendor's—failure to understand that USPSTF guidelines provide for the optimal screening frequencies in order to balance harms and benefits, rather than a minimum threshold. Age restrictions for screenings are analogous to age restrictions for drivers; legislators have determined that the hazards of allowing those younger than a certain age to drive exceed the benefits. In both cases, waiving the age restrictions would be counterproductive.

Nor is cost a factor in the USPSTF's grades. The USPSTF charter does not allow it to consider costs in grading. ²³⁶ A cost-benefit calculation, as opposed to a harms-benefit calculation, would necessarily result in fewer recommended tests unless screens were costless. Nebraska's decision to waive clinical guidelines is therefore irrational, even if it had been based on the misconception that USPSTF guidelines are constrained by cost considerations.

- 231. See, e.g., Williams, supra note 35.
- 232. The more people who get screened, and the more comprehensive the screen, the higher the price. Few vendors put their pricing right on their websites. Group Health Cooperative would be an example of one that does. *Pricing for Biometric Screenings*, GROUP HEALTH (2013), https://producer.ghc.org/static/pdf/shared/forms/health-plan/population-health/Bio-pricing.pdf (last visited Apr. 1, 2017).
- 233. Erika Fry, Corporate Wellness Programs: Healthy or Hokey?, FORTUNE (Mar. 15, 2017), http://fortune.com/2017/03/15/corporate-health-wellness-programs/.
- 234. WELCOA, FIRST OF ITS KIND: THE STATE OF NEBRASKA'S INTEGRATED PLAN FOR HEALTH 7 (2012), available at https://www.welcoa.org/wp/wp-content/uploads/2014/06/case_study_nebraska.pdf ("[P]reventive coverage within the Wellness Plan is greater than health care reform guidelines, in an effort to encourage the use of preventive care.").
- 235. Id. at 9.
- 236. The USPSTF grades are developed weighing harms and benefits. Costeffectiveness does not affect grades but is listed in "other considerations." See Update on Methods: How to Read the New Recommendations Statement, U.S. PREVENTIVE SERVS. TASK FORCE (July 2007), https://www.uspreventiveservicestaskforce.org/Page/Name/update-onmethods-how-to-read-the-new-recommendation-statement.

As part of waiving those guidelines, Nebraska mailed a reminder to get colonoscopies seven times to twenty thousand employees. The reminder featured a model far too young to need a colonoscopy. ²³⁷ Rather than admit that it had made an error in over-screening the population, the vendor boasted in a prominently displayed sidebar that these screenings had saved the lives of 514 people who had "early stage" cancer. 238 It is not clinically possible for this to have happened. Assuming that five thousand people were screened, ²³⁹ one would expect to find only a couple of cases of cancer, since only about 135,000 new cases are diagnosed annually in the entire United States.²⁴⁰ The vendor then admitted that it had lied about finding 514 cases.²⁴¹ In 2016, the state canceled the program after the vendor admitted it had falsified data.²⁴² The Koop Committee then altered the original application to replace the references to the 514 cases of cancer with a reference to 514 generally harmless polyps. 243 Nebraska's program is not an outlier. Quite the contrary, it received a Koop Award in 2012 and Goetzel referred to it as a "best practice" or "exemplar" on several separate occasions. 244

Examples of inappropriate screening and screening frequencies abound.²⁴⁵ Companies that market USPSTF D-graded screens in order to

- 237. Al Lewis, Mr. Goetzel Covers Up his Cover-Up: The Latest on the Nebraska Koop Award, They Said What? (Sept. 25, 2015), https://theysaidwhat.net/2015/09/25/lies-damn-lies-and-the-nebraska-state-employee-wellness-program/ (providing the no longer circulated Nebraska colonoscopy flyer).
- 238. WELCOA, *supra* note 234, at 14 ("Life-saving, cost-saving catches . . . [of] 514 new early-stage cases of cancer.").
- 239. This assumption is based 5000 being roughly the number of Nebraska employees who agreed to repeat blood draws, which are far simpler and less invasive than colonoscopies.
- 240. Key Statistics for Colorectal Cancer: How Common is Colorectal Cancer?, CANCER.ORG, https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html (last visited Apr. 1, 2017).
- 241. Lewis, supra note 237 (providing the sidebar).
- 242. Id.
- 243. Al Lewis, *Nebraska's Award-Winning Wellness Program Meets an Ignominious Demise*, They Said What? (Apr. 26, 2016), https://theysaidwhat.net/2016/04/26/nebraskas-award-winning-wellness-program-meets-an-ignominious-demise/.
- 244. See, e.g., Ron Goetzel et al., Do Workplace Health Promotion (Wellness) Programs Work?, 56 J. OF OCCUPATIONAL & ENVTL. MED. 931 (2014); Lewis, supra note 237 (quoting and providing screen shots of comments subsequently scrubbed from Ron Goetzel's article, Debunking the Myths About Workplace Wellness, EMPLOYEE BENEFITS NEWS (Nov. 6, 2014)).
- 245. See, e.g., Williams, supra note 35; Al Lewis, The Great Debate, Part 8: Optum's Seth Serxner Jumps In, Throws Himself Under the Bus, THEY SAID WHAT? (Nov. 21, 2016), https://theysaidwhat.net/2016/11/21/the-great-debate-part-8-optums-seth-serxner-jumps-in-throws-himself-under-the-bus/ (Quoting Seth Serxner as

increase revenue despite the documented likelihood of harms from those screens include Star Wellness, AngioScreen, Total Wellness, HealthFair, and Healthfairs USA. ²⁴⁶ Healthfairs USA not only advertises inappropriate screenings with alleged ninety-nine percent accuracy rates, but also offers to bill employees' insurance company directly so that their employer customers do not pay for them. ²⁴⁷

Connecticut's wellness program requires mammograms for women under thirty-nine years old,²⁴⁸ while the USPSTF recommends that women start receiving mammograms at age fifty.²⁴⁹ The USPSTF very specifically states that women should not have routine mammogram screens²⁵⁰ during their forties.²⁵¹ It does not address whether women should have mammograms during their thirties because there is no controversy around whether women that young should routinely get them. It is nearly universally acknowledged that they should not.²⁵² And yet Connecticut requires them.

