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The Radiation Control for Health and Safety Act of 1968: History, Accomplishments, and Future

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Abstract

Prior to 1968, control of radiation-emitting electronic devices was left to state and local governments, whose regulations proved both inconsistent and ineffective. This was highlighted by General Electric's 1967 recall of 90,000 television sets believed to emit dangerous levels of radiation. Congress soon proposed a federal radiation control bill. The hearings revealed the general lack of data on the harms of radiation exposure and the vast amount of unnecessary radiation that Americans were exposed to each year. As enacted on October 18, 1968, the Radiation Control for Health and Safety Act authorized the Food and Drug Administration to set federal radiation standards, to monitor compliance, and to conduct research. The FDA's Bureau of Radiological Health actively administered the act. The act has produced safe electronic products, considerable scientific knowledge, and a public well aware of the risks of radiation exposure. But for all of its successes, the act has also had its problems. The act does not require pre-market approval, choosing instead to respond once problems arise. The FDA has also seen significant budget cuts and must prioritize its obligations under all the acts it administers. The FDA has turned to the internet to communicate its message to manufacturers and consumers, but at the same time must counter the rise of the popular media and its ability to excite the public regarding potential radiation hazards. How the FDA allocates its decreasing funds and works with the mass media will determine the future of the act.

I. Introduction

A child swallows a penny, and his father can watch the penny move through the child's body using a

fluoroscope.[1] A person injures his leg, and his doctor can use an x-ray device to determine the extent of the injury. A worker's coffee is cold, and he can heat it quickly in a microwave. The twentieth century saw a proliferation of new technology that had the potential to protect people's health and to provide consumer convenience and entertainment. The x-ray was discovered in 1895 by Wilhelm Roentgen.[2] The x-ray's benefits for medical diagnosis were discovered soon after. As the century progressed, consumer goods such as color television sets provided in-home entertainment, while the microwave oven provided convenience to an increasingly busy population. Tanned skin was becoming more popular, which resulted in the increased use of sunlamps. These new and exciting products seemed to increase the overall quality of life. In 1967, however, a General Electric ("GE") recall of 90,000 television sets alerted Americans to the risks of using these products.

GE discovered that its sets were emitting excessive radiation that had the potential to harm viewers who sat near the sets. However, the radiation exceeded only voluntary industry-set standards, as there was no federal regulation of radiation emitting products. State and local governments provided some regulation, but it was both inconsistent and ineffective. Bills were introduced in both the House of Representatives and the Senate in 1967 to enact a radiation control act. Congress quickly realized that the problem extended far beyond color televisions. X-ray examinations represented ninety percent of human radiation exposure, and the techniques and equipment were resulting in unnecessary exposure to both the patient and the physician. Congress also realized that scientists knew very little about the dangers of radiation. Witnesses testified that biological harm could be caused by much lower amounts of radiation as a result of a lifetime of exposure, and that harm could result not just from ionizing radiation such as x-rays, but also from non-ionizing radiation

[1] Ricki Lewis, *Radiation Continuing Concern With Fluoroscopy*, FDA Consumer, Nov. 1993, at 18, 18.
[2] Egon Weck, *A Primer on Medical Imaging – Part One*, FDA Consumer, Apr. 1989, at 24, 24.

such as microwaves and visible light. An accident in Pennsylvania during the legislative hearings prompted passage of the Radiation Control for Health and Safety Act of 1968 ("RCHSA").

While the act was admittedly a compromise weakened by manufacturers' lobbying efforts, it still provided the Food and Drug Administration ("FDA") with vast authority to conduct research, to set safety standards, to monitor compliance, and to impose civil penalties. Research quickly led to technological advances in the electronic devices themselves and contributed to a better understanding of the biological harms associated with radiation exposure. The FDA also began a public education campaign to alert consumers to the protective measures they should take in using certain electronic products. The primary focus of the act, however, was the setting of enforceable radiation standards. The early standards revealed that measures needed to produce safe electronic products were typically low cost and easy. In the absence of enforceable standards, however, there had been little incentive to expend resources in this area.

The RCHSA's early success is partially attributable to the cooperation between the Bureau of Radiological Health and the manufacturers, and the commitment of federal resources to achieve the act's goals. Both factors are now declining. The FDA must now prioritize its activities under not just the RCHSA, but related statutes such as the Medical Devices Amendments and the Mammography Quality Standards Act. With the rapid development of technology, it is expected that new radiation-emitting products will be produced. Should the FDA invest resources to determine the dangers of these products, or should it trust professional organizations to set appropriate standards and instead devote its resources to monitoring and enforcement? The FDA's ability to spread its message on the internet quickly is countered by the rise of a rather uninformed popular media more interested in ratings than science. The media has great power to promote a single unsubstantiated study or freak accident and consequently the ability to undo years of research and public education by the FDA. Well-considered collaboration with the popular media may be the next logical step in ensuring a safe and knowledgeable citizenry.

