



FDA Regulation of Health and Fitness Equipment

Citation

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I.

Although estimates indicate that roughly twenty-five percent of all consumer spending in the United States is on products regulated by the Food and Drug Administration¹ (FDA), one area of tremendous consumer spending for the most part has been left unregulated by the FDA -- money spent on products from the health and fitness industry. Research into FDA regulations and into the legislative history of the 1938 Food, Drug and Cosmetic Act (FDCA)² as well as the subsequent 1976 Medical Device Amendments³ reveals no explicit exemption for health and fitness equipment, nor is there any articulated and specific rationale provided for why the FDA has forgone regulating such equipment. It seems that the FDA's decision to not regulate athletic and fitness equipment stems from prudential reasons such as resources and tradition rather than a jurisdictional limitation or a congressional mandate. This practice of non-regulation by the FDA may well be changing, however, with the increasing popularity of such fitness devices as heart-rate monitors, blood-pressure kits, body massagers and relaxation aids.⁴ As new "quasi-medical devices continue to push the bounds of the FDCA definition of a medical device and with growing popular support for using the FDA to regulate previously off-limit products such as tobacco,⁵ the FDA may very well broaden its regulatory scope into the health and fitness industry. By focusing on the specific example of the scuba industry, this paper will examine first, whether the FDA has the authority to regulate athletic equipment as medical devices.⁶ Part two will

¹See Peter Barton Hutt and Richard A. Merrill, *Food and Drug Law* 17 (2d ed. 1991).

²Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C §§ 301-392 (1994).

³Pub. L. No. 94-295, 90 Stat. 540 (1976).

⁴See Farley, Gregg A. and Mark R. Obenstine, *Heal Thyself: The Increasing Popularity of Quasi-Medical Devices Raises the Question: Should the FDA Regulate Them?*, L.A. Daily Times, Feb. 14, 2000, at S18.

⁵See, e.g., David A. Kessler, *Let's Get on with FDA Regulation of Cigarettes*, Houston Chron., Apr. 7, 2000, at A (former Commissioner of the FDA argues that support for innovative ways to regulate tobacco can overcome recent Supreme Court ruling that FDA does not have the authority to regulate tobacco).

⁶As one author has remarked "whether or not a product constitutes a 'device' carries with it enormous regulatory implications.... An unregulated product would not need to undergo premarket review, nor... comply

explore the plausible reasons for why the FDA in the past has chosen not to regulate athletic equipment and whether those rationales still make good sense. Part three will discuss whether the scuba industry can serve as an example for other sectors of the health and fitness industry that seek to avoid FDA regulation.

II.

The FDCA grants clear authority to the FDA to regulate medical devices⁷; therefore, the first step in determining whether athletic equipment, more specifically scuba equipment, can be regulated by the FDA is to determine whether such equipment falls within the statutory definition of a medical device. The statute defines a medical device as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is --

(1)

(2)

(3)

Scuba, and most other athletic equipment easily satisfy the instrument, apparatus or machine requirement, but such equipment must also fit within one of the three sub-categories. Although some very advanced and cutting-edge scuba equipment might fit within category two --- use in with the FDA's good manufacturing practices.' Bradley Merrill Thompson, FDA Regulation of Medical Devices 29 (1995).

⁷See 21 U.S.C. §§ 351-360 (1994).

the diagnosis of a condition⁹ --- the most logical place for scuba to fit under the medical device definition would be category three --- affecting the structure or function of the body.

Scuba, which stands for self-contained underwater breathing apparatus, signifies both an activity and the equipment necessary to engage in that activity. The equipment that makes up the basic scuba package consists of an air tank to hold compressed air, a regulator made up of a first and second stage which delivers compressed air to the diver, air pressure and depth gauges, a buoyancy control device, a mask and fins. More sophisticated equipment includes underwater computers to measure depth, bottom time and air consumption. Typical diving accessories include weights, lights, a compass, a knife, a wetsuit, gloves and booties. Of this equipment, the air tank, regulator and possibly the gauges and mask are the most likely candidates for regulation by the FDA because each one of these pieces of scuba equipment either directly or as an accessory affects a basic function of the body. This paper will focus on the air delivery system.

1. How Scuba Equipment affects a structure or function of the body

Common sense dictates that if a diver wishes to stay underwater for any length of time, that diver must have an air source. A recreational scuba diver's air source consists of the air tank and regulator. Arguably, the mere fact that scuba equipment allows a diver to breath in an otherwise alien environment could be enough to qualify as a medical device under a literal textual reading of the medical device definition because breathing certainly counts as a function of the body¹⁰; however, additional support for the argument that scuba equipment could be classified

⁹Some very advanced computerized scuba equipment can actually measure heart rate and breathing rate and there is work being done on dive computers that can measure the level of nitrogen, oxygen and carbon dioxide in the blood to alert divers to potentially fatal conditions such as nitrogen narcosis, decompression sickness or oxygen poisoning.

¹⁰C.f. *United States v. 23 Articles*, 192 F.2d 308 (2d Cir. 1951). The Court found that sleep was a function of the body. Although this case was decided under the 1938 Act's definition of a medical device, the understanding of what counts as a function of the body still could be found persuasive by current courts.

as a medical device comes from the significant physiological effects on the human body from breathing air underwater.