While many vendors do not market such clearly inappropriate tests, most vendors knowingly market inappropriate screening frequencies for

saying, "[o]ur clients won't let us screen [appropriately]."); HEALTH ENHANCEMENT RESEARCH ORG., AM. COLL. OF OCCUPATIONAL & ENV'T MED. & CARE CONTINUUM ALLIANCE, Biometric Health Screening for Employers, 55 J. OCCUPATIONAL & ENVTL. MED. 1244, 1249 (2013) [hereinafter Biometric Screenings] (implying annual biometric screenings, even while citing UPSTF guidelines (at 1247) that recommend annual screenings only for blood pressure.).

- 246. Lewis & Khanna, supra note 107.
- 247. See Cancer Prevention Screening, HEALTH FAIRS USA, http://www.healthfairsusa.com/ (last visited Apr. 1, 2017) (to access their cancer prevention screening section, click "cancer prevention screening," which will lead you to a screen called "your personalized health fair," from there, click "cancer prevention screening" once again). But see Al Lewis, HealthFairs USA: A Wellness Program that Defies Description, They Said What? (Oct. 6, 2016), https://theysaidwhat.net/2016/10/06/healthfairs-usa-a-wellness-program-that-defies-description/ (critiquing Health Fairs USA).
- 248. Becker, supra note 146.
- 249. Final Recommendation Statement: Breast Cancer: Screening, U.S. PREVENTIVE SERVS.

 TASK FORCE (Jan. 2016),
 https://www.uspreventiveservicestaskforce.org/Page/Document/Recommendat
 ionStatementFinal/breast-cancer-screening1.
- 250. "Routine" and "screens" imply testing large populations with no indication for the test. Some women, due to genetic predisposition or their own history, have indications—and should get mammograms before age 50. However, those would not be considered "screens."
- 251. Id.
- 252. *Id.*; see also Sarah Khlein, *Why Getting a Mammogram May Cause More Trouble Than It's Worth*, PREVENTION (Jan. 19, 2016), http://www.prevention.com/health/trouble-getting-mammogram-40 (providing a lay explanation of the inadvisability of mammograms for women under 40).

tests that every vendor offers.²⁵³ For example, the USPSTF has recommended that normal men and women begin receiving routine cholesterol tests at age thirty-five and forty-five, respectively.²⁵⁴ Most vendors, however, advise their customers to test employees of all ages.²⁵⁵ Only two vendors have attempted to explain their decision to ignore USPSTF guidelines.²⁵⁶ United Healthcare's ("UHC") Seth Serxner, who leads the company's wellness practice, stated that UHC flouts guidelines because clients "won't let us screen" appropriately.²⁵⁷ However, UHC's spokesperson, Lauren Mihajlov, was unable to provide an example in which a client had prevented UHC from screening appropriately, even after she insisted that such clients existed.²⁵⁸ Further, it appears that, according to Optum's own marketing materials, paying for Optum's annual—and therefore inappropriate—screenings is required as part of purchasing their group health insurance.²⁵⁹

Whereas UHC offered an excuse for ignoring guidelines, Healthmine publicly proposed a justification for its screening-maximization model; it explained that the United States "Preventative" [sic] Services Task Force is wrong, and that the more people get screened, the more likely they are to become healthier. ²⁶⁰ They offer neither a scientific rationale for this claim nor any deconstruction of the USPSTF's methodology. ²⁶¹

- 253. Only three vendors, It Starts with Me, Sterling Wellness, and Quizzify, are on the record as recommending against annual screens of all employees. See generally Validated Organizations, VALIDATION INST., http://www.validationinstitute.com/validated-organizations/#it-starts-with-mehealth (last visited Apr. 1, 2017). Yet the USPSTF lists only one screen, blood pressure, as appropriate to do on an annual basis to all adults. USPSTF A and B Recommendations, U.S. PREVENTIVE SERVS. TASK FORCE (June 2016), https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/.
- 254. Lipid Disorders in Adults, supra note 32.
- 255. While it is possible that vendors other than the three mentioned above recommend against annual screens for all employees (plus the unverified claim by Optum's Seth Serxner that Optum opposes them), the author has been able to identify no other vendor which claims to screen according to guidelines instead of annually.
- 256. See, The Great Debate, Part 8, supra note 245; Williams, supra note 35.
- 257. Audio recording: Population Health Alliance 16th Annual Leadership Forum (Nov. 2 2015), available at https://ccavoice.wordpress.com/2016/10/12/the-great-debate/ (click "here" on "Download the recording here"); see also The Great Debate, Part 8, supra note 245 (providing excerpts and explanations).
- 258. Correspondences between Lauren Mihajlov, United Healthcare, and Al Lewis, January 5, 2016 (on file with author).
- 259. Al Lewis, *Is Optum Alternative-Facting?*, THEY SAID WHAT? (Feb. 22, 2017), https://theysaidwhat.net/2017/02/22/is-optum-alternative-facting/.
- 260. Williams, supra note 35.
- 261. Id.

Wellness programs also routinely require employees to get annual checkups. Even if annual checkups were costless, it is well-established that checkups are more likely to harm than benefit employees. ²⁶² Choosing Wisely, a joint project of the American Board of Internal Medicine Foundation and *Consumer Reports*, also recommends against them for the same reason. ²⁶³ Despite these recommendations, wellness vendors and wellness programs routinely include checkups. ²⁶⁴ One vendor, Passport Health, recommends that annual physicals be expanded to include two checkup staples from the 1950s to 1980s—complete blood counts and chest x-rays ²⁶⁵—despite the overwhelming evidence that those two tests are more likely to create harms than benefits as part of a checkup. ²⁶⁶ Passport Health's website also states:

Fortunately, the detrimental side effects and mounting costs of many diseases can be avoided altogether. What is the best way to avoid disease? The answer is simple: *early detection*. Indeed, employee wellness programs that include physical exams and biometric testing can detect diseases in their earliest and most treatable stages, significantly reducing employer medical expenses and, of course, also potentially saving employees' lives.²⁶⁷

Bravo Wellness's president was quoted as part of a *USA Today/Kaiser Health News* article questioning the benefits of workplace wellness as

^{262.} Ateev Mehrotra & Allan Prochazka, *Improving Value in Health Care—Against the Annual Physical*, 373 N. Eng. J. Med. 1485, 1487 (Oct. 2015).