Not to be overlooked, however, is the fact that the problems facing the FDA regarding radiation exposure are relatively mild when compared to the problems of the 1970's and 1980's. Radiation-emitting electronic products that comply with federal standards are now safe, and concern has shifted to improper uses. While the FDA may have more trouble detecting the rogue manufacturer trying to save a little money by producing substandard products, many factors other than the chance of FDA detection strongly advise against short cuts. Unlike the manufacturers in the 1970's who had to conduct expensive research to produce safe products, the technology is now well-developed and commonplace in the manufacturing of electronic products. The RCHSA accomplished the goals set by Congress in 1968, and, consequently, today's regulators are left with a lesser burden. The FDA's challenge will be with newer technology whose long-term effects are not yet known.

This paper discusses the progress of the Radiation Control for Health and Safety Act of 1968. It begins with an extensive discussion of the legislative history. A thorough understanding of the state of the law and of science prior to the passage of the act is essential to evaluate properly the contributions the act has made. It then discusses the major provisions of the act, the extent of the FDA's authority, and the administrative network in which it operates. This is followed by a discussion of the regulation of specific products, namely, x-ray devices, microwaves, sunlamps, lasers, and cell phones. The history of the regulation of these products further explains the FDA's authority under the RCHSA. The final section summarizes the contributions the act has made to society by discussing the value of both the enforceable standards and the commitment to public education. The RCHSA has resulted in products that are protective of human health and a public that is aware of the dangers of excess radiation and is changing some of its behaviors accordingly.

II. The Road to Federal Radiation Control

The Radiation Control for Health and Safety Act was enacted on October 18, 1968, as an amendment to the Public Health Service Act "to provide for the protection of the public health from radiation emissions from electronic products."[3] Prior to its enactment, radiation exposure had been regulated largely by the states[4] based on recommendations from the Advisory Committee on X-Ray and Radiation Protection.[5]

High dose radiation had long been known to be fatal. Large-scale atmospheric testing of nuclear weapons and the resulting radioactive fallout prompted the Eisenhower Administration to unify radiation control activities in the Public Health Service in 1958[6] and to create the Federal Radiation Council in 1959.[7] The National Center for Radiological Health ("NCRH") was established in 1967.[8] However, as the nation entered the "electronics age" and saw a "vast expansion in the number, diversity, and usefulness of electronic products," the reliance on advisory committees and inconsistent state regulations proved insufficient.[9] Potentially dangerous radiation was now known to emit not just from x-ray machines and nuclear weapons, but also from standard consumer goods such as color televisions and microwave ovens.[10] The need for uniform and enforceable federal safety standards was clear.

A. The TV Debacle

[3]Pub. L. 90-602, 82 Stat. 1173 (1968).

[4]The Atomic Energy Act of 1946 gave the Atomic Energy Commission ("AEC") authority to regulate certain artificial radioactive materials, but its jurisdiction did not extend to consumer goods or medical devices. Alan R. Bennett & Robert A. Dormer, *FDA and Radiological Health: Protecting the Public From Radiation Hazards*, *in* II FUNDAMENTALS OF LAW AND REGULATION 299, 299 – 300 (David G. Adams, Richard M. Cooper, & Jonathan S. Kahan eds., 1997).

[5]Bennett & Dormer, *supra* note 4, at 299. The organization was composed of industry representatives and was later renamed the National Council on Radiation Protection. Though it received a congressional charter in 1964, it remained a private body. *Id.*

[6]Robert T. De Vore, *New FDA Resource: Consumer Radiation Protection*, FDA PAPERS, Oct. 1971, at 4.

[7]Bennett & Dormer, *supra* note 4, at 300. Like the National Council on Radiation Protection, the Federal Radiation Council served solely as an advisory body. It was composed of heads of executive agencies but relied on the President to direct other agencies to comply with the standards it suggested. *Id.*

[8]*Id.* The Center also served a purely advisory function. It later became the Food and Drug Administration's ("FDA") former Bureau of Radiological Health and is now the Center for Devices and Radiological Health ("CDRH"). *Id.*

[9]De Vore, *supra* note 6, at 4.