For basic recreational scuba the air in a diver's tank is identical to the air a diver would breath on the surface, only the air in the tank has been compressed to allow a diver to carry a larger air supply. For simplicity's sake, assume the air we regularly breath is composed of eighty percent nitrogen and twenty percent oxygen.¹¹ The ratio of nitrogen to oxygen never changes, even when a diver descends underwater. What does change is the amount of pressure (water and atmospheric) on the diver and on the air in a diver's body. Because water weighs more than air, it takes less water to exert more pressure. The deeper a diver descends the greater the weight, and the greater the pressure.

Well established laws of physics dictate that several things happen to air and the human body under pressure.¹² First, we know from Boyle's law that "for any gas at a constant temperature, the volume will vary inversely with the absolute pressure while the density will vary directly with the absolute pressure."¹³ This means, that with a given change in pressure, the amount of gas will change as well. When pressure increases, volume decreases; on the other hand, when pressure decreases volume increases. In the context of diving this change in volume becomes very important because regulators deliver air to a diver at the same pressure as the surrounding water (ambient pressure). As a diver descends, the air in her lungs, ears, sinuses, masks and BCs will compress and become denser. When a diver ascends, the air in these same places will expand. Over expansion problems can occur if a diver does not ascend properly and allow

¹¹An 80/20 ratio is in fact very close to actual air composition. Air, which is a mixture of gases, consists of 78.08% nitrogen, 20.95% oxygen, 0.03% carbon dioxide, and .094% other gases.

¹²See generally Alex Brylske, Understanding the Physics of Diving: The Math-hater's Guide to Gas Laws, Dive Training 20 (March 1993) (explaining in easy to understand terms the various gas laws that affect scuba divers).

¹³Scuba Schools International, Divecon: Dive Control Specialist Manual 5-6 (1993).

the air pressure in her lungs to equalize.¹⁴

Besides directly affecting the air in a diver's body, pressure exerts indirect effects on the human body as well. Two additional laws of physics, Dalton's Law and Henry's Law, help explain these indirect effects. Dalton found that while a gas mixture is made up of several different gases, each component gas will continue to demonstrate its own individual behavior as though the other gases did not exist. One behavior of gases is that they exert what is called partial pressure. Since the air a diver breathes consists of eighty percent nitrogen and twenty percent oxygen, then it stands to reason that eighty percent of the pressure is exerted by the nitrogen and twenty percent by the oxygen. Dalton also found that the partial pressure of a gas increases with the increased ambient pressure. Henry's Law states that the amount of gas that will dissolve in a liquid is a function of the partial pressure of that gas. In other words, the higher the partial pressure, the more gas that is dissolved. For divers the liquid a gas dissolves into is the bloodstream. The outcome of these three laws -- Boyle's, Dalton's, and Henry's -- is that as a diver descends: 1) the pressure increases and the air breathed becomes denser; 2) the partial pressure in the lungs increases and a higher partial pressure of nitrogen is diffused into the blood through respiration; and 3) a diver's body tissue absorbs more nitrogen. The absorption of nitrogen into the blood and tissues is not itself a problem; the body can tolerate large increases of nitrogen. Problems can arise, however, because the body cannot release nitrogen quickly. If the pressure which is holding the excess nitrogen in the blood and tissues is decreased too rapidly, the nitrogen will return to gas form in the tissues.

This results in decompression sickness, one of the most serious maladies of scuba diving.¹⁵

¹⁴There are four principle lung expansion injuries: air embolism, pneumothorax, mediastinal emphysema, subcutaneous emphysema. All four result from air escaping from the lungs, but they differ depending on where the air goes after it escapes and the severity of injury. See e.g., Scuba Schools, Divecon, supra note 13, at 6-1 to 6-23.

¹⁵For a more comprehensive discussion of decompression sickness, see generally Alex Brylske, What Causes

Besides the injuries that have been described above, two additional problems that can result from breathing air at depth are nitrogen narcosis and oxygen poisoning. Divers experience nitrogen narcosis¹⁶ at depths greater than sixty feet. Nitrogen narcosis is only serious if a diver ignores the symptoms. The effects of narcosis go away completely upon ascending to a shallower depth. Oxygen poisoning, while much more serious, is unlikely to occur while diving recreationally. Due to Dalton's Law, the increased partial pressure from oxygen at depth can cause the effect of a diver at extreme depths breathing the equivalent of pure oxygen -- this can be poisonous if done for too long of time.

This abbreviated discussion of the physics of diving and the physiological effects on the human body underscores the conclusion that scuba equipment does in fact affect a structure and function of the body. Scuba equipment is specifically designed to allow a diver to enter into an alien environment. Regulators are designed to adapt to the pressure underwater and to allow a diver to breath normally. To be more precise regulators --- first and second stage --- are designed to adjust to the increased pressure and to take high-pressure air from a scuba tank and deliver it to the diver at a lower, breathable pressure. For breathing to be easy, the air delivered to the diver equals the water's ambient pressure.¹⁷ It seems indisputable that Scuba equipment was designed to and does in fact affect the structure and function of the body, thus the question becomes whether that suffices to bring such equipment within the medical device definition.