^{263.} Consumer Reports, Health Checkups: When you Need Them—and When You Don't, Choosing Wisely (Mar. 2014), http://www.choosingwisely.org/patient-resources/health-checkups/.

^{264.} See e.g., David Rook, Effective Wellness Programs Focus on Screenings and Immunizations Over Behavior Modification, JP GRIFFIN GROUP (July 9, 2015), https://www.griffinbenefits.com/employeebenefitsblog/effective-wellness-programs-screenings-immunizations (providing an example of a program that simply assumes the employees will get a routine annual checkup); Routine Annual Physical (500 points) and/or Biometric Screening (125 points), BP, http://hr.bpglobal.com/LifeBenefits/Shared/Pages/BP-Life-benefits/BP-Wellness-Programs/Routine-Annual-Physical----500-Points.aspx (last visited Apr. 1, 2017) (offering incentives for annual checkups).

^{265.} Employee Physical Examinations, PASSPORT HEALTH USA, https://cdn.passporthealthusa.com/wp-content/uploads/2013/12/ROI-Physical-Exam.pdf?127b2a (last visited Apr. 1, 2017).

^{266.} *Id.*; Harriet Hall, *Re-thinking the Annual Physical*, SCIENCE-BASED MEDICINE (Feb. 21, 2012), https://www.sciencebasedmedicine.org/re-thinking-the-annual-physical/.

^{267.} See Employee Physical Examinations, supra note 265.

saying that annual physicals could lead to fewer cancers, ²⁶⁸ a claim with no support in academic literature. ²⁶⁹

Wellness programs also encourage unhealthy dieting behaviors by rewarding employees for participating in crash-dieting contests. There is no evidence that corporations can help employees maintain weight loss in the long term.²⁷⁰ No program reported in the academic literature has ever tracked employee weight for a period exceeding a year, including dropouts, and showed sustained weight loss.²⁷¹ The single study lasting a year ("Penn Study") was also the most rigorous in terms of study design.²⁷² The study showed that a variety of incentives and penalties aimed at promoting weight loss had virtually no impact.²⁷³ Further, once the incentives and penalties were removed, employees regained the weight.²⁷⁴ Even Goetzel admits that biggest-loser contests "aren't actually effective, and can be quite harmful when people try to lose weight too quickly."²⁷⁵

As was the case with the Connecticut study, which was also performed by investigators connected to the wellness industry, the Penn Study's investigators also came to a conclusion that was much more optimistic than the data;²⁷⁶ the data appeared to support a conclusion that incentives and penalties do not work to cure obesity any more than they work to cure other diseases.²⁷⁷ Instead of concluding that incentives simply do not work since five combinations or permutations of incentives and penalties failed, Dr. Patel concluded that

the incentives may have failed for a number of reasons. The \$550 premium discount may not have been large enough. Bundling the financial reward into the insurance premium on a paycheck rather

- 268. Julie Appleby, *Benefits of Workplace Wellness Programs Questioned*, KAISER HEALTH NEWS (Oct. 3, 2015), http://www.usatoday.com/story/news/2015/10/03/kaiserworkplace-wellness-programs-overtesting/73109946/.
- 269. See High Impact Journals, Superfund Research Program, NAT'L INST. OF ENVTL. HEALTH Sci., https://tools.niehs.nih.gov/srp/publications/highimpactjournals.cfm (last visited Apr. 1, 2017) (listing "high-impact literature," which includes New England Journal of Medicine, the Journal of the American Medical Association, and Health Affairs, between 2009 and July 2016).
- Alfred Lewis, Vikram Khanna & Shana Montrose, Employers Should Disband Employee Weight Control Programs, 21 Am. J. of Managed Care e91, e92-93 (2015).
- 271. See generally High Impact Journals, supra note 269.
- 272. Mitesh S. Patel, et al., *Premium-Based Financial Incentives Did Not Promote Workplace Weight Loss in a 2013-15 Study*, 35 HEALTH AFF. 71, 71 (2016).
- 273. Id. at 76.
- 274. Id.
- 275. Greg Kunkel, *Conversation with Dr. Ron Goetzel: A Culture of Well-Being* (Feb. 19, 2016), https://perksatwork.nextjump.com/2016/02/19/culture-of-health/.
- 276. Patel et al., supra note 272, at 77.
- 277. Id. at 71.

than making a separate payment to the worker may have affected how it was perceived. Other details—such as the fact that participants weighed themselves at work rather than at home—may have been off-putting to some participants.²⁷⁸

He did not conclude that the wide variety of incentives and penalties tested failed because it is not possible to pay people to lose weight or fine them if they do not. That conclusion would have been supported by the five examples of incentives and penalties in the study.²⁷⁹ He also never addressed why a company would offer a \$550 incentive to its employees to encourage them to lose weight when most evidence finds no link between weight and healthcare spending or productivity.²⁸⁰ A 2017 study published in the *Journal of Occupational and Environmental Medicine* supports that finding as well, showing that incentives have no effect on health outcomes. Researchers associated with a very highly regarded wellness vendor conducted this study, and thus would not have been tainted by investigator bias.²⁸¹

Due to the political difficulty of creating RCTs in a corporate setting, only one employer has ever conducted and published an RCT on diet. ²⁸² Both groups consisted of diabetic or overweight employees. ²⁸³ The study group did not lose more weight than the control group, ²⁸⁴ and members of the study group increased their consumption of carbohydrates relative to the control group while reducing their consumption of fat. ²⁸⁵ The authors concluded that this was a successful outcome, ²⁸⁶ though carbohydrate consumption is widely believed to be a factor hastening the development and progression of diabetes. ²⁸⁷

