THE INSTABILITY DEFECT OF FOOTWEAR SOLES PROPOSED ACTION PLAN

A CALL FOR IMMEDIATE ACTION NOW TO OVERCOME THE MAJOR PUBLIC HEALTH EMERGENCY

Based on the information currently available to me, the actions outlined below reflect what I believe is the best general plan of action with which to proceed now. I believe that plan at least constitutes a reasonable starting point for detailed discussions of potential actions by the parties who would be directly involved in implementing them.

IMMEDIATE ACTION BY THE ENTIRE FOOTWEAR INDUSTRY IS NECESSARY

I believe that the current situation in which the footwear industry's core product is defective is clearly dangerous and therefore unsustainable. Currently, all wearers of footwear are at significant risk for serious but preventable injuries. Even the greatest sports superstars are often injured, their careers interrupted or cut short by avoidable ankle sprains and directly related other injuries that are more serious. Major sports championships in the NCAA and NBA, as well as nearly every sport at every level, are often decided randomly by preventable ankle sprains and related severe injuries instead of by actual athletic performance.

Far worse, my conservative, mid-level estimate indicates that 20,000 deaths, 3.2 million emergency department visits, and 700,000 hospitalizations – all potentially avoidable – occur every year in the U.S. at an annual cost of \$65 billion just for medical care.

Seemingly irrefutable proof – so uncomplicated it can be replicated by anyone, whether scientific expert or daily wearer, and without any equipment other than a pair of conventional shoes – has been presented here that the inherent instability of shoe soles is the underlying cause of a majority or perhaps even most fall injuries and their cost. They are easily avoidable by restoring the naturally inherent stability of the bare human foot to the shoe sole, as I have proven over many decades with the many different footwear prototypes that incorporate simple basic design corrections that allow their soles to retain part or all of that inherent barefoot stability.

Due to its near total lack of truly fundamental scientific research, particularly on the critical biomechanical relationship between shoe sole structures and injuries, the footwear industry has blindly continued the unquestioned use of a more than 2000-year-old standard design for the most basic structure of shoe soles. The use of the new, far better barefoot stability standard, together with modern sole materials, as well as modern digital design and

manufacturing technology, will enable the footwear industry to eliminate the existing stability defect in footwear soles without difficulty in little more than a few years.

I believe that the one-time financial cost for this across the entire industry of perhaps a few billion dollars is miniscule compared to the existing annual medical and economic cost of the stability problem. Moreover, it is a smart long-term investment because it is almost certain to be more than offset by the potential financial benefit to the industry from substantially increased sales of new footwear products that are not only much safer, but also much more comfortable.

Confronted with the apparently unequivocal proof of conventional shoe sole instability by the **Standing Ankle Spraining Simulation Test** presented here, easily verifiable by anyone with shoes, it is hard to imagine how maintaining the status quo of defective shoe soles can be defended with a straight face by the industry. That would seem like an actual mission impossible. The only possible defense is the famously hilarious one attributed to Groucho Marx, who is purported to have said "are you going to believe me or your own lying eyes?" Or more precisely in this case, your own lying bare foot.

Instead, with knowledge of the simple but apparently incontrovertible evidence presented in detail here, the best and apparently only viable option for the footwear industry is to just do the right thing. Together its members must step forward boldly and solve at long last this heretofore overlooked ancient problem and to do so as quickly as possible.

Failure to do so is not an option. This is a major health and safety emergency, needlessly continuing year after year, decade after decade, century upon century. A major industry effort must be undertaken as an essential public service necessary to end the artificial plague of avoidable serious injuries caused by defective conventional footwear. That defective footwear is easily correctible with known means that can be further developed commercially without undue effort or time. It is not rocket science.

Therefore, I believe that each and every footwear company should act immediately, either independently or in coordination with others in the clear interest of safety, to use and develop further the proven sole stability solutions described in this book to eliminate the stability defect in its footwear products.

THE FIRST STEP IS NEEDED IMMEDIATELY

It will of course take time to manufacture new, more stable footwear. But the first step for the footwear industry is relatively simple and should be taken almost immediately to protect the public.

In my opinion, the evidence presented in this book provides sufficient justification for the footwear industry, without undue delay, to use the media in all of its forms to warn the public to raise its awareness of the potential risks inherent in instability defect of footwear soles, as well as the unforeseen need to use shoes with newfound caution until corrected shoe sole designs are publicly available. The warnings should specifically be included with all footwear advertising in every form of marketing, including social media.

In addition, I believe such warnings should include the following clear notice with all footwear for sale with conventional soles having the instability defect:

<u>WARNING: UNSTABLE FOOTWEAR – Safe For Non-Athletic Use Only, Due to</u> <u>Risk of Ankle Sprains and Falls</u>.

The warning could include a brief explanation of the sole stability problem (optionally, also with initial plans for design solutions, both near term and long term). The warning could be a simple notice on a marketing website or a flyer included in the shoe box or other packaging, for example. I believe that every footwear company should act as soon as possible to ensure that no conventional footwear is sold without this essential fair warning to all of its consumers of their heretofore unknown risk.

At the same time, I believe the footwear industry should rapidly develop the quick fix, the lateral side bumper (FIGURES 88A & 88B) based on the midfoot lateral sole extension (FIGURE 88). Prior to sale, it could be retrofitted onto conventional footwear with the stability defect by a footwear company or one of its manufacturers, distributors, retailers, or contract services like shoe repair shops.

After sale, provision should be developed to enable any existing footwear to be returned to the footwear company or its manufacturer, distributor, retailor, or contract service to be retrofitted with some form of the lateral side bumper. In addition, the lateral side bumper could be offered to consumers as a standalone product that could be attached to defective footwear by do-it-yourself consumers with permanent or temporary glue or other attachment means, such as by Velcro-like means. The bumper could be of general design for use with any category of shoe or could be designed specifically for an individual shoe model, particularly those in widespread use.