[10]*Id.*

The shortcomings of the absence of federal regulation of radiation-emitting products were revealed in May 1967 when GE recalled 90,000 color television sets believed to emit dangerous levels of radiation. Representative Paul G. Rogers noted that GE notified NCRH in January of that year of the potential problem but delayed taking immediate action in favor of conducting new studies.[11] A letter issued by NCRH on May 18, 1967, commended GE's voluntary recall and simply stated that "[a]s of now there is no evidence in the hands of NCRH to suggest that any television receivers... have excessively exposed viewers of television sets."[12] Rogers informed the House that he wrote to the Department of Health, Education, and Welfare ("HEW") regarding his concern over potential radiation emissions from televisions and was told that any radiation emission was negligible. Rogers learned the morning of May 23, 1967, that the Public Health Service believed "that the level of radiation could reach as much as 600 times of the amount recognized as the safe level" yet had taken no action. He called for public hearings to determine the extent of the danger and to take effective action.[13] On June 13, 1967, Rogers and John Jarmin introduced House Bill 10790, which eventually became the Radiation Control for Health and Safety Act.[14]

On June 22, 1967, Representative John E. Moss, Chairman of the Subcommittee on Commerce and Finance, discussed his findings concerning the NCRH letter. Concerned about James Terrill's statement that viewers were not known to have been excessively exposed to radiation, Moss asked Terrill to explain the basis for NCRH's determination. Moss described the reply as "at the very minimum... startling."[15] Terrill revealed that although the radiation leakage beam was directed downward, NCRH believed that the height at which some televisions were placed did result in exposure to excessive radiation. Additionally, people sitting close

[11] 113 Cong. Rec. 13628 (1967) (statement of Paul G. Rogers), *reprinted in* I Legislative History of Radiation Control for Health and Safety Act of 1968 2 (U.S. Bureau of Radiological Health 1975) [hereinafter "I Legislative History"].

[12] 113 Cong. Rec. 13628, 13629 (1967), *reprinted in* I Legislative History, *supra* note 11, at 2 (letter of James G. Terrill, Jr.).

[13] *Id.*

[14] Radiation Control for Health and Safety Act of 1967, H.R. 10790, 90th Cong. (1967), *reprinted in* I Legislative History, *supra* note 11, at 4.

[15] 113 Cong. Rec. 16964, 16965 (1967), *reprinted in* I Legislative History, *supra* note 11, at 6 (statement of John E. Moss).

to televisions could be exposed to excessive radiation. The radiation was not expected to affect people who watched television in "normal viewing" conditions, though it was possible that even those people could be overexposed. Terrill concluded that "any color television receiver suspected of emitting excessive X-radiation which could expose individuals in other than a normal viewing situation should not be operated in that location [until repaired]."[16] Based on NCRH's verification of the dangers, Moss asked for hearings to reassure the public that the government would prevent unsafe products from entering the marketplace.[17]

The Senate introduced versions of the bill to the Committee on Commerce[18] and the Committee on Labor and Public Welfare[19] on July 10, 1967. The House introduced a total of seven bills between June and August of 1967.[20] Representative Jarmin announced that the House Subcommittee on Public Health and Welfare would begin hearings on x-radiation related to color televisions on August 14, 1967.[21]

B. The Initial House Hearings

The initial hearings on House Bill 10790 concerned radiation emissions from televisions. Several government witnesses noted that federal regulation would have protected consumers from unnecessary and excessive radiation exposure by preventing the GE televisions from ever reaching the marketplace. The existing laws provided the federal government with no authority to enforce standards or to require testing or reporting of potential radiation hazards. GE acted responsibly in recalling and repairing the televisions, but it was not compelled to do so by law.[22] Wilbur J. Cohen stated that 7.4 million color television receivers had

[16] *Id.* (letter of James G. Terrill, Jr.).

[17] *Id.*

[18] S. 2067, 90th Cong. (1st Sess. 1967), *reprinted in* I Legislative History, *supra* note 11, at 12.

[19] S. 2075, 90th Cong. (1st Sess. 1967), *reprinted in* I Legislative History, *supra* note 11, at 14.

[20] Bennett & Dormer, *supra* note 4, at 301.

[21] 113 Cong. Rec. 20483 (1967), *reprinted in* I Legislative History, *supra* note 11, at 19.