While whether increased carbohydrate consumption is harmful is controversial, whether employer-sponsored crash-dieting programs are harmful is not. These programs, also known as biggest-loser contests or

- 278. Id. at 76.
- 279. As this article was going to press, another study came to the same conclusion—that incentives did not generate weight loss or other behavior change. Nathan A. Barleen et al., *Outcome-based and Participation-based Wellness Incentives*, 59 J. Occup. Envil. Med. 304 (2017).
- 280. Lewis et al, supra note 270, at e91-e94.
- 281. Barleen et al., supra note 279.
- 282. See S. Mishra et. al, Nutrient Intake in the GEICO Multicenter Trial: The Effects of a Multicomponent Worksite Intervention, 67 Eur. J. CLINICAL NUTRITION 1066 (2013).
- 283. Id. at 1067.
- 284. Id. at 1068.
- 285. Id.
- 286. Id. at 1070.
- 287. See Jeff S. Volek & Richard D. Feinman, Carbohydrate Restriction Improves the Features of Metabolic Syndrome. Metabolic Syndrome May be Defined by the Response to Carbohydrate Restriction, 2 NUTRITION & METABOLISM 1, 4 (2005).

weight-loss challenges, may actually be harmful for two reasons: first, the monetary reward creates an incentive to binge before the first weigh-in and then fast before the last, and second, repeated involvement in these contests causes weight cycling, which has a negative impact on health.²⁸⁸ One website suggests that employees cheat in these contests, teaching them to gain as much weight as possible as quickly as possible so that by the initial weigh-in, the employee is "a big bloated sloshing mess that needs to go to the bathroom really bad."²⁸⁹ Further, a recent study published in the *New England Journal of Medicine* finds that, while bad for everyone, weight-cycling is especially risky for people with diagnosed or undiagnosed heart disease. Ironically, this is exactly the cohort whose future heart events and claims costs should be most concerning to employers.²⁹⁰ Absent any refutation of these apparently significant harms from crash-dieting contests, it is difficult to imagine a good reason to undertake them.

Wellness is unusual in healthcare because its evidentiary basis is so non-existent that critics need not develop their own databases and engage in a debate about whose facts are right. Instead, as has been shown multiple times in this article, it is usually possible to show that the industry's own data, taken at face value, shows the opposite of what it intends to show. Or, as stated in lay terms in *Surviving Workplace Wellness*: "In wellness, you don't have to challenge the data to invalidate it. You merely have to read the data. It will invalidate itself." ²⁹¹

Nowhere is this more evident than in the Wellsteps program conducted on behalf of the Boise School District, which won a Koop Award.²⁹² The harms are laid out both objectively and subjectively in Wellsteps' application. Objectively, it lists changes in employees' weight, glucose, cholesterol, and blood pressure, stating that there were 5293 year-over-year improvements and 6397 deteriorations in health status. Thus, the organization's health, objectively speaking, deteriorated. A deterioration in employees' health of this magnitude cannot be explained by aging for many reasons, the most important of which is that the data was adjusted for age

^{288.} See Weight Cycling . . . Facts About "Yo-Yo" Dieting, MEDICINENET (last updated Aug. 27, 2003), http://www.medicinenet.com/script/main/art.asp?articlekey=21745; see also Heather Sayles Lehman, Why 'The Biggest Loser' At Work Doesn't Work, HUFFINGTON POST (Jul. 12, 2016), http://www.huffingtonpost.com/entry/why-the-biggest-loser-at-work-doesnt-work_us_577c37f5e4b0ad1e7bff6504.

^{289.} Biggest Loser Competition? Here is How to Win!!, HEALTH STATUS, https://www.healthstatus.com/health_blog/body-fat-calculator-2/biggest-loser-competition-win/.

^{290.} NYU LANGONE MED. CTR., Body Weight Fluctuations Linked to More Deaths in People with Coronary Artery Disease, NewsWise (Apr. 4, 2017), http://www.newswise.com/articles/body-weight-fluctuations-linked-to-more-deaths-in-people-with-coronary-artery-disease.

^{291.} AL LEWIS & VIK KHANNA, SURVIVING WORKPLACE WELLNESS WITH YOUR DIGNITY, FINANCES AND (MAJOR) ORGANS INTACT 24 (2014).

^{292.} Aldana, supra note 165.

and sex. Confirming the net risk-factor deterioration was the subjective answer to the single most important question in a health interview designed to rate employee health: "How would you rate your health?" The average answer declined from 7.96 to 7.92 over two years. 294

It is therefore possible to conclude that—at least in one, carefully measured, award-winning program described as the best program of 2016—wellness programs harmed employees. But both harms were obscured; the columns listing improvements and deteriorations were not totaled in the award application, nor did anyone on the Koop Committee total them, ²⁹⁵ even though an article in which the Committee members were quoted had already questioned the total. ²⁹⁶ Further, the employees' perception that their health had deteriorated was described as an "improvement" in the preceding paragraph and was ignored when the Koop was bestowed upon Wellsteps for this performance. ²⁹⁷

D. The Ethics of Wellness: Deliberate or Negligent Data Falsification

The self-described wellness-industry leaders, including the members and sponsors of HERO and the Health Project, regularly produce data that is demonstrably false. ²⁹⁸ Consider McKesson, the 2015 award winner. McKesson achieved a one-percent risk reduction, which generated a seven-percent cost reduction. If every one-percent reduction in risk truly did generate seven percent in cost savings, then a fifteen-percent reduction in risk factors for heart disease and diabetes would theoretically be more than enough to wipe out all spending on everything.

The Nebraska example was similar. While the application did not disclose exactly how much money the 5199 screened employees spent based on yearly employer-paid healthcare spending for a single employee,

^{293.} See, e.g., A. Bowling, Just One Question: If One Question Works, Why Ask Several?, 59 J. EPIDEMIOLOGY & CMTY. HEALTH 342 (2005).