DEFINITE FOOTWEAR STANDARDS FOR STABILITY ARE NECESSARY

In my opinion, the evidence presented in this book strongly suggests that in the future all footwear for sale should carry a mandatory safety label indicating the standard of stability that the shoe model meets, based on the simple **Standing Ankle Sprain Simulation Test**. The basic safety standards for footwear soles that I would suggest are as follows:

STABLE FOOTWEAR: Safe For Athletic Use – Barefoot-like Sole Stability

Guaranteed: Like the examples of my '93 Prototype and the ARIG slide sole, all footwear soles for use in performing athletic functions must fully comply with a simple new footwear sole standard based on remaining as stable as a bare foot during the Standing Ankle Sprain Simulation Test and should be clearly labelled as such in the language appropriate for the market and include a brief explanation of the standard. The single safety standard must protect not only wearers with a normal range of subtalar joint motion, but also wearers who are considered to be pronators or supinators.

SEMI-STABLE CONVENTIONAL FOOTWEAR: Okay For Limited, Non-

Athletic Use – Only Marginal Sole Stability Guaranteed: These non-athletic shoes are for everyday casual uses like standing and walking. Standard design improvements to conventional shoe soles such as FIGURES 88, 89, 90, 91A & 91B that at least include the midfoot lateral sole extension, which at least removes the ankle sprain trigger by filling-in the typical midfoot indentation on the lateral side centered around the base of the fifth metatarsal bone (as seen in a horizontal view), would be the minimum criteria meeting this improved stability standard.

These designs at least comply with significantly improved stability, as demonstrated during the **Standing Ankle Sprain Simulation Test** and should be so labelled, including a description of the specific stability improvements guaranteed, and include a brief explanation of the standard.

However, this should be a temporary standard to exist for some reasonable transition period, perhaps five years, and then replaced with a tighter standard. That standard should be based on the soles of classic vertically-sided conventional athletic shoes and everyday street or fashion shoes (even the forefoot of high heel shoes) that are improved even more, as demonstrated with the almost vertically-sided **ARIG slide sole** design with parallel upper and lower surfaces shaped like the wearer's barefoot sole. The **ARIG** design or a more conventional version of it with some central flattening (like the inner surface of the classic Birkenstock sandal) can also include other effective design modifications like a wider toe box.

Unfortunately, and unavoidably, this middle category is a grey area that is less distinct than the definitive extremes of barefoot stability versus conventional shoe instability, but defines a category of shoe soles with stability that is still noticeably better than conventional shoe soles. It is a valuable distinction to maintain, especially during the multi-year transition to the goal wherein the public has become fully aware of the conventional shoe sole stability problem and the ultimate long-term goal in which most if not all commercial footwear has the safest, barefootlike athletic shoe stability and comfort.

WARNING: UNSTABLE FOOTWEAR – Risk of Ankle
Sprains or Falls and Serious Injuries All unstable footwear with a conventional sole structure (or worse!) that fails the Standing Ankle Sprain Simulation Test must include this mandatory warning when offered for sale, including a label with a clear warning symbol like FIGURE 101.



FIG. 101

THE U.S. GOVERNMENT SHOULD ESTABLISH PUNITIVE TARIFFS AND FINES ON DANGEROUSLY UNSTABLE CONVENTIONAL SHOE SOLES

Only about 1% of all footwear sold in the U.S. is currently produced in the U.S. The other 99% are imported from foreign factories, mostly in Asia.

Therefore, attaching substantial tariffs to uncorrected footwear that must be labelled

WARNING: UNSTABLE FOOTWEAR is one possible approach to initially regulate the safety of U.S. footwear. Such tariffs would provide a strong financial incentive to import only stable footwear, while at the same time without prohibiting conventional footwear labelled **WARNING: UNSTABLE FOOTWEAR** during the unavoidable transition period of several years required to convert design and manufacturing operations.

The tariffs could start relatively low for the first few years and then increase substantially over time. However, a potential limitation with this approach is the current practice of direct-to-consumer sales by Asian factories enabled by the existing \$800 tariff exemption.

In addition, deterrent-level high import fines for mislabeled footwear could be included for unsafe conventional footwear that should properly be labeled "WARNING: UNSTABLE FOOTWEAR" but are falsely mislabeled to claim safety compliance, fully or partially, with the Standing Ankle Sprain Simulation Test while at the same time actually unable to meet the claimed standards.

THE GOLD STANDARD FOR PUBLIC SAFETY ESTABLISHED BY THE U.S. AIRLINE INDUSTRY

There has been no fatal crash of a commercial airplane in the U.S. since 2009, when a single crash of a turboprop airplane caused 50 fatalities. A single U.S. fatality due to the fractured fan blade of an engine occurred in 2018. Since 1996, the U.S. fatal accident rate has been reduced from one for every two million flights to one for every 120 million flights, a staggering reduction that is sixty times lower.

For comparison with the U.S. footwear industry, recall that for the most optimistic estimate is that if only 10% of accidental falls are due to the footwear sole instability, the result is a medical catastrophe that occurs every year, with 4,000 deaths, 646,000 ER visits, and 140,000 hospitalizations, with a medical cost of about \$13 billion for each year. In other words, roughly the equivalent of a 9/11 event every year.

Given the far higher level of complexity of modern jet aircraft and the U.S. airline industry and the inherently extreme difficulty of its massive efforts, past and ongoing, to maximize flight safety, it is utterly unconscionable that the safety record of the U.S. footwear industry with its relatively simple footwear products is so extraordinarily poor in comparison. Based on the evidence presented in this book, there is no other way to put it: the safety record of the U.S. footwear industry is unimaginably bad. I firmly believe that it cannot and must not continue.

The U.S. airline industry's safety success should serve as a model for the footwear industry. The model's success has been primarily based on voluntary industry improvements rather than mandatory government regulations. Those voluntary improvements were faster and less obtrusive than if they had been imposed by outside regulation. The rest of the world is now trying to copy the U.S. airline safety model.