[22] *Radiation Control for Health and Safety Act of 1967: Hearings on H.R. 10790 Before the House Subcomm. of Pub. Health and Welfare of the Comm. on Interstate and Foreign Commerce*, 90th Cong. 8 (1st Sess. 1967) (statement of Horace R. Kornegay), *reprinted in* I Legislative History, *supra* note 11, at 82 [hereinafter "*1967 House Hearings*"]. General Electric ("GE") actually provided technical assistance to NCRH during the hearings regarding its improved testing procedures, and NCRH modeled its study of televisions on the revised GE monitoring program. *Radiation Control for Health and Safety Act: Supplemental Hearing on H.R. 10790 Before the House Subcomm. on Pub. Health and Welfare of the Comm. on Interstate and Foreign Commerce*, 90th Cong. 20 (2d Sess. 1968) (statement of James G. Terrill, Jr.) [hereinafter "*1968 House Hearings*"], *reprinted in* II Legislative History of Radiation Control for Health and Safety Act of 1968 637, 649 (U.S. Bureau of Radiological Health 1975) [hereinafter "II Legislative History"].

been manufactured in the United States in the previous two years but that no one knew how many of those sets were emitting hazardous radiation. While the Public Health Service had begun a program to evaluate radiation exposure from television sets, little was being done about other electronic devices also believed to emit radiation. Cohen supported the bill's grant of authority and responsibility to HEW to conduct research and control radiation hazards.[23]

The increasing use of electronic products that inherently release radiation reinforced awareness of the dearth of knowledge regarding the dangers of radiation exposure. Following the television recall and the government's conflicting statements regarding potential dangers, consumers were left with little confidence that their home products were safe. Representative Jarmin summarized the current state of the knowledge:

> It is my understanding that, unless exposure has been sufficiently intense to produce bodily injury which would be quickly apparent, the health effects from radiation may not appear for years and even may not become manifest except in some aberration in children born to a parent who had been unknowingly irradiated. What confronts us is an invisible enemy of human health which often may work in ways imperceptible to the victim of [sic] his or her physician to produce effects which may be harmful to more than one generation of a family. Electromagnetic radiation, which many kinds of electronic products produce in various forms, is something that all persons should avoid completely.[24]

Dr. William H. Stewart, Surgeon General, elaborated: "I think the odds [of genetic damage resulting from the GE televisions] are very low. When one is talking odds there is always that one or two. That is why we feel it is terribly important that these sets get back."[25]

Congress recognized that the general lack of knowledge had to be corrected before effective standards could be established.[26] Among the potential known dangers of radiation exposure in general were leukemia and other cancers, cataracts, burns, sterility, and other birth defects. While the dangers of high dose radiation

[23] *1967 House Hearings*, *supra* note 22, at 5 – 6 (Letter of Wilbur J. Cohen).
[25] *Id.* at 16 (Statement of Dr. William H. Stewart).
[26] *Id.* at 10 (Statement of L. H. Fountain).

exposure were well documented, the effects of low dose exposure resulting from standard consumer products in the home represented a major gap in knowledge.[27] The need for a federal research program was clear. Of particular concern in establishing a research program was the large number of programs involved in the current federal regulatory system. Representative L. H. Fountain estimated that federal grants included "more than 175 general programs funded under more than 400 separate agencies... administered by 19 different departments and agencies and by more than 140 separate Federal bureaus and divisions."[28] The proposed bill would authorize the Secretary of HEW to administer the radiation program within its current structure and would eliminate the need for another new agency or bureau.[29]

The House debates initially focused on the GE televisions but quickly expanded to include other radiation concerns. The hazards of increased medical and dental x-ray use and methods currently utilized to limit radiation exposure were thoroughly discussed.[30] The American College of Radiology urged enforceable national standards and "federal responsibility for fixing and enforcing standards for medical x-rays." The College requested that funding be provided for research and training to minimize radiation exposure not just to the patient, but also to the radiologists and x-ray technologists who are constantly exposed to x-ray machines.[31] Dr. Karl Z. Morgan, Director of the Health Physics Division at Oak Ridge National Laboratory, believed the primary concern should be the elimination of unnecessary or wasteful diagnostic exposure. Noting that over ninety percent of all exposure in the United States was due to medical exposure, Dr. Morgan believed total exposure to manmade sources could be as low as nineteen percent of the current value if the use of

[27] *Id.* at 14 – 15 (Statement of Dr. William H. Stewart). Dr. Stewart testified in detail about the potential dangers related to the GE televisions and the 1,800 sets that GE had not been able to recover. His full testimony can be found in the 1967 Hearings at 10 – 18. James G. Terrill, Jr., the director of NCRH, provided testimony on the technical details of radiation, including how electronic products generate radiation, why the GE televisions leaked radiation, the potential biological effects of excessive radiation exposure, and other potential emitters of radiation. Mr. Terrill also presented a study entitled "Radiation Exposure in Parents of Children with Mongolism (Down's Syndrome)," which concluded that "there appears to be a definite association between maternal exposure to ionizing radiation and Mongolism." *Id.* at 18 – 76. Technical testimony on different types of radiation and ways manufacturers could protect consumers from excessive radiation was provided by James F. Young, Vice President of Engineering for General Electric. *Id.* at 150 – 189.