^{294.} Aldana, supra note 165.

^{295.} See Boise School District: Critique, HEALTH PROJECT, http://thehealthproject.com/winner/boise-school-district/ (last visited Apr. 1, 2017).

^{296.} See Begley, supra note 10 (providing the above quotes); How the 2016 Koop Award Raises Lying to an Art Form, supra note 158 (providing a critique of that article and the Koop Committee's reaction to it).

^{297.} Aldana, supra note 165.

^{298.} Begley, *supra* note 10 (addressing the 2015 and 2016 Koop award winners); Shutan, *supra* note 107 (addressing 2015's Koop Award controversy); Martha Stoddard, *Nebraska's Acclaimed Wellness Program Coming under Fire*, OMAHA WORLD HERALD (July 15, 2013), http://www.omaha.com/livewellnebraska/nebraska-s-acclaimed-wellness-program-under-fire/article_ccf3e8d8-4348-54e6-bb83-cca843dcd9a7.html (addressing the controversy surrounding the 2012 winner). *TheySaidWhat?.com* invalidates most award-winners since 2010. Enter the name of the winner into the "search" box.

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one can assume that the employees spent about five thousand dollars each, ²⁹⁹ or about twenty-six million dollars in total. About three percent of them fell to low-risk status. Though so few employees fell to low-risk status, Nebraska alleged it saved \$4.2 million. ³⁰⁰ If every three-percent reduction in risk truly did save \$4.2 million, then an eighteen-percent reduction in risk factors for heart disease and diabetes would theoretically be almost enough to wipe out all spending on everything.

The most dramatic example is the 2016 award winner, Wellsteps, whose CEO was a Koop committee member until shortly before the award was announced. Employee risk factors actually increased, but costs allegedly fell by roughly one-third, more than in any other program. The Health Project did not address this apparent invalidity when bestowing the Koop on Wellsteps, though the deterioration in health indicators is easily tallied or observed from the figures in the award applications. Further, when asked about how an award for employee health improvement could go to an applicant admitting that employee health deteriorated, Goetzel explained that the committee "would look askance at an application which said everything went exactly right." 303

There were also two instances where applications for Koop Awards were falsified retroactively. 304 One was the 2011 Eastman Chemical/Health Fitness Corporation award discussed above, in which the x-axis labels were eliminated once an exposé was published. 305 The other was for the 2012 Nebraska award, whose outcomes report originally included claims of

- 299. Christina Merhar, FAQ How Much Does it Cost to Provide Health Insurance to Employees (Sept. 28, 2015), https://www.zanebenefits.com/blog/faq-how-much-does-it-cost-to-provide-health-insurance-to-employees.
- 300. Stoddard, supra note 298.
- 301. Steven Aldana, Workplace Wellness Beats the S&P Again and Again and . . . , LINKEDIN (Dec. 31, 2015), https://www.linkedin.com/pulse/workplace-wellness-beats-sp-again-dr-steven-aldana.
- 302. See Aldana, supra note 165 (Tallying the total improvements and the total deteriorations revealed in Table 4 shows that 5293 indicators improved while 6297 deteriorated. Observing the decline in Table 2 from 7.96 to 7.92 in self-rated health is the subjectively reported counterpart to the objectively reported biometrics.); see also Begley, supra note 10; Albert Einstein Meets Koop, supra note 208.
- 303. Begley, supra note 10.
- 304. These awards are shown, together with recently added their "Erratum" statements that acknowledge the correctness of our work. See generally C. Everett Koop National Health Awards, HEALTH PROJECT, www.thehealthproject.com (last visited Apr. 1, 2017).
- 305. Frakt, *supra* note 102 (discussing the x-axis and the "failure" of the original analysis); *see also* Al Lewis, *Koop Award Committee Meets Sergeant Schultz*, They SAID WHAT? (Sept. 8, 2015), https://theysaidwhat.net/2015/09/08/koop-award-committee-meets-sergeant-schultz/.

"cost-saving, life-saving catches" on 514 state employees alleged to have colon cancer. 306

Life-Saving, Cost-Saving 'Catches'

With its targeted messaging strategy, the State of Nebraska has helped to catch 514 new cases of early stage cancer before it was too late!

Figure 8. The original heading and the original claim that Nebraska's wellness program and its vendor, Health Fitness Corporation, made in reference to cancer victims.

As described earlier, it is not possible to catch 514 cases of colon cancer by screening several thousand people; in the United States, only about one in 3000 people are diagnosed with it annually. Screening several thousand people should have yielded only a very small number of cases; to catch 514 cases, they would have had to screen more than 1.5 million people. Statistically, it should have been quite apparent to the Koop evaluators that the claim was falsified. This was especially true after Health Fitness Corporation's Chief Medical Director and Wellness Officer admitted that the claim was falsified. When confronted with the impossibility of the claim that Nebraska caught 514 new cases of colon cancer in 2012, the Chief Medical Director described the difference between having cancer and not having cancer as "semantics."

^{306.} Though the actual type of cancer is not mentioned in the screenshot, the cancers were mostly colon cancer, as disclosed by the medical director of the project, Dennis Richling, in Stoddard, *supra* note 298, and now stated in the application, screenshotted below, as "mostly colon."; The screenshot below is drawn from the original outcomes report, which is available from the author, but which has been removed from the Health Fitness Corporation website; the colon cancer flyer is available in Al Lewis, *The Latest on Nebraska: Ron Goetzel Covers up his Cover up*, THEY SAID WHAT? (Sept. 21, 2016), https://theysaidwhat.net/2016/09/21/the-latest-on-nebraska-ron-goetzel-covers-up-his-cover-up/.

^{307.} Colorectal Cancer Facts and Figures, Am. Cancer Soc'y, https://www.cancer.org/research/cancer-facts-statistics/colorectal-cancer-facts-figures.html (last visited Apr. 1, 2017).

^{308.} Stoddard, supra note 298.

^{309.} Id.