2. The Role of Intent in Defining Medical Devices

Decompression Sickness, Dive Training 22 (April 1993), and Alex Brylske, Understanding Decompression Sickness: All Bends are not Equal, Dive Training 22 (May 1993).

¹⁶Also known as the rapture of the deep, nitrogen narcosis can cause a diver to feel drunk or sluggish. A 'narced' diver experiences difficulties with problem-solving and object fixation. By ignoring narcosis symptoms a diver can put herself in great danger.

¹⁷See generally Demystifying Regulators: Understanding the 'Magic Machine' that makes diving possible, Dive Training 28 (Nov. 1992) (discussing various types of regulators and how they function).

In determining whether or not a product qualifies as a medical device, the FDA and the courts have relied in part on an intended use test. Many products such as exercise equipment have dual uses. One use may qualify the product as a medical device and the other use may not; therefore, the FDA, in order to differentiate between those products that can be regulated under the FDCA and those products that cannot, looks to the use to which products are put. The current contours of the intended use test have been articulated by the FDA in regulations explicating the meaning of 21 U.S.C. 321(h). For instance the FDA states that it ‘‘ will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstance surrounding its distribution.’’¹⁸ Furthermore, the regulations state that the most important factors in determining intended use include ‘‘labeling, advertising, and other representations accompanying the product.’’¹⁹

The problem with this intended use test is that leaves enormous gray areas in which it remains unclear whether or not a product falls within the medical device definition. For example, scuba equipment comes with no therapeutic or diagnostic claims, nor do the manufacturers or sellers of such equipment make such claims on the product, through advertisements or through representations at the point of sale; however, it is clearly the intent of the manufacturers and the sellers of scuba equipment that the products be used in such a way as to affect a structure or function of the body. The products are designed to enable a diver to spend time below water breathing compressed air which as explained above has a definite effect on a function of the body.

¹⁸48 FR 53032 at 53034.

¹⁹Id.

An additional complication is that the FDA has exempted certain exercise equipment from the medical device definition. In 48 F.R. 53043 the FDA states that “[w]ith respect to exercise equipment, FDA regulates as devices only those products that are intended for medical purposes.’’ The problem comes from the circularity of this definition. What does medical purpose mean? For clarification the FDA refers back to the comments made to 21 C.F.R. §809.1. Those comments in turn restate the statutory definition of a medical device. ‘‘FDA will regulate a product that has both medical and nonmedical uses as a medical device if it is intended for a medical purpose, that is, for ‘use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease,’ or ‘to affect the structure or any function of the body.’’’

It is clear from an exchange in correspondence between the general counsel for the Consumer Product Safety Commission (CPSC) and the chief counsel for the FDA that the FDA intended to exclude from regulation as medical device exercise equipment used in recreational and sporting activities when such equipment’s labeling and advertising only makes simple fitness claims.²⁰ The examples of permissible language referred to in this correspondence include: providing aerobic fitness: improving circulation, physical fitness, muscle or body tone; increasing muscle size; reducing inches; burning calories; and developing endurance, strength and coordination.²¹ Examples of exercise equipment referred to in this correspondence that the FDA does not consider to be medical devices include toning tables, exercise bikes, bust developers, treadmills, rowing machines, weight-lifting apparatuses and jump ropes.²² Some of this exact same equipment,

²⁰See Letter from Thomas Scarlett, Chief Counsel, Food and Drug Administration, to James V. Lacy, General Counsel, U.S. Consumer Product Safety Commission (May 6, 1983) (on file with author).

²¹See id. at 2.

²²See id. at 3.

however, when used in conjunction with a disability or physical therapy regime does qualify as a medical device; for example, 21 C.F.R. §890.5360 specifically mentions therapeutic exercise bicycles, treadmills and rowing machines.

One possible way to differentiate when exercise equipment qualifies as a medical device from when it does not would be to focus on where the equipment is purchased. If purchased in a sporting goods store, used at home or in a gym and used in connection with a sport or recreational activity, the equipment would seem to fall outside of the intended medical use test. If the same equipment however was used in a hospital or clinic, purchased from a medical supply store or pharmacy on advice of a doctor, then such equipment would seem to qualify as intended for medical use.

None of this analysis however helps in addressing the problem of equipment that falls within the gray area of the regulations -- as arguably scuba equipment does. Although manufacturers and sellers of home exercise equipment often advertise and intend that such equipment will affect a structure or function of the body, it is on a much less drastic scale than scuba equipment. Scuba is a great sport for toning the body, improving physical fitness levels, and providing aerobic fitness, but the intent of scuba equipment is to do much more. As described above, the use of scuba equipment has a significant effect on the respiratory and circulatory functions of the body. Such effects do not readily fall within the category of simple fitness claims, but neither do they fall within a category of therapeutic or diagnostic claims. An additional point differentiating scuba from other exercise equipment is the potentially fatal consequences from the misuse or malfunctioning of scuba equipment. Given that the reason why Congress granted the FDA power to regulate medical devices in the first instance was to help ensure the safety

and well-being of the citizenry,²³ it seems reasonable that the increased safety risks from certain exercise equipment should matter.

Based on the ambiguity of the intended use test, the manner in which scuba equipment affects functions of the body, and the potential for harm inherent in scuba, one can reasonably argue that the FDA could regulate scuba if it so chose. This is not to say that the FDA should in fact regulate scuba, it is simply a basis for launching a discussion of potential reasons why the FDA has not undertaken such regulation and what lessons can be learned for other quasi-medical devices that wish to avoid FDA regulation.