THE U.S. NATIONAL TRANSPORTATION SAFETY BOARD

An essential part of the necessary safety effort by the footwear industry is effective research and testing to provide independent evaluation carefully targeted exclusively on the effectiveness of the industry's effort. The footwear industry's effectiveness in correcting the unnatural stability problem of its conventional shoe soles must be monitored by an outside entity that is completely independent of the footwear industry, which has an obvious and unavoidable conflict of interest in monitoring its own actions.

That conflict rules out the existing standards organization, **ASTM International** (formerly the **American Society for Testing and Materials**), the small footwear committee of which is composed almost exclusively of footwear industry representatives and consultants. The relatively small **U.S. Consumer Products Safety Commission** is not well designed for the kind of highly proactive oversight needed at this initial developmental stage of the stability technology. Its conventional oversight roles might be more appropriate when fully developed stabile sole technology is widely adopted in commercial footwear products. For the existing footwear sole defect situation, it clearly is not feasible for the Commission to use its principal regulatory tool to issue a recall for a billion or more conventional shoes, leaving the entire U.S. population barefoot.

The **U.S. National Transportation Safety Board** investigations of commercial airplane crashes is the best model of a highly intensive independent investigation of a catastrophic problem in which every available fact is assembled and carefully reviewed, and no detail is overlooked. Certainly, the Safety Board's role in leading the effort to create the outstanding safety record of the airline industry is a gold standard for effective results. It is the airline safety model now followed by the rest of the world. Moreover, a major effort is are currently underway to use the Safety Board model to reduce the mistakes made in hospitals that are alleged to cause an estimated 250,000 unnecessary patient deaths each year and another such effort to guard against major cybersecurity vulnerabilities.

Can the airplane crash safety model work for crashes involving footwear? After all, single large airplane crashes and millions ankle sprains or falls seem to have very little in common. Except for one key point. Other than my attempt in this book, I can say with some confidence that there has never been an intensive investigation that identified a scientifically valid cause of even a single ankle sprain or fall, much less a general cause for all of them. The medical consensus is that the human ankle is defective and causes ankle sprains and falls. However, that is no more than an unexamined assumption used to explain the obvious instability and clearly mistakes an effect for a cause.

I firmly believe the evidence described in my book is valid and I stand by it. However, my personal research resources were very limited in all respects, so my results should only be considered preliminary findings, however compelling. As simple and straightforward as they are, uniquely verifiable by anyone without equipment, they should still undergo formal empirical

confirmation using the best available research resources in terms of expertise and facilities that are free from any conflict of interest from the footwear industry.

The National Transportation Safety Board could investigate single ankle sprains in the same way it intensively investigates an airplane crash, using the same kind of expert investigators, including structural engineers, and research facilities. It can evaluate every detail without bias. It can do so repetitively with multiple ankle sprains and falls under differing conditions until the definitive causes and preventive measures I have identified are confirmed or modified or rejected, and new and better measures proposed and evaluated.

Although the U.S. National Transportation Safety Board may not be specifically authorized to investigate the many millions of human injuries due to the defective footwear soles crashes now occurring, it is certainly true that human locomotion in footwear is indeed the most basic form of human transportation. Therefore, improving the safety of walking and running should logically be an important function of the Transportation Safety Board. Consequently, the Board may be able to play a direct role, especially since conventional footwear sole instability has caused an ongoing national medical emergency of unusually significant magnitude due to the vast number of footwear crashes.

If the National Transportation Safety Board is not currently so authorized under existing law, then legislative authorization to expand the Board's regulatory mandate to footwear safety would be required by both houses of Congress and by the President – a lengthy, complicated, and uncertain process at best. If successful, unless otherwise available, funding through the Federal budgetary process might then be needed to implement the new mandate – another lengthy, complicated, and uncertain process.

However, it may be possible to provide any required authorization much more quickly through an Executive Order by the President, at least on a temporary basis. It is also possible that authorized but unobligated Federal funding might be redirected to the Transportation Safety Board from another source by the Office of Management and Budget (OMB), again if approved by the President.

LACK OF EFFECTIVE ACTION & PROACTIVE COOPERATION BY THE FOOTWEAR INDUSTRY COULD BE SELF-DEFEATING IN A MAJOR WAY

A strong word of caution. Although as noted above there has been no fatal crash of a commercial airplane in the U.S. since 2009, in recent years there have however been two spectacular airplane crashes <u>in other countries</u> involving 346 fatalities. Both involved a new Boeing jet, the 737 MAX, and the causes involved were commercial pressure, fatal design flaws and failed oversight by Boeing.

The sobering history, still ongoing, of the many serious missteps by Boeing provides a cautionary tale that may provide useful guidance of what not to do in difficult circumstances. Boeing's circumstances are analogous in some general ways to those confronting the footwear industry as a whole now and the fatal design defect in the conventional shoe soles marketed by

its many member companies.

Among the critical changes made by Boeing to correct its deficiencies was the appointment of a Chief Aerospace Safety Officer and a board-level committee on aerospace safety. Those reactive changes should now be proactively made by every footwear company, including the appointment of a Chief Footwear Safety Officer and a Board-level committee focused on footwear safety. I strongly believe the Chief Footwear Safety Officer should report directly to each company's CEO and also report to the Board's Footwear Safety Committee, as well as the Chairman of the Board. Simply put, I believe no footwear company should have any more important priority going forward than finally making its commercial footwear products safe for its customers!

Moreover, I believe the Chief Footwear Safety Officer should have absolute authority to test all new footwear models using the **Standing Ankle Sprain Simulation Test** and, based on the test results, delay production pending required redesign and retest of any preproduction sample or production sample of a footwear model that fails to meet either the Stable Standard or the Semi-Stable Standard. **I believe no footwear models should ever go into commercial production without the explicit prior approval of the Chief Footwear Safety Officer**, whose sole decision should be reviewable only by the CEO and appealable by the Officer to the Board's Footwear Safety Committee.

NIKE SHOULD USE ITS UNIQUE LEADERSHIP ROLE IN THE FOOTWEAR INDUSTRY

Because its financial and R&D resources dwarf those of the rest of the footwear industry, leadership for the footwear industry effort to correct the sole stability defect, particularly in the U.S., should be provided by **Nike**, led by CEO John Donahoe; Chairman, Mark Parker; and Co-Founder, former CEO and Chairman, and now Chairman Emeritus, Phil Knight.