[28] *1967 House Hearings*, *supra* note 22, at 10 (Statement of L. H. Fountain).

[29] *Id.*

[30] *Id.* at 193 – 208 (Statement of James W. Nelson, Jr.).

[31] *Id.* at 320 – 29 (Statement of the American College of Radiology).

x-ray diagnostic procedures were more carefully scrutinized.[32] Dr. Morgan disputed the assumption of some doctors that the probability of pregnancy was low and that x-ray examinations therefore resulted in very little hazard.[33] He was particularly concerned about a March 1957 report that stated that some obstetricians advocated the use of pelvimetry as part of a routine examination.[34] Dr. Morgan also confirmed that occupational exposure had previously resulted in shorter life spans for radiologists but that current techniques had eliminated the risk.[35] Dr. Morgan concluded by providing a list of sixty-three ways to reduce medical diagnostic exposure.[36]

The American Dental Association ("ADA") contested the conclusions drawn by Dr. Morgan and others who testified before the House. Dr. Albert G. Richards, speaking for the ADA, emphasized the importance of dental x-rays and the level of training dentists and hygienists received regarding radiology and radiation protection. Dr. Richards discussed the ADA's private efforts to educate its members through videos, essays, and clinical presentations, and its public efforts to register x-ray units and to encourage compliance with state radiation laws.[37] Dr. Richards' statements were in direct contradiction to a survey of dental x-ray units in Pinellas County, Florida. The survey concluded that dental x-rays constituted an important source of unnecessary exposure; that a large percentage of dentists and dental technicians had inadequate training; that x-ray sales and repair personnel were inadequately trained to make proper adjustments to protect patients and office personnel; that the greatest source of unnecessary exposure resulted from bad technique;

[32] *Id.* at 363 – 67 (Statement of Dr. Karl Z. Morgan).

[33] *Id.* at 366 – 67. In fact, a report of the U.S. Public Health Service indicated that 4.1 million women had live births in 1963. Of these women, 915,000 had one or more medical x-ray visits during pregnancy, while 420,000 had one or more dental x-ray examinations. The report estimated that twenty-two percent of pregnant women had one or more x-ray examinations during pregnancy. *Id.* at 367.

[34] *Id.* at 367. Dr. Morgan admitted that studies of the relationship between in utero exposure and childhood cancer were mixed, but that a report by Dr. Brian McMahon combined all of the data and found that mortality from leukemia and other cancers was 40 percent higher in children who had been exposed to diagnostic x-ray in utero. The excess risk due to in utero exposure amounted to about one cancer death per 2,000 children exposed. *Id.* at 369 – 70.

[35] *Id.* at 371.

[36] *Id.* at 375 – 377. The recommendations covered such topics as education and training; rules, records, legal matters, and inspections; x-ray equipment and safety devices; x-ray films and associated equipment; and techniques and procedures.

[37] *Id.* at 408 – 12 (Statement of Dr. Albert G. Richards).

and that public health or other government involvement was necessary for optimum protection.[38] Rogers commended the ADA on its awareness of the problem of unnecessary radiation exposure and its efforts to regulate privately but noted that considerable work needed to be done at a more accelerated pace.[39]

At the close of the 1967 hearings, an accident occurred at the Van de Graaff accelerator facility at Gulf Oil's Research and Development Laboratory in Pennsylvania that further demonstrated the problems resulting from the absence of federal regulation.[40] On October 4, 1967, three employees at the facility were conducting a standard x-ray analysis on an oil sample. The oil sample was placed in the accelerator in the target room and the employees returned to the accelerator control console. The target room and the control console were separated by two doors, and the accelerator, control console, and doors were connected by a safety interlock system. After the sample had been irradiated, the operator removed the key from the control console, proceeded through the two doors, and removed the sample. The employees noticed that the cooling system was not working properly. While one chemist left with the sample, the two other men remained in the room to try to repair the system. One man began feeling ill some time after and was sent to the hospital. An evaluation of the film badges the men had been wearing revealed that they had all been exposed to relatively high levels of radiation. The accelerator had not shut off after irradiating the sample despite the four separate measures that should have shut it off. Exposure was believed to be as long as twenty-four minutes. It was unclear if this was due to human error or the failure of the safety interlock system.[41]