The wording elsewhere on Nebraska's original award application was changed accordingly on November 2, 2015, after a noted health economist and journalist inquired about the impossibility of the award-winning finding. In 2012, prior to the journalist's inquiry, the award application indicated that "during the two year period, 514 new cases were detected with an early stage of cancer... unfortunately, 26 new cases were diagnosed with a late stage of cancer." After the journalist's inquiry, the application was revised to state that "during the two year period, 514 benign colorectal polyps and precancerous lesions of the cervix were detected and 26 new cases were diagnosed." The original statement in question appeared in a formal 2012 letter from the Nebraska governor's office as part of the original application.

While negligence and general innumeracy cannot be ruled out in some cases, deliberate falsification is widespread.³¹⁴ One example is Wellsteps' ROI Calculator, an allegedly interactive model designed to demonstrate the financial benefit of wellness programs. The model allows users to enter a range of assumptions for possible annual healthcare spending and percentages of employees who smoke or are obese, both before and after the program.³¹⁵ The model, however, is fabricated. If the cell labeled "Annual % Cost Increase" is set to zero, as an economist would recommend in order to avoid confounding the results with inflation, the model invariably yields a savings of \$1359 per employee in the final year of the calculation, no matter what variables the user enters for obesity and smoking, as the two following screenshots illustrate. In the first example, the program was perfect, wiping out obesity and smoking in a workforce in which nearly every employee was an obese smoker.

^{310.} Linda Riddell, of www.healtheconomy.net, interviewed Mr. Goetzel but did not publish the interview.

^{311.} See Al Lewis, Cancergate: Did a Koop Award Committee Member Commit a Crime?,

THEY SAID WHAT? (Mar. 29, 2016),

https://theysaidwhat.net/2016/03/29/cancergate-did-a-koop-award-committee-member-commit-a-crime/.

³¹² Id

^{313.} See State of Nebraska, HEALTH PROJECT, http://thehealthproject.com/winner/state-of-nebraska-wellnessoptions/ (last visited Apr. 1, 2017).

^{314.} Visit ROI Calculator, WELLSTEPS, https://www.wellsteps.com/roi/resources_tools_roi_cal_health.php (last visited Apr. 1, 2017), which will be the first example. Enter "0" for "Annual % Cost Increase." Then enter whatever variables you like in the other 6 boxes. Then hit: "Calculate" and "Impact of Wellness Programs." As of this writing and for the previous 5 years, the "savings" column will max out at \$1358.50/employee regardless of changes in obesity or smoking over the course of the program.

^{315.} See Id.



Figure 9. Wellsteps ROI model when highly favorable information is entered. 316

In the next example, the workforce was perfectly healthy to begin with, so no improvement was possible, but the savings are still \$1359.



Figure 10. Wellsteps ROI model when there is no improvement possible.317

^{316.} Id.

^{317.} Visit Id. Enter "0" for "Annual % Cost Increase." Then enter whatever variables you like in the other 6 boxes. Then hit: "Calculate" and "Impact of Wellness Programs." As of this writing and for the previous 5 years, the "savings" column will max out at \$1358.50/employee.

In other words, the answer is always the same, regardless of the other variables entered, once inflation is eliminated.

Wellsteps' reaction to this author's initial exposé on this topic was to prevent modelers from entering increases in smoking and obesity rates or low annual rates of spending.³¹⁸ Prior to the exposé, even dramatic deteriorations in workforce health generated \$1359 in savings.³¹⁹ Annual spending figures below \$1359 per employee created negative spending in the final year.³²⁰ Of course, negative spending is mathematically impossible; it would require the health plan to pay the employer a monthly premium.

The model's underlying algorithm, which has shown \$1359 per employee in savings in the last year since its inception, remained unchanged. Wellsteps' public reaction to this exposé was to send out a mass email to health-insurance brokers stating that the model was based on "every wellness ROI study ever published." This email was sent to a broad distribution list; multiple people forwarded this email to this author. The email alleged that "11,000 brokers and consultants have used" Wellsteps' ROI calculator to "estimate the impact of wellness on health care costs . . . produce client-specific reports that show wellness impact, [and] help [their] clients implement effective wellness programs." 323

Wellsteps is a particularly compelling example for two reasons. First, it demonstrates wellness vendors' perception that human-resources executives and consultants are so innumerate that they will believe what they are told or accept invented figures because eleven thousand other people are alleged to have accepted them, rather than enter data into the model to test the self-evident proposition that the model is fabricated. Second, this example demonstrates the failure of self-regulation in this field. Rather than be sanctioned, as Wellsteps would be if it presented this model to the general public and were subject to consumer protection regulations, Wellsteps' CEO maintained his seat on the Health Project until he resigned before the Health Project bestowed its 2016 award on his company to avoid the obvious conflict of interest. As a member of The

^{318.} See Id. (showing it is no longer possible to enter increases in smoking or obesity, or annual spending below \$2000/person.).

^{319.} Al Lewis & Vik Khanna, Why Are Al Lewis and Vik Khanna Such Jerks?, HEALTH CARE BLOG (Apr. 24, 2014), http://thehealthcareblog.com/blog/2014/04/24/why-are-al-lewis-and-vik-khanna-such-jerks/.

^{320.} Id.

^{321.} Entering any set of assumptions into the model generates \$1359/employee in savings in the final year, provided that "0%" is entered into "annual % cost increase." *ROI Calculator*, *supra* note 314.

^{322.} Al Lewis, Wellsteps ROI Calculator Doesn't Calculate ROI . . . and That's the Good News," They SAID WHAT? (July 23, 2014), https://theysaidwhat.net/2014/07/23/wellsteps001/.

^{323.} Id.

Health Project, he helped bestow the Koop on many other programs whose outcomes were invalid.