III. Potential Rationales for Why the FDA Has Not Regulated Scuba Equipment.

Based on the FDA's public records -- regulations, general counsel memorandum, correspondence -- it does not appear that the agency ever considered in depth the specifics of the scuba industry and whether or not it makes sense to fit scuba equipment under the rubric of exercise equipment not intended for medical use thereby exempting it from regulation as a medical device or under the rubric of a medical device thus allowing for regulation. The only exception to this general lack of documentation is a Current Good Manufacturing Practices (CGMP) memo in which a representative from the FDA responded to a question about whether scuba diving tanks of air are regulated as a medical gas. The FDA response to this question was no, and a referral was made to the CPSC for questions about regulators and regulator fittings. The FDA referred questions about scuba air tanks to the Department of Transportation which addresses cylinder specifications and hydrostatic testing requirements.²⁴ This CGMP memo clearly indicates FDA awareness that

²³See generally Peter Barton Hutt, A History of Government Regulation of Adulteration and Misbranding of Medical Devices, 44 Food Drug Cosmetic Law Journal 99 (1989) (discussing how the first medical device laws came into being and how concern over fraudulent and potentially harmful devices lead to regulation).

²⁴FDA Human Drug CGMP Notes, Sep. 1996 <<http://www.fda.gov/cder/hdn/hdn996.htm>>.

the agency does not regulate scuba equipment. What cannot be extrapolated from this abbreviated reference to scuba gear is that the FDA ever fully considered how scuba equipment differs from other forms of exercise equipment; therefore, the following explanations for why scuba equipment has not been regulated are arguments based on what the FDA could and should consider when deciding to regulate not necessarily on anything the FDA has ever considered in depth.

1. Safety Arguments

First, one of the reasons that the FDA may never have considered the scuba industry and scuba equipment in depth is that the occasion may never have arisen. Scuba, despite the potential for injury, is statistically a very safe sport. The Divers Alert Network (DAN)²⁵ uses comprehensive data collecting methods to assure that most, if not all, scuba diving deaths and serious accidents are reported to it. According to DAN, about 100 North Americans die while scuba diving each year.²⁶ In 1995 DAN reported 590 cases of non-fatal diving injuries, most of which required referral to a hyperbaric chamber facility. Considering that there are between three to five million recreational scuba divers in the United States alone²⁷, while these numbers are not insignificant, they do not rise to a level of severe public concern over the safety of this sport. Because Scuba, although not without risk, is generally considered to be safe, the FDA may never have had cause to consider regulation. Quite possibly if the public perception of scuba diving changed and a perceived threat to public safety arose, the FDA might feel compelled

²⁵DAN is a non-profit organization established in 1981 to promote diver safety. Affiliated with Duke University Medical Center, DAN is supported by membership dues (200,000+ members), sponsoring corporations, and the sale of dive-safety-related materials such as textbooks, videos, and oxygen equipment. Since its founding DAN has gained world-wide reputation as the pre-eminent source for information on diving safety, and as an aid for divers in need of immediate help and/or referral to a hyperbaric chamber. See <<http://www.diversalertnetwork.org/>>.

²⁶See Divers Alert Network, Annual Report on Diving Accidents and Facilities (1997); see also Morgan, Anxiety and Panic in Recreational Scuba Divers, 20 Sports Med. 398, 398-99 (1995) (claiming that between three and nine deaths per 100,000 scuba divers occur each year).

²⁷See Lawrence Martin, M.D., Scuba Diving Explained: Questions and Answers on Physiology and Medical Aspects of Scuba Diving (1997).

to consider whether it needed to step in and regulate in this area. Without this perceived threat and without an unambiguous authority to regulate, the FDA currently has no reason to take on increased responsibilities in this area.

Coupled nicely with the safety arguments, but relevant to all other considerations about why the FDA does not regulate scuba equipment is the continual reality that the FDA faces budgetary and resource limitations. Because the public is not clamoring for regulation of the scuba industry and because the lack of therapeutic or medical intent makes it ambiguous whether scuba equipment can be defined as a medical device, the FDA has no incentive to expend limited monetary and personnel resources regulating and enforcing in this area. Furthermore, without clear regulatory authority or public will the FDA has no leverage to ask Congress for a larger appropriation to expand its regulatory mission.

2. Agencies Sharing Regulatory Jurisdiction

The safety argument alone, however, cannot entirely explain the FDA's lack of regulation because the FDA has certainly chosen to regulate products that pose even less of a risk than scuba equipment, for example exercise bikes²⁸ and teething rings.²⁹ Part of the reason why the FDA may not regulate scuba equipment is that the agency simply does not understand to what extent scuba could be classified as a medical device. Moreover, there are other federal agencies that have been appointed by Congress to guard the public safety: the Consumer Products Safety Commission and the Federal Trade Commission to name just two. Because the FDA may not see how scuba equipment fits within the medical device definition and because these other agencies have jurisdiction to regulate these products, the FDA may feel there is no need to intervene and to regulate.