Further investigation indicated that the company received the results of the film badge evaluations two days

[38] George R. McCall & Clyde H. Stagner, *Report of Initial Survey of Dental X-Ray Units, Pinellas County (Fla.) Health Department*, *reprinted in 1967 House Hearings*, *supra* note 22, at 413. Pinellas County began surveying dentists' offices in 1961 but decided to resurvey the offices following a request from a dentist. The second survey determined that the dentist had been overexposing himself to radiation for five years. Another survey revealed that a dentist and his assistant had received excessive radiation to their hands due to the practice of holding dental film in patients' mouths during x-ray exposure. Of the forty-three offices and seventy-one dental x-ray units surveyed, "34 timers were inaccurate, 15 required additional filtration, 8 required proper collimation. Three offices had inadequate x-ray protection for personnel, two dental units lacked preset timers to stop x-ray exposures, and in seven dental offices personnel were holding the dental film during x-ray exposures. In addition, gonadal shielding was used in only five offices and only fourteen dark rooms were adequately light tight. In almost every office recommendations were made for the reduction of personnel exposure to radiation. . . ." *Id.* at 415.

[39] *1967 House Hearings*, *supra* note 22, at 416.

[40] Bennett & Dormer, *supra* note 4, at 301.

[41] *1967 House Hearings*, *supra* note 22, at 426 – 28 (Statements of James G. Terrill and Dr. Raymond T. Moore).

after the accident and immediately notified the Pennsylvania Department of Health. NCRH was not notified until October 10, or six days after the accident, as there was no duty to notify the federal government following serious x-ray exposure. The interlock system had not been checked prior to the accelerator's activation because the state and the company did not require routine checks. The target room provided no visible or audible indication that the accelerator had not been turned off. Dr. Raymond T. Moore, who visited the facility after the incident, stated that it would be very difficult for an individual to identify the noise of a running accelerator. Mr. Terrill and Dr. Moore recommended mandatory notification in cases of serious x-ray exposure to ensure high quality medical care, and a requirement to check fail-safe systems.[42] This incident concluded the initial hearings on House Bill 10790.[43]

C. The Initial Senate Hearings

The initial Senate Hearings on Senate Bill 2067 began on August 30, 1967.[44] The Senate began by modifying the act to provide more discretion to HEW by expanding coverage to include, but not be limited to, the entire range of radiation emitting devices.[45] Senator E.L. Bartlett stated that a federal radiation control program would supplement current state, local, and regional programs. The Senate's current bill only regulated standards prior to introduction into commerce, with inspections and regulations post-sale being left to the states. Senator Bartlett noted, however, that the course of the hearings could reveal the need for federal regulation post-sale following the model of the Atomic Energy Commission ("AEC").[46]

[42] *Id.* at 430 – 31.

[43] Several statements were submitted for the record following the close of the hearings. Professor Russell H. Morgan recommended that the bill include only ionizing radiation because it was the only form of radiation known to produce biological effects. *Id.* at 435. However, this seemed clearly to contravene a central purpose of the bill, which was to understand the effects of all forms of radiation on consumers to ensure maximum protection. The American College of Radiology noted that the benefits of properly administered x-ray procedures outweighed the risk but recognized that other consumer goods provided no comparable benefit and should not require technical proficiency for safe operation. It therefore supported federal standards for all radiation emitting products. *Id.* at 441 – 42. Two studies on microwave ovens were also presented. *See* H. S. Seth & S. Michaelson, *Microwave Hazards Evaluation*, 35 Aerospace, Aug. 1964, *reprinted in 1967 House Hearings*, *supra* note 22, at 453; Joseph H. Vogelman, *A Comparative Analysis of Biological Effects of Microwave Energy*, *reprinted in 1967 House Hearings*, *supra* note 22, at 460.

[44] *Radiation Control for Health and Safety Act of 1967: Hearings on S. 2067 Before the Senate Comm. on Commerce*, 90th Cong. 1 (1st Sess. 1967), *reprinted in* I Legislative History, *supra* note 11, at 364 [hereinafter "*1967 Senate Hearings*"].

[45] *1967 Senate Hearings*, *supra* note 44, at 3.

[46] *Id.* at 5.