As discussed earlier, Interactive Health's consulting firm, Zoe Consulting, originally wrote a report misattributing massive savings to trivial risk reduction. A subsequent version of report from which that instructive example was extracted, currently available on the Interactive Health website, now omits the table and does not include any acknowledgement of the one-percent favorable risk migration or an explanation for how such a trivial risk reduction could support the eight-figure savings claims. Zoe Consulting also claims in this revised report to be a "two-time C. Everett Koop award-winner for outcomes achieved in maternity and disease management," which is also false. 324

Optum's claim that the company wants to screen appropriately but "clients won't let [them]" is belied by marketing materials that say "participation in our wellness program is a Savings4Health requirement," 325 and Savings4Health does require annual biometric screens. 326 The marketing materials also continue to cite the Harvard Study as justification for the ROI from wellness, along with an ROI claim attributed to WELCOA that WELCOA's Executive Director says neither he nor anyone now at WELCOA made or, to his knowledge, believes. 327

V. The Employee Health and Wellness Program Code of Conduct

Lest the reader reach the conclusion that all wellness vendors and consultants are dishonest or incompetent, there are certainly exceptions. The program at Cummins—which itself is recognized as a "best place to work" recently received a very favorable profile in Fortune. The author himself participates in an exemplary program at his wife's workplace, Boston College. Screening is done every three years—roughly corresponding to USPSTF guideline—and measures USPSTF A- and B-rated biometric values only. The advice offered on the health risk assessment and by the wellness coaches—who are employees of Harvard Pilgrim Health

^{324.} Interactive Health & Zoe Consulting, Inc., supra note 198, at 9; Winners Listed Alphabetically, Health Project, http://thehealthproject.com/winning-programs/winners-listed-alphabetically/ (last visited Apr. 1, 2017) (providing a list of Koop award winners).

^{325.} Lewis, supra note 259.

^{326.} Missouri Health and Wellness Programs and Guidelines for Each, UNITED HEALTHCARE (May 2014), http://broker.uhc.com/assets/UHCEW696595_wellness.grid.6_17.pdf.

^{327.} Lewis, supra note 259.

^{328.} *The 25 Best Places to Work*, FORBES, https://www.forbes.com/pictures/elhm45eeke/no-20-cummins/#d4ad6cc25f1a (last visited Apr. 1, 2017).

^{329.} Fry, supra note 233.

Care, which itself is consistently rated among the country's best health plans³³⁰—is also up to date and in accordance with best practices.

Further, one wellness vendor, U.S. Preventive Medicine ("USPM"), is among the thirty-nine employee-health-services vendors to achieve validation of its outcomes through the Care Innovations Validation Institute.³³¹ USPM was able to reduce WSMAs by a substantial percentage, as indicated in the writeup.³³²

It may also be possible to offer a wellness program that neither forces employees to participate nor incentivizes employees to take short-term steps that may harm long-term health, while focusing employees on long-term health and rewarding them for staying healthy.³³³ However, this approach is at total variance with the industry's focus on near term results.

The Ethical Wellness website³³⁴ offers a voluntary Employee Health and Wellness Program Code of Conduct. It captures best practices, in contradistinction from most of this article. Vendors, consultants, wellness practitioners, and employers may endorse this Code³³⁵ if they believe they can adhere to the standards of, for example, not harming employees and not lying about outcomes.³³⁶ Employers do not endorse the Code of Conduct lightly, because if they were to endorse and then violate the Code, it could create a cause of action as a material misrepresentation.

The rapidly increasing number of vendors and consultants who are endorsing this code—as of this writing, none of which are also portrayed in this essay—does indicate that much of the industry agrees with this article's findings that the behaviors and actions of leading figures and award committees in this field are unacceptable, and that ethics and competence should be recognized and rewarded.

- 330. HARV. PILGRIM HEALTHCARE, HARVARD PILGRIM HEALTH CARE RATED AMONG THE NATION'S HIGHEST-RATED HEALTH PLANS BY NCQA (2016), available at https://www.harvardpilgrim.org/pls/portal/docs/PAGE/MEMBERS/ABOUT/NEW S/NEWSROOMPDF/PR-NCQA-2016.PDF.
- 331. Product and Service Vendors, VALIDATION INST., https://www.validationinstitute.com/validated-organizations/ (last visited Apr. 1, 2017) (Disclosure: the author's company, Quizzify, the leading employee health-literacy vendor, also has validation from the Validation Institute.)
- 332. About this Validation: USPM, VALIDATION INST., https://www.validationinstitute.com/validated-organizations/#uspm (last visited Apr. 1, 2017).
- 333. Al Lewis, A Wellness Program Everyone Can Love, Ins. Thought Leadership (Apr. 11, 2017), http://insurancethoughtleadership.com/a-wellness-program-everyone-can-love/.
- 334. www.ethicalwellness.org
- 335. An example of a Fortune 500 employer that endorses the Code would be Cummins. Cummins was also profiled for its innovative approach to wellness in *Fortune*, and is named by *Fortune* as a "best company to work for." *See* Fry, *supra* note 233.
- 336. Quizzify is also an endorser of the Code of Conduct.

A voluntary code of conduct is no substitute for oversight, and the wellness industry completely lacks vendor-specific regulations, licensing and educational requirements, and other forms of oversight.³³⁷ This lack of regulation allows one major vendor, Star Wellness, to sell franchises, with requirements for franchisees that are not found in other, regulated, healthcare endeavors.

Star specifically states that "you do not need a medical background" to sell franchises. ³³⁸ Instead, it assures applicants that a background in sales is sufficient, and lists municipality administration as an alternative qualification. ³³⁹ The major requirement is a \$67,000 franchise fee. ³⁴⁰ Once a franchisee has paid, he receives up to five days of classroom training. ³⁴¹ Then, he is a wellness vendor, and can give employees advice with no restrictions and no recourse if the advice is incorrect.

The very existence of this unregulated franchise opportunity illustrates why wellness providers should be regulated. Indeed, there are three independent reasons why they should be subject not just to any regulations, but rather to stricter regulations than other healthcare providers. First, possible harms to employees alone would be a sufficient reason for basic oversight. Second, the involuntary nature of wellness prevents employees from making a free-market response to these harms. Employees cannot just ignore these vendors. Other healthcare costs people money if they opt in. Wellness costs people money if they opt out.