Because of its unique capabilities and position in the industry, I believe that Nike has a special obligation if not a duty to provide a public service in the form of an immediate, all-hands-on-deck, company-wide effort to fix the avoidable sole instability problem and lead its adoption throughout the footwear industry.

At least because of his founding role 50 years ago in the creation of the modern athletic shoe industry as it currently exists and his wealth of personal relationships at all levels within Nike, the athletic footwear industry and the entire world of sports and business, I believe that Phil Knight is in a unique position even in retirement to at least call the key shots to make this happen at Nike.

Nike is by far in the best technical, financial, manufacturing, and marketing position in the footwear industry to take the detailed initial guidance I have provided in this book and use it to provide consumers with a wide variety of commercial footwear products with reduced instability almost immediately and free from instability defects in the near future.

To further assist in its effort to the extent I am able, I will provide Nike with a significant number of production samples of my *ARIG slide*, as I will do with other athletic and non-athletic

footwear companies. Those slides can provide a basic structural model in its simplest form to copy. The *ARIG slides* also serve as a simple proof of concept that footwear soles can provide barefoot-like stability, lest any diehard skeptics need tangible proof.

Based on the history of the athletic shoe market of the past few decades, the Nike *Free* footwear models being an excellent example, it is likely that many or most of the commercial footwear sole solutions developed by Nike will serve as basic design models for the rest of the footwear industry throughout the world to use to modify into their own commercial designs.

It is therefore critical that Nike act as quickly as possible to remove the sole stability defect from its commercial footwear products. And as it is doing so, I believe Nike should as a public service provide footwear production samples as soon as they are available to other footwear companies before the Nike footwear models are available commercially to the public, as I am doing with my *ARIG slide*, for their use as general models for development of safe footwear products.

I firmly believe that wherever consumer safety is concerned, as it clearly is here, this kind of helpful collaboration between otherwise highly competitive shoe companies should prevail without exception during this medical crisis to reduce its duration as much as possible. The safety of consumers should always come first!

AN INDEPENDENT U.S. FOOTWEAR SAFETY BOARD, WITH GUARANTEED FUNDING FROM NIKE

If the National Transportation Safety Board is not authorized currently to play a role involving direct involvement, it could still take on an informal advisory role that would be especially effective in this unusual set of circumstances and would be particularly valuable during a start-up phase of a formal footwear sole stability investigation.

As a temporary or permanent alternative, or with a supplemental role to the National Transportation Safety Board, my suggestion is that a **U.S. Footwear Safety Board** be established quickly and voluntarily by the U.S. footwear industry based directly on the model of the **U.S. National Transportation Safety Board**. It should operate completely independent of that footwear industry, with a mandate to identify conclusively the cause of footwear defects like the footwear crashes and to develop effective solutions with the voluntary cooperation of the footwear industry. To do so, it must undertake intensive independent research and development of effective testing of U.S. footwear for safety.

I think the **Footwear Safety Board** should focus on the prevention and treatment of acute and chronic injuries, starting with reducing and eliminating the artificial lateral sole instability that causes ankle sprains, breaks, and falls by testing and otherwise overseeing general and specific sole design corrections. The overall goal of the **Footwear Safety Board** could be simple: to ensure that commercial footwear sold in the U.S. is as safe as possible. Like the U.S. National Transportation Safety Board, it should aim for the highest possible standards in order to become the safety oversight model that is copied by the rest of the world.

I believe the Board's basic ongoing function should be to investigate and monitor the safety and efficacy of all footwear, with an emphasis on the interaction between footwear sole structures and personal injuries, both acute and chronic. It should set the formal standards, like the **SASS Test**, as well as set and monitor rigorous compliance systems, including industry-wide labelling of safety levels for commercial footwear soles.

The top management of the Board should be drawn principally from the orthopedic medical, medical engineering, podiatry, and biomechanical fields with a firm policy of maximum independence from the footwear industry to ensure unconflicted investigations and oversight. There must never be a revolving door of personnel between the Board and the footwear industry.

To ensure a rapid start-up and uninterrupted operation, I believe that the independent U.S. Footwear Safety Board should be exclusively funded by Nike, by far the U.S. leader in the branded athletic footwear industry, which is the "high tech" part of the footwear industry, with 42.6% of the U.S. market in 2021. I think that is reasonable since, for example, Nike in its most quarter had a net profit almost four and a half times the net profit of the other dominant athletic footwear company, Adidas. Nike can therefore afford to provide funding with far less difficulty than any other footwear company. Nike can well afford the substantial investment necessary to eliminate the far greater economic cost of the ongoing medical disaster.

I think the theoretical alternative of a shared funding approach involving many footwear companies is fraught with inherent complications that would probably ensure a lengthy delay, inviting government and other interventions that could be counterproductive to correcting the stability defect quickly and effectively. Clear leadership within the industry is called for. And, obviously, Nike has the largest financial stake in correcting the serious industry-wide problem.

I believe the **U.S. Footwear Safety Board** should be funded upfront by Nike on a guaranteed multiyear basis without oversight by Nike or any other entity within the industry, which would be best way to ensure its independence from the footwear industry. I believe Nike should guarantee at least \$100 million every year for the next ten years for internal U.S. Footwear Safety Board operations, so that long term employment and other contracts can be made, ensuring that the Board's research and testing can be completely insulated from any outside financial pressure.

I think the best way to proceed would be for the Footwear Safety Board to consist principally of a medical team led by the **Hospital for Special Surgery (HSS)**, with other team members from the **Mayo Clinic** and other eminent medical and podiatric facilities. The Board should select a Director, preferably a medical doctor, and other highly qualified staff members.