The testimony of Hanson Blatz, director of the Office of Radiation for the New York City Department of Health, illustrated the strengths and weaknesses of local regulation. While the New York City Department of Health had adopted and enforced standards to protect citizens from excessive or unnecessary radiation, citizen inquiries and complaints revealed that unnecessary radiation was being emitted from wrist and pocket watches; religious articles; static eliminators; voltage rectifier tubes; radioactive blankets; bandages; electric heating pads; and television sets. Additionally, considerable quantities of radium had been lost by physicians, generally the result of carelessness on the part of the shippers, users, and carriers. However, a local law that revoked physicians' licenses to possess radium if the loss occurred due to carelessness had been successful in essentially eliminating losses.[47] New York State required the licensing of x-ray technicians, a clear step to improve the quality and safety of x-ray procedures, but Mr. Blatz noted that only fifteen percent of x-ray operators fell within this category. The majority of owners and users of x-ray equipment were physicians in private offices who had no formal training in radiology. Shielding of x-ray equipment to protect passersby was dependent on an honor system that many operators overlooked. The New York City system actually represented what Mr. Blatz believed was the most comprehensive radiation control program in the country.[48] Though Mr. Blatz did not believe that a federal research program for x-rays was

[47] *Id.* at 11 – 12 (Statement of Hanson Blatz). Between 1963 and 1965, there had been nine losses of radium, all due to carelessness. After the health commissioner notified the physicians of the revocation policy, only one loss occurred. The lost radium was eventually recovered. *Id.* at 12.

[48] *Id.* at 16 – 18. New York City had an office and laboratory with forty-five people devoted to radiation control. Other cities had programs through their states' health departments, and none exercised the control that New York City did over radiation emissions. New York State had a division of radiological health, but it depended on counties to develop individual programs. It had no enforcement authority, which resulted in some counties being quite inactive. *Id.* at 17.

necessary,[49] he supported federal radiation standards.[50] He agreed that authority should be given to set standards for microwave ovens, laser equipment, and electronic heating equipment.[51]

The current federal regulatory regime was outlined towards the end of the hearings. Government regulation of radiation was "divided among the fifty State governments, several city governments which have been granted such authority, six Federal departments, a Federal Council, and a Federal Commission."[52] The Department of Agriculture set standards for bacon irradiation. HEW administered the Public Health Service and NCRH, but neither department had authority to enforce standards. The FDA regulated the effects of radiation in food processing but not the effects of exposure on the processors or the public. The Department of Interior had authority to regulate health effects related to mining, which technically covered exposure to radiation. The Department of Transportation regulated the transport of dangerous materials, including radioactive materials. The Department of Labor had recently begun regulating radiation exposure in uranium mining. The Bureau of Standards of the Department of Commerce had been conducting research on x-rays but had no authority to set standards. The Federal Radiation Council advised the President on radiation matters but also had no enforcement authorities. The AEC had the most extensive experience and regula-

[49] Mr. Blatz believed the hazards of x-rays and the methods of limiting excess or unnecessary radiation exposure were well known and therefore did not require additional research. *Id.* at 18. He submitted an article that detailed his research on radiation exposure and methods of reduction. Hanson Blatz, *Common Cause of Excessive Patient Exposure in Diagnostic Radiology*, *reprinted in 1967 Senate Hearings*, *supra* note 44, at 25. Dr. Karl Z. Morgan disagreed with Mr. Blatz's conclusions, however. Dr. Morgan believed that research in the United States was actually lagging behind research conducted by the Soviet Union regarding the effects of ionizing radiation on the central nervous system. While Dr. Morgan agreed with Mr. Blatz's statement that more was known about the effects of radiation than other environmental hazards, he noted that the fortunate lack of radiation accidents had resulted in limited data on the effects on humans. Dr. Morgan therefore suggested improved mandatory training in radiology; a federal research program; federal inspections of x-ray devices (both he and Mr. Morgan noted the common use of outdated x-ray devices and the attendant dangers); and specific standards for maximum dose exposure. *1967 Senate Hearings*, *supra* note 44, at 35 – 38.

[50] *1967 Senate Hearings*, *supra* note 44, at 18 – 20. Mr. Blatz also noted that enforcement of standards was actually fairly easy. An example included watches that were manufactured with radium to allow them to glow. It was discovered that young people often placed the watches near their abdomens, only inches from their reproductive organs, and that the watches exceeded allowable exposure limits set out in the New York City Health Code. Mr. Blatz's department notified the manufacturers and policed a few stores where the watches were sold. The manufacturers learned quickly that the watches could not be sold in New York City and removed them from the market. Mr. Blatz believed that the watches were exported to be sold elsewhere. *Id.* at 18 – 19.