Finally, paternalistic programs necessitate the highest evidence-based standards of all. Very few healthcare-related interventions are *de facto* required. Those that are, such as seat belts and childhood vaccines, have cost-benefit ratios so high that, with rare exception, no one even studies them anymore. For instance, vaccines have wiped out smallpox and polio in the United States at a cost of only a few dollars per dose to maintain immunity against the slight chance the virus will be introduced again.³⁴²

- 339. Id.
- 340. Id.
- 341. Id.

^{337.} A list of existing laws and regulations may be found at *Biometric Screenings*, supra note 245. The laws and regulations pertain exclusively to the drawing and analysis of blood. They do not cover the clinical validity of the advice or the advisability or USPSTF ratings of the screened biometric values.

^{338.} Medical Services Franchise Questions – Star Wellness, STAR WELLNESS USA, http://starwellnessusa.com/franchiseopportunity/franchisefaqs/ (last visited Apr. 1, 2017).

^{342.} David Williams, Cost, Need Questioned in \$433-Million Smallpox Drug Deal, L.A.

TIMES (Nov. 13, 2011), http://articles.latimes.com/2011/nov/13/nation/la-nasmallpox-20111113 (noting Smallpox vaccines only cost \$3 per dose); E. C. Pune,
Injecting Competition, ECONOMIST (July 19, 2013),
http://www.economist.com/blogs/feastandfamine/2013/07/polio-vaccines
(noting Polio vaccines cost \$5 per dose).

Seat belt cost-benefit ratios exceed 100 to 1.343 Wellness is the only *de facto* required healthcare intervention that has a negative benefit-cost ratio, according to the industry's own data. Even the wellness industry's leading proponent, Ron Goetzel, claims that a one-to-one ROI is acceptable "only if you can improve the health . . . of your workers." This article has shown, however, many instances of likely or actual negative impacts on health—too-frequent screening, inappropriate screening, crash-dieting contests, carefully measured deterioration in employee health caused by the 2016 best wellness company, and a complete lack of impact on health outcomes on a nationwide level—that would cause one to question the entire premise that financially coercing employees into corporate wellness programs is good for employers, society, or employees.

Despite the potential for harms arising from ignoring USPSTF guidelines, it is unlikely that Congress would pass a law prohibiting harmful screening practices, given the BRT and the United States Chamber of Commerce's influence. Their priority is preserving employers' ability to tie thirty to fifty percent of employee healthcare premiums to employee behavior. It is unlikely they would support any constraints on workplace wellness, even to preserve employee health, if such constraints would impede employer discretion over the deployment of screening and other wellness programs. The House Committee on Education and the Workforce recently approved exactly that, on a party-line twenty-two to seventeen vote. The Preserving Employee Wellness Programs Act would allow employers to genetically screen both employees and their families as part of wellness programs and would increase the cap on penalties by applying it to the entire family premium instead of just the employee-specific premium.³⁴⁵ Were this bill to be enacted, it would free wellness programs from the constraints imposed on employers by the Americans with Disabilities Act and the Genetic Information Nondisclosure Act, while making non-participation more financially onerous for employees.³⁴⁶

Therefore, this article advocates only a politically feasible regulation that would require employers to disclose the likelihood of harms from crash-dieting contests, annual checkups, and screens not carrying a USPSTF grade of A or B, and to give employees the option to undertake a different, harmless wellness activity to avoid forfeiture. Under this regulation, absent

^{343.} Lives Saved in 2015 by Restraint Use and Minimum-Drinking-Age Laws, U.S. DEP'T OF TRANSP. (Aug. 2016), https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/812319 (noting roughly 14,000 lives per year are saved by seatbelts).

^{344.} Kunkel, supra note 275.

^{345.} Preserving Employee Wellness Programs Act, H.R. 1313, 115th Cong. (2017-2018).

^{346.} Reed Abelson, *How Healthy Are You? G.O.P. Bill Would Help Employers Find Out*, N.Y. TIMES (Mar. 10, 2017), https://www.nytimes.com/2017/03/10/health/workplace-wellness-programs-health-genetic-data.html.

the provision of an alternative, safer activity available to employees, employers would not be allowed to impose any financial forfeiture.

As one example of a way to promulgate that regulation, consider the Employee Health and Wellness Program Code of Conduct ("Code"). 347 WELCOA, the largest wellness trade association, has enthusiastically endorsed it as a founder. It therefore must be acceptable to a large swath of its vendor members. Other leading vendors, including Limeade, Redbrick, Sterling, Sonic Boom, and It Starts with Me, have endorsed it directly. Conversely, the Code has met with strong resistance from some vendors this article profiles—vendors who, by definition, would be in violation of the Code anyway. 348 Wellsteps, for instance, referred to the originators of the Code—including this author—as "a gang of bullies." 349 Perhaps a workable compromise would be that vendors could be required to either adopt the Code or disclose why they have elected not to adopt the Code, with consequences as described in the previous paragraph.

Further, vendors themselves should be subject to oversight and licensure. There should be a professional education requirement to ensure that providers understand the screens, contests, and other activities they are performing or administering. A background in sales or municipal administration, plus five days of classroom training and three days of onthe-job supervision, should not be sufficient to receive a license to perform involuntary medical tests on employees.

These proposed regulations would give employees the opportunity to avoid being harmed by a wellness vendor. In this industry, absence of harm to employees would be a noticeable improvement over the current state of affairs.

^{347.} Code of Conduct, *supra* note 11.

^{348.} See Al Lewis, Optum, HERO Lead Backlash Against Code of Conduct, THEY SAID WHAT? (Sept. 7, 2016), https://theysaidwhat.net/2016/09/07/optum-hero-lead-backlash-against-employee-health-code-of-conduct/.

^{349.} Al Lewis, *Wellsteps: We Don't Need Your Stinkin' Code of Conduct*, They SAID WHAT? (Nov. 29, 2016), https://theysaidwhat.net/2016/11/29/wellsteps-we-dont-need-your-stinkin-code-of-conduct/.