The Board should include members or senior advisers who are eminent foot and ankle leaders in orthopedic medicine, like Armen S. Kelikian, MD, and in podiatry, like Steven I. Subotnick, DPM. The Board should also include leading biomechanical researchers with particularly important technical experience, such as Michael Rainbow, PhD, who has critical expertise in the important new gold standard in foot, ankle, and other joint motion measurement using optical motion capture and dynamic biplanar radiographic images combined with CT scans

to make 3D bone models in motion.

I also believe that additional funding of at least \$300 million per year, again guaranteed every year for the next ten years, should be provided by Nike to the U.S. Footwear Safety Board for independent footwear safety research and treatment programs. That funding should be distributed in the amount of at least \$100 million per year to HSS, at least \$100 million per year to the Mayo Clinic, and at least \$100 million per year to orthopedic and other medical, biomedical engineering, podiatric, and biomechanical facilities, as selected by the U.S. Footwear Safety Board. 10

Although the \$400 million annual funding to be provided by Nike is quite substantial, it seems more than fully justified by the extraordinary magnitude of the existing medical crisis caused by defective footwear soles and by the crucial independent role of the U.S. Footwear Safety Board would have in ensuring the elimination the far greater medical and economic costs of the footwear defects. For financial perspective, remember that my estimate of the medical cost alone in the U.S. alone ranges from a minimum of at least \$13 billion each year to a maximum of \$129 billion each year based on CDC statistics. The estimated loss in quality of life is from \$107 billion to as high as \$1,067 billion each year.

The results of a successful investigation by the U.S. Footwear Safety Board and its development of safety testing protocols can be used by similar footwear safety boards established in other countries. Footwear companies headquartered in other countries or regions can act to help establish other such independent regional or national footwear safety boards.

MEDICAL RESEARCH IN THE FIELD OF ORTHOPEDICS

The **Hospital for Special Surgery (HSS)**, led by Louis Shapiro, President and CEO, and Bryan Kelly, Medical Director and Surgeon-in Chief, and the **Mayo Clinic**, led by President and CEO Gianrico Farrugia, and Chairman Samuel A. DiPiazza, are together the leading medical systems in the field of orthopedics and medical care, which must provide effective treatments for the medical effects on the modern human body of the footwear sole stability defect. I believe that HSS and Mayo should lead the medically-based research into developing and testing the most effective footwear solutions for minimizing the incidence and severity of the acute and chronic orthopedic injuries they treat, including foot and ankle injuries at all levels, including in professional and amateur sports, and with particular focus on the impaired stability of the elderly and disabled.

As noted previously, without proper and timely treatment, 15 percent to 40 percent of the 10 million ankle sprains that are treated medically each year become chronic injuries with greater instability and risk of repeat sprains, as well as continued pain and swelling. Most critically, the risk of developing serious bilateral asymmetry throughout the body becomes much greater. About 1% of ankle sprain patients each year, totaling about 100,000 patients, remain disabled for life. I believe a much larger percentage are predisposed to at least partial disability later in life,

from osteoarthritis and other chronic diseases. For example, chronic ankle instability is associated with the reduced hip strength and altered knee mechanics that are factors in osteoarthritis.

The potential for footwear sole instability to lead directly to acute and chronic orthopedic and other injuries, as well very serious and widespread chronic diseases like osteoarthritis, have never been investigated in light of the role that footwear sole instability appears to play in initially causing them. An in-depth medical investigation of many idiopathic diseases will likely indicate that many of them may be effectively treated, eliminated, or prevented by general footwear sole corrections or by disease or patient-specific footwear sole modifications.

BIOMECHANICS AND BIOMEDICAL ENGINEERING

The science behind the ankle sprain simulation tests, both standing and leaping & landing, is so simple it appears on the surface to be irrefutable. In fact, it is so basic that, even with no scientific expertise, anyone can prove for themselves the fundamental instability of conventional shoe soles compared to the barefoot.

Nevertheless, the existing research detailed in this book is unavoidably raw because the general field of shoe sole lateral instability, and its interaction with the ankle and the subtalar joint at the limit of its full range of supination and pronation motion, has been completely ignored in formal scientific research. Given the existing major medical disaster made possible by that academic ignorance, I believe the glaring omission should be corrected now as a highest possible research priority.

In my opinion, therefore, the most effective way to proceed would be for Toni Ardt, the most recent President of the **International Society of Biomechanics (ISB)**, who ended his term in late July, 2021, should head an emergency ISB task force to establish a formal international research program focused on this mission critical, but entirely overlooked area of biomechanics research.

Every aspect of potential fine-tuning of standards for footwear lateral stability should be fully explored, including at least the **Standing Ankle Sprain Simulation Test** (and the Leaping & Landing Ankle Sprain Simulation Test) under varying conditions, such as obstacle-triggered or including cutting motions, in both laboratory work and live sporting events at all levels, from the youngest walking children to the most elderly. New sole designs should undergo formal lab testing overseen for compliance with the basic standard set by the **Standing Ankle Sprain Simulation Test**.

It is important to emphasize here that currently there are absolutely no existing structural standards of any significance for footwear soles. As anyone can see from the existing commercial products, footwear soles can take any imaginable shape whatsoever into which the human foot can fit, even if only partially. Footwear advertising is lightly regulated at best and almost nothing else in the footwear industry is. It is in effect the Wild West for shoe design and manufacturing. I believe that the existing situation is far more dangerous than either the public

or the footwear industry itself has been aware.

The initial projects should include formal review and replication of the informal artificial footwear instability results shown in this book, using many different shoe types and widely diverse populations including a variety of pressure and force sensors together with high-speed videography.

In addition, dynamic, biplanar radiographic images of the foot and lower leg should be combined with computed tomography (CT) scans of the distal tibia and entire foot to make CT-based 3D bone models in loadbearing motion during the SASS Test and the similar Leaping & Landing Test. This relatively new technique is so accurate it has established a new gold standard in accuracy, far exceeding (and making obsolete) what was previously available, and making possible for the first time completely accurate measurement of the ankle and subtalar joint during locomotion and, specifically, the SASS Test and the Leaping & Landing Test. This effort should be led by Michael Rainbow, PhD, who is best qualified to provide leadership with the necessary expertise.