²⁸See 21 C.F.R. § 890.5370

²⁹See 21 C.F.R. § 890.5550

The extent to which it makes a difference whether the FDA or the CPSC regulates scuba equipment depends in large part on how the FDA would classify scuba equipment under code section 360c.³⁰ If scuba gear was considered a Class I medical device then it would only be subject to the general controls of the FDCA: sections 351 (adulteration); 352 (misbranding); 360 (registration and inspection of producers); 360f (banned devices); 360h (notification); 360i (records and reports); 360j (general provisions). If scuba gear was deemed a Class II device then it would be subject to special controls such as having to adhere to performance standards and postmarket surveillance.³¹ If scuba gear was deemed a Class III device then it would be subject to premarket approval by the FDA.³² The CPSC, on the other hand, administers the Consumer Product Safety Act (CPSA)³³ which does not put products into classes. The CPSA requires product certification and labeling³⁴ much like the FDCA, but CPSA while allowing the CPSC to promulgate consumer product safety standards setting forth performance requirements, warnings and instructions,³⁵ does not make the promulgation of these standards mandatory in the way the FDCA makes performance standards and premarket approval mandatory for Class II and III devices. In fact, a search of the Federal Regulations and the CPSC web-site revealed no promulgated safety standards for any scuba equipment. This suggests that the scuba industry would prefer the regulatory regime of the CPSC rather than the FDA because the CPSC can be less onerous and more congenial to industry self-regulation. If scuba equipment was classified as a Class II device, and therefore made subject to performance standards, regulation by the CPSC would seem to be preferable for the additional reason that the CPSA allows for the promulgation of voluntary standards,³⁶ and

³⁰21 U.S.C. §360c (1994).

³¹See id. at §360c (a)(1)(B).

³²See id. at §360c (a)(1)(C).

³³15 U.S.C. §§2051-2081 (1988).

³⁴See id. at §2063.

³⁵See id. at §2056.

³⁶See 15 U.S.C.A. § 2056(b) (1988).

offers limited compensation to persons who participate with the Commission in the development of those standards.³⁷

There is an argument going the other way, however, that when CPSC safety regulations do exist, manufactures can make intended-medical-use claims to avoid the CPSC regulations and come under the less stringent Class I FDA requirements thereby avoiding the liability that could result from failure to comply with CPSC adopted standards.³⁸ Therefore, in order to better understand the different effects of FDA regulation versus CPSC regulation a threshold question must be resolved: If scuba equipment can be classified as a medical device should it fall within Class I, Class II or Class III?

Of the exercise equipment that the FDA does regulate as medical devices, most of the equipment has been classified into Class I or Class II. Exercise components and nonmeasuring exercise equipment have been classified into Class I. Examples include weights, dumbbells, straps, and adaptive hand mitts.³⁹ Measuring exercise equipment has been classified into Class II. Examples include exercise bicycles with measuring instrumentation, a manually propelled treadmill with measuring instrumentation, and a rowing machine with measuring instrumentation.⁴⁰ Additionally in 1996 the FDA reclassified power exercise equipment into Class I from Class II.⁴¹ It is difficult to say which of these types of exercise equipment are most analogous to scuba equipment. Following

³⁷See id. at § 2056(c).

³⁸See Gary E. Gamerman, Intended Use and Medical Devices: Distinguishing Nonmedical ‘‘Devices’’ from Medical ‘‘Devices’’ Under 21 U.S.C. §32(H), 61 Geo. Wash. L.Rev. 806, 827 (1993) (positing how manufactures can effectively game the system by taking advantage of the medical device definition).

³⁹See 21 C.F.R. §§ 890.5350 and 890.5370.

⁴⁰See 21 C.F.R. § 890.5360.

⁴¹See 61 FR 1117-01.

the logic of the argument that scuba equipment could be considered a medical device in the first instance, it would seem to be more analogous to Class II exercise equipment. What most differentiated scuba equipment from other forms of recreational and exercise equipment was the potential for fatal injuries. This logic suggests that if the FDA were to classify scuba equipment it would probably find that general controls are insufficient and that performance standards are necessary thereby requiring a Class II classification.

Moving outside of the exercise equipment category, scuba equipment is most analogous to medical gas delivery systems. In that area the FDA places products into both Class I and Class II.

For instance, Class I devices include oxygen masks,⁴² non-rebreathing masks,⁴³ pressure regulators,⁴⁴ gas pressure gauges,⁴⁵ and gas pressure calibrators.⁴⁶ These devices seem similar to the scuba air delivery systems and overall scuba gear packages. Class II devices include portable oxygen generators,⁴⁷ gas machines for anesthesia,⁴⁸ and hyperbaric chambers.⁴⁹ These devices may be more advanced than typical recreational scuba equipment; although, the hyperbaric chamber applies the same laws of physics to affect the body in the same manner as breathing air at depth. Admittance to a hyperbaric chamber is how most diving injuries are treated.

In the end none of the analogies fits perfectly, creating the problem that if the FDA were to regulate scuba equipment it might fall into Class III because of lack of substantial equivalence to a product already on the market. The FDCA defines substantial equivalence in part as having the same intended use.⁵⁰ Ironically this leads back to the very problem of whether or not

⁴²See 21 C.F.R. § 868.5580

⁴³See id. at § 868.5570.

⁴⁴See id. at § 868.2700.