In addition to this new and much more accurate empirical research, accurate computer simulation of the fall and ankle spraining biomechanisms is critically important. Scott Delp of the Department of Mechanical Engineering at Stanford University is the acknowledged longtime leader and pioneer in biomechanical computer simulation and could provide overall leadership in this effort. He could be assisted by Matt DeMers, who has focused on ankle sprain mechanism simulation with Scot at Stanford and, now with Apple, on electronic monitoring of user health by analysis of gait for speed and asymmetry, which could be extremely useful in identifying those in an extremely large population that are at risk of falling.

In addition, it would be important to include expertise in epidemiology, which could be led by an excellent epidemiologist with extensive footwear experience, Ramus Ostergaard Nielsen, PhD.

Finally, there is an urgent need to correct the fundamental problem that caused this catastrophe, the apparent total lack of qualified structural engineers in footwear sole design. In both the short and long terms, this void must be filled. The effort to do should have the highest priority.

Funding for these projects should be provided by the U.S. Footwear Safety Board.

CRITICAL LEADING ROLES BY MANY OTHER INDIVIDUALS AND ORGANIZATIONS

Besides the involvement of those directly involved in the footwear industry, particularly the athletic shoe industry with Nike and Adidas in the lead because of their size and resources, many other individuals and organizations could play major roles to play in solving the dangerous footwear instability problem as quickly as possible.

Of special importance are the various individual superstars and sports leagues that are the best-known users of today's athletic footwear products. The superstars have a powerful personal

incentive to help fix the defect that potentially injures them both physically and their careers. I believe they have a personal duty to do so as well. The sports leagues have a responsibility to protect all of its members' athletes.

THE SPECIAL LEADING ROLE OF MAJOR SUPERSTAR ATHLETES

Superstar professional basketball athletes have a uniquely critical role in the transformation of the athletic footwear industry from unstable to stable shoes, given their central role in marketing athletic footwear. NBA major superstars like Stephen Curry, Kevin Durant, and Kawhi Leonard have major shoe contracts and get to help design their own signature basketball shoes that are marketed with great advertising fanfare by the shoe companies.

These three superstars have all had significant ankle sprain and other serious injuries due to the instability of existing basketball shoes that have seriously interrupted their professional careers. Therefore, it is in their own best interests, as well as an important public service, to use the considerable leverage of their athletic stardom to insist that new safe designs for their signature shoes be in full compliance with the true barefoot stability standard set by the **Standing Ankle Sprain Simulation Test**. It is also in the best interests of their agents, managers, and business managers. There is no personal financial cost to any of them for doing so. In addition, they should insist that any existing conventional shoe sole models they have to wear are modified by the shoe company they endorse to include the **midfoot lateral sole extension**.

In the NBA, there are many other superstars in a position to do the same thing. Above all others, of course, is Michael Jordan of Nike's Jordan Brand signature shoes. Other major basketball superstars with signature shoe contracts include LeBron James, Giannis Antetokounmpo, Kyrie Irving, James Harden, Zion Williamson, Donovan Mitchel, Dwyane Wade, Russell Westbrook, Damian Lillard, Paul George, Klay Thompson, Jayson Tatum, Ja Morant, Jimmy Butler, Luca Doncic, and Zack LaVine. Many other major superstar endorsers with shoe contracts and signature shoes exist in other sports like football, baseball, tennis, golf, soccer, and track & field.

Both for their own benefit, and as a service to their public, all of them should require that shoes that they endorse are fully compliant with the stability standard of the **Standing Ankle Sprain Simulation Test.** Again, there should be no financial cost to any of them for doing so.

In addition to superstar athletes, the footwear industry now also has superstar designers like Kanye West, with his famous Yeezy line of designer Adidas shoes, and Pharrell Williams also for Adidas, as well as the dean of famous footwear designers, Nike's Tinker Hatfield, all of whom can play similar role to the superstar athletes by insisting on the incorporation of the barefoot stability standard of the **Standing Ankle Sprain Simulation Test** in their designer shoes. And again, there should be no financial cost to any of them for doing so.

LEADING ROLES FOR MAJOR PROFESSIONAL SPORTS LEAGUES LIKE THE NBA, NFL, MLB, AND FIFA, AND THEIR ASSOCIATED UNIONS

The NBA and NFL have played a leading role in providing invaluable data during Covid-19 pandemic that has not been available anywhere else, due in part to their uniquely intensive testing protocols. That unique data has been of significant benefit to researchers. Together with other professional sports leagues, it is again in their self-interest to play a leading role in providing uniquely rich data to successfully end this footwear-instability pandemic.

Since the existing shoe instability affects all NBA players, the **National Basketball Association (NBA)**, led by Adam Silver, Commissioner, and the **National Basketball Players Association (NBPA)**, headed by Tamika Tremaglio, Executive Director, and CJ McCollum,
President, need to take a joint leading role in developing safe footwear. Both groups should
require that players in all NBA games and practices, including the G League, wear basketball
shoes that fully comply with the stability standard set by the **Standing Ankle Sprain Simulation Test** as soon as possible. In addition, any existing conventional shoe sole models
the players of their teams have to wear should be modified to include the **midfoot lateral sole extension**.

State-of-the-art motion capture cameras should be provided to record live NBA game and practice action at ground level, particularly under the basket, but in other areas of the court as well, which would provide real world data for biomechanical scientists to carefully study the underlying causes of actual injuries, especially of the foot and ankle, but the lower extremity and pelvis, as well as the upper body.

The **National Football League**, led by Commissioner Roger Goodell, and the **National Football League Players Association**, led by President J. C. Tretter and Executive Director DeMaurice Smith, should undertake the same effort in parallel to that of the NBA and the NBPA.

Major League Baseball, led by Commissioner Rob Manfred, and the **Major League Baseball Players Association**, led by Executive Director Tony Clark, should work in a parallel effort to that of the NBA and NFL and their player associations.

The International Federation of Association Football (FIFA), led by President Gianni Infantino, together with its six confederations and 211 national associations, as well as national professional leagues like the English Premier League or the German Bundesliga should also work in parallel with the NBA, NFL, MLB, and their players associations.

Medical Advisory Groups like that at the Atlantic Coast Conference should be established at the professional sports leagues where they do not currently exist and should take a leading role in supporting the establishment of a league-wide requirement that all athletic footwear used in league athletic activities fully comply with the stability standard set by the Standing Ankle Sprain Simulation Test. Obviously, certain sports leagues, such as those for hockey and skiing, cannot comply with the new standard due to the special functional requirements of their footwear, such as ice skates and ski boots.

For all of these organizations, all necessary funding should be provided in advance by the team and/or league sponsors from the footwear industry.

THE NATIONAL COLLEGIATE ATHLETIC ASSOCIATION WITH MEMBER COLLEGES & UNIVERSITIES

The **National Collegiate Athletic Association (NCAA),** led by Mark Emmert, President, and Brian Hainline, Chief Medical Officer, should play a similar role is establishing a NCAA-wide requirement for all member colleges and universities that athletic footwear used by all players in NCAA games and practices must fully comply with the stability standard set by the **Standing Ankle Sprain Simulation Test**. In addition, any existing conventional shoe sole models the players of their teams have to wear should be modified to include the **midfoot lateral sole extension**.

State-of-the-art motion capture cameras should be provided to record a large sampling at all Division levels of live action of games and practices at ground level, particularly under high activity areas like the basket or goal, which would provide real world data for biomechanical scientists to carefully study the underlying causes of actual injuries, especially of the foot and ankle, but the lower extremity and pelvis as well as the upper body. Funding should be provided in advance by the footwear industry.

In addition, Division I conferences, as well as individual colleges and universities, including athletic directors and basketball and football coaches at major programs are similar to professional superstars in the sense that many of their athletic programs that they control receive enormous endorsement deals, as much as \$20-30 million a year, with the athletic shoe companies like Nike, Adidas, and Under Armour.

Basketball coach Mike Krzyzewski retired from Duke University in April, 2022, after an unprecedented career at both the collegiate and international/professional basketball levels. Coach K is in a uniquely qualified position to be an exceptionally successful chairman of a task force of elite basketball and other coaches to lead the rapid adoption of newly designed basketball and other court shoes with extreme barefoot-like stability for sports like basketball, volleyball, and tennis where such stability is most critical, also including other major sports like football, soccer, and baseball. Running, including track and field, and golf should be included.

Since their young student players are not protected by unions, all of these NCAA conferences, colleges and universities have a special duty to protect their student athletes from avoidable injury by negotiating requirements with shoe companies that any athletic shoes supplied to their athletic programs fully comply with the stability standard set by the **Standing Ankle Sprain Simulation Test**.

Medical Advisory Groups like that at the Atlantic Coast Conference should take a leading role at the conference and the college and university levels in supporting the establishment of a NCAA-wide requirement that all athletic footwear used in NCAA athletic activities fully comply with the stability standard set by the Standing Ankle Sprain Simulation

Test

MAJOR BROADCAST AND CABLE TELEVISION NETWORKS, AS WELL AS INTERNET STREAMING SERVICES

Transmissions of major sporting events of all kinds involving athletic footwear should include cameras located at ground level so that the interaction between shoe sole and ground can be accurately shown to the viewing public to educate them as to this important injury mechanism

PERSONAL POSTSCRIPT

I do not plan to play any direct role in the above described suggested actions by U.S. National Transportation Safety Board or Footwear Safety Board, the footwear industry, and other organizations involved in this proposed action plan. I plan to avoid any potential future conflict of interest in order to best remain a position as an impartial observer and therefore a trustworthy supporter or critic of their future activities, as appropriate.

My plan is to operate a small footwear company to develop and test prototypes that demonstrate new stable footwear sole designs, especially where I think my efforts may be particularly needed, such as for the elderly and mobility impaired.

My primary contribution is my two books that describe the basics of the two fundamental defects in conventional footwear soles. Together with my rich portfolio of relevant and now expired footwear patents, which provide a wealth of detailed design information on new and more stable footwear structures, they provide sufficient guidance for all parties to proceed effectively.

I have undertaken the long and difficult work of writing them as an important public service. It has taken a great many years – many decades actually – far longer than I expected when I started. I regarded that service as a duty that I was personally obligated to undertake and complete as best I could, since no one else apparently could or would. Whatever success my efforts achieve is directly based on some pivotal insights that I literally stumbled upon at the very beginning and probably understood correctly only because they were viewed at that time with a beginner's lack of preconceived notions, as well as a personal bent toward very deep skepticism.

Anyway, I can only see clearly from the view at 40,000 feet (perhaps more like 100,000 feet). Too many details blur my vision. Now is the time for the true footwear and medical professionals to take over and handle the challenging detailed work of finding and developing the best practical solutions for safe and effective footwear soles down where the rubber meets the road.

ENDNOTES

(p. 4) Preferably, sale of such dangerous footwear should be controlled by the Federal or state governments and available <u>only</u> to those 21 or older (for which minimum wearer age it is a somewhat physically safer, since the normal growth phase is over by then and a reasonably informed decision can be assumed).

Enforcement within the U.S. of the safe athletic and non-athletic use guarantees and the unstable warning should be very straightforward. There would be a powerful incentive for their proper use, since any company that markets footwear that fails to provide the stability guaranteed or fails to include the warning with unstable footwear would be libel for false advertising claims and/or personal injuries, potentially in lawsuits with class-action status.

- **2.** (p. 5) **Pasztor**, A. (2021). The Airline Safety Revolution. *The Wall Street Journal*, April 17-18, C1-2.
- 3. (p. 6) I attended several **ASTM** footwear committee meetings and gained a certain notoriety at the first from climbing onto the top of the meeting conference table to demonstrate, at the eye level of the seated members, the major difference between conventional shoe soles and the bare foot when in the lateral ankle spraining position of extreme supination. My unusually in-your-face style of demonstration was apparently to no avail, since none of the members of the committee seemed interested nor did the committee ever take any action on the footwear-based ankle instability defect.