⁴⁵See id. at § 868.2610.

⁴⁶See id. at § 868.2620.

⁴⁷See id. at § 868.5440.

⁴⁸See id. at § 868.5160

⁴⁹See id. at § 868.5470.

⁵⁰See 21 U.S.C. § 360c(i) (1988).

scuba equipment can be defined as a medical device in the first instance. The intended use of scuba gear is to enable a diver to descend below water and that entails intending to affect the function of the body. Again no medical or therapeutic results are intended as would be the case with any of the medical gas delivery equipment. If one focuses on the literal intent of how a product will affect the structure or function of the body to define use, however, scuba equipment and medical gas delivery equipment seem to have the same intended use.

The very fact that it would be difficult to classify scuba equipment under the FDCA, both in terms of whether such gear constitutes a medical device in the first instance and in terms of what class of device to place it under in the second instance, may itself be a reason why the FDA has forgone regulation and left the problem to other agencies. An illustrative comparison can be drawn to a recent inquiry to the FDA regarding the importation of sports oxygen. Sports oxygen is a small pocket-sized, personal use oxygen system which is popular in Japan as well as other places. Apparently one of the claims made by the manufacture of the sports oxygen system was that the system would enhance athletic performance. This claim, if made in relation to a home exercise unit or most other traditional sports recreational equipment, would seem to fit within what the FDA has previously determined to be acceptable fitness related claims.⁵¹ In this instance, however, the FDA deemed the sports oxygen to be a new drug and disallowed its importation into the country until the manufacturer has filed a new drug application and been approved. This decision was based in part on the oxygen flow rate of the sports oxygen system which was below FDA standards and in part on supposed labeling claims relating to the treatment of medical conditions.⁵²

⁵¹See Scarlett Letter, supra note 20, at 2-3.

⁵²See FDA Human Drug CGMP Notes (March 1997) <<http://www.fda.gov/cder/hdn/cnotes37.htm>>; FDA Import Alert <http://www.fda.gov/ora/fiars/ora_import_ia6637.html>.

Other than the athletic enhancement claim, the FDA never specified what labeling claims it found to violate FDA regulations, but arguably even if the manufacturer had re-labeled the sports oxygen using only claims found on unregulated sports equipment, the FDA would still have banned the importation of this product. What makes the sports oxygen system different from scuba equipment that uses blends of gases, some with higher concentrations of oxygen than found in normal air? Why would the FDA choose to regulate a sport oxygen system if it is marketed entirely as a recreational sports accessory, makes no medical claims, and its intended use is not medical even if it does in some way affect the structure or function of the body? One possible answer is that the FDA can fit sports oxygen into a definable category of the FDCA. The FDA already regulates oxygen as a drug. Moreover the use of sports oxygen is not a traditional recreational use with a history and wide base of support in this country. Scuba on the other hand defies easy classification within the regulatory scheme and enjoys a wide base of support as a recreational sport in this country. The FDA may be making a practical decision to regulate where and when it can without creating difficult classification issues and without upsetting a regulatory system already in place by other agencies.

3. Scuba Industry Self-Regulation

Besides difficulty of classification, another practical consideration that could possibly be compelling to the FDA in a decision to regulate or not regulate is the level of self-regulation achieved by an industry. This leads to the final and perhaps most compelling reason for why the FDA has not and should not regulate scuba equipment --- the scuba industry has done a remarkable job of self-regulation. The six major scuba certification agencies have formed an association

know as the Recreational Scuba Training Council (RSTC). RSTC members agree to abide by minimum course content requirements, and they agree on safety standards and training standards. RSTC is a member of the American National Standards Institute (ANSI), a nonprofit organization that certifies an industry standard has been arrived at through open discussion and with due process. RSTC certification agency members, in training new divers or training specialty divers, all abide by an industry standard, called ANSI Z-86.3 (soon to be revised and reissued as Z-375.1). This standard was written by the RSTC and blessed by ANSI. Although only six scuba certification agencies are members of RSTC, as a practical matter all have to meet the RSTC/ANSI standard in order to buy liability insurance and defend themselves from lawsuits.

The self-regulation of the scuba industry is being done in large part at the level of the certification training agencies, not necessarily by the manufactures of scuba equipment, but the resultant levels of safety indicate that government regulation is not needed. The scuba industry in the United States has a history of self-regulation dating back to the start of scuba becoming popular as a sport.⁵³ Scuba as a recreational sport began to catch on in the United States in the 1950s. Initially there were no scuba diving certification agencies and many recreational divers used equipment without training and without necessarily any understanding of the physics of diving and the effects of breathing air underwater---as a result some injuries and fatalities occurred. The YMCA responded to the need for organized training and created the first scuba certification course in 1959. Other certification agencies quickly entered onto the scene, many affiliated with dive shops that sold scuba equipment. By 1970 the dive industry had created its own standard that scuba air tanks would not be filled with compressed air unless a diver could present a current, valid certification card. In 1980 Dan was formed, and in 1986 RSTC

⁵³See generally Alex Brylske, A Brief History of Diving: Parts I and II., Dive Training (Aug. & Sep. 1994).

was formed.