With an equivalent lack of success, I also met several times with officials at the **National Institutes of Health (NIH)** and at the **Centers for Disease Control (CDC)**, and attended in 1993 the **CDC** sponsored **Second World Conference on Injury Control** in Atlanta.

- **4.** (p. 6) As an example of the probable difficulties likely to be encountered if the Consumer Products Safety Commission now undertakes regulation of footwear soles, this timely article covers the public clash between the at-home fitness giant, Peloton, and the CPSC, showing how slow, complicated and messy consumer product recalls can be, as well as related problems with management and enforcement tools. **Terlep**, S. (2021). Peloton Tested a U.S. Safety Watchdog. It Wasn't the First. **The Wall Street Journal**, Updated August 7.
- **5.** (p. 6) **Pasztor**, A. (2021). Can Hospitals Learn About Safety From Airlines? *The Wall Street Journal*, September 4-5, C4. The same safety investigation model based on the National Transportation Safety Board is also being used by a new Cyber Safety Review Board. See **Volz**, D. (2022). Major Cyber Bug in Log4j to Persist as 'Endemic' Risk for Years to Come, U.S. Government Board Finds. *The Wall Street Journal*, July 14.
- **6.** (p. 7) See "**Boeing's Fatal Flaw**," a **PBS Frontline** documentary that was broadcast on October 26, 2021 (available on **Amazon Prime**). See also "**Boeing's Deadly Design**," a **CNBC American Greed** episode, S15/Ep10 (2022), AmericanGreed.CNBC.com. Finally, on

February 18, 2022, **Netflix** released a documentary, "**Downfall: The Case Against Boeing**," which quickly became one of the ten most watched films in the English language world-wide on Netflix for that week.

In addition, see **Tangel**, A. (2021). Boeing Shareholders Reach Settlement in 737 MAX Board Oversight Suit. *The Wall Street Journal*, November 4, and, an update on the ongoing Boeing saga, Boeing Dreamliner Defects Further Bog Down Production. *The Wall Street Journal*, November 20-21. A later saga update at **Tangel**, A. and Katz, B. (2022). Boeing, Airbus Face Off at Farnborough International Air Show. *The Wall Street Journal*, July 15. And see **Tangel**, A. (2022). Boeing Closes In on Making New Dreamliner Deliveries. *The Wall Street Journal*, July 17. Also, **Tangel**, A. & Cameron, D. Boeing Clears Hurdle for Resuming 787 Dreamliner Deliveries, *The Wall Street Journal*, August 1.

See also the excellent book, *Flying Blind: The 737 MAX Tragedy and the Fall of Boeing* by Peter Robison (2021), Doubleday, for its detailed, step-by-step analysis of the Boeing debacle. It includes many all-too-obvious potential parallels to a footwear industry that some might say was flying blind while operating at ground level in shoes with a deadly stability defect. What is not parallel is the magnitude of the tragedy, since sixty times as many deaths occurred in one year in the U.S. alone from just wearing defective shoes than from all flying world-wide in Boeing's defectively unstable 737 MAX jet.

At any rate, Boeing's actions seem like a textbook case study of what not to do when dealing with a life-threatening critical design defect. The crash of two 737 MAX jets that killed 346 people cost Boeing over \$20 billion and destroyed its well-established reputation as the leader in commercial jet airplane technology and safety that had been carefully built over the previous half century.

- 7. (p. 7) Tangel, A. (2022) Boeing Changes Will Make Planes Safer, Executive Says. *The Wall Street Journal*, May 24.
- **8.** (p. 8) **Phil Knight** is also the best-selling author of *Shoe Dog*, the very popular memoir of his personal journey in founding Nike and its precarious early years. (2016, Scribner.)
 - 9. (p. 10) Sporting Goods Intelligence, July 22, 2022, p. 2.
- **10.** (p. 10) A quarterly results comparison was used because annual results are difficult to compare because of Covid -19 economic fluctuations and fiscal years that differ by half a year.

I think that \$400 million a year guaranteed for ten years is appropriate funding to be provided by the footwear industry as indicated, but attempting to formulate a reasonable basis for apportioning a fair share for each footwear company to contribute and then obtaining their both agreement and actual payment would seem to be an impossible mission. To avoid protracted delay at a time when action is required as soon as possible, as it is here, I would suggest a different funding approach that I think is both simple and fair.

For many years Nike has earned a very large share of the industry's profits. For example, in recent reported quarters (*Sporting Goods Intelligence*, p. 2, July 1 & July 1, 2022), Nike earned four and a half times the profits of the next largest company, Adidas. Other footwear companies and their profits are much smaller. Over the next ten years, Nike's new, non-defective footwear, both more stable <u>and</u> more comfortable, is likely to expand its profitability substantially.

Consequently, I think the best available alternative would be for Nike to fund annually the entire \$400 million a year at \$100 million a quarter guaranteed for ten years by itself, with no strings attached (and indexed for U.S. inflation), for a decade total of \$4 billion. For Nike, it would be a prudent and relatively trivial investment (less than 7% of its recent quarter profits for each of four quarters) helping to enable a substantial net profitability increase for itself in future years, while at the same time providing an indispensable industry and public service.

Other footwear companies would be left unencumbered to fund their own development of stable conventional footwear based on the information provided in this book (and, later on, many of them can base their design corrections on Nike's stability corrections, as many have done with the **Free** and **Vaporfly** model lines).

11. (p. 12) The same lab techniques should be employed in the **SASS Test** studies as were used in this pioneering running study by **Peltz**, C. D., Hakadik, J. A., Hoffman, S. E., McDonald, M., Ramo, N. L., Divine, G., Nurse, M. and Bey, M. J. (2014). Effects of footwear on three-dimensional tibiotalar and subtalar joint motion during running. *Journal of Biomechanics* 47, 2647-2653.

12. (p. 14) Cohen, B., Radnofsky, L., & Beaton, A. (2021). Scientists Needed Help Against Covid-19. They Asked Sports. *The Wall Street Journal*, March 11, 2021.

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