Although the certification agencies and the scuba equipment manufacturers are separate entities, they have a symbiotic relationship. Certification agencies readily acknowledge that the whole profession of scuba instruction evolved from the need to show purchasers of scuba equipment how to use it safely,⁵⁴ and that the certification agencies need safe equipment in order to practice and develop their sport. Moreover many of the agencies make money by operating out of dive shops that offer a full range of services from training to sales of equipment. The manufactures need the dive instructors, dive masters and dive shops to retail their goods. Often times dive instructors make additional income by earning commissions on scuba gear purchased by their students. Manufactures offer deep discounts on the cost of gear, especially new innovative gear, to dive professionals because it is well known in the industry that students mimic their instructors and purchase the same brands as they see their instructors use.⁵⁵ Because the certification agencies and in turn the certified instructors are well versed and very conscious about the need for safe dive equipment, they as a group insist that manufactures make safe equipment. When products are viewed as unsafe or unreliable, they are shunned by the diving profession. The fact is that the market demands safe gear and therefore that is what the manufactures supply.

The symbiotic relationship between certification agencies and scuba equipment manufactures also helps achieve another goal of the FDCA---effective labeling of risk information to avoid harms of misbranding. The FDA increasingly relies on hazard warnings and dissemination of risk information to promote public safety. The problem that arises, not just with medical devices but also with drugs and food, is that only so much information can be placed on a label

⁵⁴See Scuba Schools, DiveCon, supra note 13, at 8-7.

⁵⁵See id. at 8-8.

and placing the information in a pamphlet accompanying the product does not ensure that the consumer will actually read or understand the information. The scuba industry has in large part solved this problem through the creation of certification programs. Part of the RSTC/ANSI standards for minimum course content include instruction on the risks of scuba diving, the necessary equipment, how to maintain that equipment and how to respond in the unlikely event that the equipment malfunctions. If the FDA regulated scuba equipment, they could require labeling by the manufactures but the labeling would not be nearly as effective as what is already taking place in the private market.⁵⁶

In addition to the market forces that police the safety of dive equipment, many dive affiliated businesses also police safety. For example Rodale Inc.---a corporation that publishes Rodale's Scuba Diver Magazine and maintains Rodale's Scuba Diver website--- contracts with ScubaLab, an independent testing operation to perform evaluative and comparative testing on scuba equipment. Rodale's publishes the results of ScubaLab's tests in their magazine as well as in their buying guide.⁵⁷ This independent testing provides consumers with objective information about scuba gear, and highlights any potential problems with safety, effectiveness, reliability and value. Besides providing information to consumers, this independent service provides incentives to manufactures of scuba equipment to create safe and reliable gear that can withstand the testing and receive

⁵⁶Prof. Kip Viscusi in his writings about hazard warnings has used the scuba industry as an example of effective risk information dissemination. He argues that the concept of warning labels:

should be sufficiently broad to include not only on-product warnings, but also other mechanisms for hazard communication, such as videos, training manuals, and safety education programs. Because of the perils of scuba diving, participants in that sport are required to become certified for open water diving by one of two major international organizations. This training program includes a detailed discussion of the risks associated with scuba diving and training in how to avoid these risks. Although these hazards cannot be conveyed through a simple on-product warning, such as a label on an air tank, this information transfer is still a warning. However, because the message that must be conveyed is complex, an on-product warning is not sufficient to alert persons to the risks inherent in the activity. Consequently, the overall concern should be whether the entire hazard communication system, including warnings and other mechanisms of information transfer, is sufficient to enable the recipient to make sound risk-averting decisions.

Kip Viscusi, Individual Rationality, Hazard Warnings and the Foundations of Tort Law, 48 Rutgers L. Rev. 625, 626 (1996).

⁵⁷See Rodale's Online: Buying Guide <<http://www.scubadiving.com/gear/scubalab.shtml>>.

recommendations by Rodale's.

Not all private certification activities work out as well as Rodale's program. The Federal Trade Commission (FTC) had to get involved when the National Association of Scuba Diving Schools, Inc. (NASDS), a marketing and management organization, created a seal of approval that it sold to retail stores to affix to scuba equipment. The seal suggested that the equipment had met some objective standard for safety and quality when in fact NASDS had done no testing and did not ensure that stores did not affix the seal to unapproved products. The FTC received a consent order to prevent NASDS from continuing what the FTC considered false, misleading and deceptive practices in violation of the Federal Trade Commission Act.⁵⁸ This example of a failed self-regulatory attempt does not suggest that the scuba industry needs additional regulation, if anything it shows that current, less intrusive regulatory agencies such as the FTC can step in when self-regulating practices get out of hand.⁵⁹

One final consideration under the topic of self-regulation is the role played by tort law and potential tort liability in ensuring that scuba equipment meets safety and effectiveness standards. Again the symbiotic relationship between manufacturers and certification agencies plays a role because the insurance costs to certification agencies and dive shops is directly tied to the overall risk inherent in the industry---this includes risk of equipment failure. Scuba equipment

⁵⁸See In the Matter of Nat'l Assoc. of Scuba Diving Schools, Inc., Consent Order, 100 F.T.C. 439 (July 1982).

⁵⁹One problem that the scuba industry and scuba retailers face when trying to self-regulate is the current doctrine of antitrust law. Many steps taken ostensibly to ensure safety in the industry have been ruled unreasonable restraints on trade under the antitrust rules. See U.S. v. Scuba Retailers Ass'n., 6 Trade Reg. Rep. (CCH) ¶ 45,096 (S.D. Fla. 1996) (trade association of scuba equipment retailers tried to curtail mail order sales); Justice Department Moves to Block Retailers of Scuba and Diving Equipment from Curbing Mail Order Competition, 23 NO. 1 NAAG Antitrust Rep. 14 (Jan/Feb. 1996). Some scuba equipment manufactures, such as US Divers, voluntarily limit sales to retail stores, refusing to sell to mail order or Internet companies because they want to control point of sale advice on safe use and to ensure that equipment is being sold to certified divers. See US Divers <<http://www.aqualung.com/public.htm>>. It remains an open question whether the Justice Department's antitrust efforts will hurt the safety levels achieved by the scuba industry.

manufactures in making cost-benefit assessments of the optimal safety level of the equipment they produce must consider not only the potential costs arising from tort liability law suits, but cost in terms of lost sales to retailers due to increased insurance costs. The incentives for the manufactures weigh in favor of making safe gear so that the overall risk level of the industry stays low, and therefore insurance premiums stay low allowing for more stores and more divers.⁶⁰

Whether it is based on fear of tort liability, market incentives, the symbiotic relationship with certification agencies and dive shops, or a combination of all of these, scuba equipment is highly reliable and rarely causes diving accidents.⁶¹ The overall effectiveness of the scuba industry's regime of self-regulation provides strong evidence about why the FDA has not and should not regulate this industry.

IV.

This paper started out by arguing that the growing popularity of quasi-medical health and fitness devices might lead the FDA to expand its regulatory control over the health and fitness industry. After laying out the example of the scuba industry and scuba equipment, several points about how quasi-medical devices might be treated by the FDA and what the implications are for these products can be ascertained.

⁶⁰See Mario R. Arango & William R. Trueba, Jr., *The Sports Chamber: Exculpatory Agreements Under Pressure*, 14 *U. Miami Ent. & Sports L. Rev.* 1, 30-31 (1997) (discussing scuba industry incentives to keep insurance costs low and the exorbitant cost of tort liability law suits).

⁶¹See, e.g., Phyllis G. Coleman, *Scuba Diving Injuries: Causes, Remedies, and Defenses* 29 *J. Mar. L. & Com.* 519, 553 (1998).

First, the ambiguity and circularity of the medical device definition can be both a good and a bad thing for products seeking to avoid FDA regulation. If a product falls into the gray area, as arguably scuba equipment does, then a manufacturer can avoid making medical claims and market and label the product as recreational. This approach might avoid FDA regulation as a medical device. An example of this would be a pulse rate monitor marketed for use with other exercise equipment or exercise routines. The same monitor used in a hospital or clinic would be a medical device, but the device when used in conjunction with other exercise equipment becomes more quasi-medical. The manufacturer of one such device inquired of the FDA whether it would be regulated under the FDCA and the FDA found that it would not due to the lack of intended medical use.⁶² Thus avoiding medical claims and linking a device to exercise can help to avoid regulation. On the other hand, there remains the example of the sports oxygen which also arguably fell within the gray area of medical device definitions, but the FDA chose to treat that as a drug and banned its importation altogether. This illustrates the danger in marketing quasi-medical devices: If the FDA does not accept an analogy to a device already exempt from regulation, the FDA may treat the product as a new device requiring that it go through the extensive new device approval process. The way to avoid submitting an NDA is to argue that a product is substantially equivalent to an already approved device, but this of course is the very analogy that quasi-medical devices seeking to avoid FDA regulation want to disprove. This places quasi-medical devices into a conundrum about how to define and market the device in the first instance.

⁶²See Pulse Rate Monitors for Exercise Use Only -- Device Status <<http://www.fda.gov/cdhr/deviceadvice/21ddd.html#contents>> (last updated April 15, 1998).

A second point that can be drawn from the scuba industry example is that measures at self-regulation can go a long way in avoiding governmental regulation. Although good arguments have been made that tort liability alone can regulate consumer products and medical devices, the government has not yet fully accepted that argument. This indicates that something more than mere reliance on market incentives and tort liability is needed. Utilizing organizations such as ANSI might help avoid government regulation and allow new quasi-medical products to create their own voluntary standards. Certainly working with other regulatory agencies, such as CPSC, which allow for the promulgation of voluntary standards is a way to avoid the more burdensome FDA requirements. Finally, the presence in the industry of a less self-interested regulatory body that can create incentives for manufactures of goods to conform to safety and reliability standards may help to prevent FDA regulation. The scuba industry has the certification agencies which drive incentives for manufactures to conform to standards in labeling, manufacturing and performance. Other products seeking to avoid regulation might consider an analogous arrangement with an independent, non-governmental organization.

V.

The Scuba industry and the manufactures of scuba equipment have done an admirable job over the years of ensuring the quality, safety, and reliability of scuba equipment. This has been done with very little government regulation and oversight. To the extent that the FDA ever has or ever will consider regulating scuba equipment, these are the factors that it should look at. In turn these factors of self-imposed safety norms and self-regulation should be the guide for other quasi-medical devices that wish to avoid regulation by the FDA or other

government regulatory agencies.