[51] *Id.* at 23.

[52] Warren H. Donnelly, *Federal Authority to Set Standards for Radiation*, *reprinted in 1967 Senate Hearings*, *supra* note 44, at 339, 358.

tory authority, but its authority was limited to the use of source, byproduct, and special nuclear material.[53] The study recommended further research prior to setting standards and a federal radiation program in the model of the AEC.[54]

Several months after the close of the initial Senate Hearings, Senator Bartlett summarized the current state of radiation exposure.[55] Radiation exposure had become a serious problem because of the increased use by physicians, dentists, radiologists, engineers, and other professions, and because technological advances had created many new sources of radiation.[56] Senator Randolph noted that there was little current consumer danger related to microwaves and lasers because most uses were within the government. Consequently, the biological effects of radiation from microwave or laser use had not been well studied. Senator Bartlett anticipated, however, that technological advances would greatly increase their use in basic consumer products and noted that further hearings would be held to discuss these sources.[57]

D. The Passage of House Bill 10790

In President Lyndon Johnson's February 6, 1968, message to Congress, he advocated passage of the Hazardous Radiation Act:

> It has been said that each civilization creates its own hazards. Ours is no exception. While modern technology has enriched our daily lives, it has sometimes yielded unexpected and unfortunate side effects... Now modern science must be put to work on these hazards – particularly the hazards which confront the consumer. The [Radiation Control for Health and Safety Act] will give the Secretary of Health, Education, and Welfare authority to conduct intensive studies of the hazards and set and enforce standards to control them, [and] require manufacturers to recall defective equipment and devices.[58]

On March 20, 1968, the House of Representatives passed and sent to the Senate House Bill 10790. The House Interstate and Foreign Commerce Committee weakened the bill before passage by extending the time

[53] *Id.* at 358 – 60.
[54] *Id.* at 371.
[55] 113 Cong. Rec. 36229 (1967), *reprinted in* I Legislative History, *supra* note 11, at 618.
[56] *Id.* at 36231.
[57] *Id.* at 36240. Testimony was eventually received on the Army's policy regarding x-rays and lasers. *Radiation Control for Health and Safety Act: Hearings on S. 2067, S. 3211, and H.R. 10790 Before the Comm. on Commerce*, 90th Cong. 764 (2d Sess. 1968), *reprinted in* II Legislative History, *supra* note 22, at 736, 934 [hereinafter "*1968 Senate Hearings*"].

for compliance with federal standards from between six months and one year to one year and two years, respectively, and by reducing the maximum civil fine from $400,000 to $200,000. The House Committee also required that the Secretary of HEW consult with the Commerce Secretary for programs on testing and evaluating radiation and added a provision allowing appeals to the courts.[59] The House Committee's version passed by a 382-0 roll-call vote.[60] The Senate responded by holding further hearings to understand the full extent of the radiation problem.[61] The Senate Commerce Committee reported its version of the bill on July 17, 1968.[62] The Senate strengthened the bill by adding provisions directing the Secretary of HEW to conduct specific studies.[63] The Senate also increased the maximum civil fine back to $400,000 but added a provision allowing the Secretary of HEW discretion to remit or mitigate penalties.[64] The Senate Committee estimated its modifications would increase the costs of the radiation control program from $8.5 million to $10.3 million but believed this was necessary to deal properly with the absence of federal regulatory authority, state programs that were "inadequate to provide uniform, coordinated controls," and voluntary standards that were inadequate to guarantee compliance.[65]

The Senate added three amendments prior to its final passing of the bill on October 3, 1968. Senator Hugh Scott's amendment required that performance standards apply only to components "in the context of the fully assembled products for which they were intended."[66] Senator Ralph W. Yarborough's amendment

[59] 114 Cong. Rec. 7062 (1968), *reprinted in* II Legislative History, *supra* note 22, at 713. *See also Floor Action: Radiation Control*, 26 Cong. Q. 696 (1968).

[60] *Floor Action: Radiation Control*, *supra* note 59, at 696.

[61] *1968 Senate Hearings*, *supra* note 57. The hearings included updates on the current state of scientific knowledge, statements from government agencies, and testimony from affected parties.

[62] Sen. R. No. 90-1432 (1968).

[63] *Committee Roundup: Radiation Control*, 26 Cong. Q. 2054, 2056 – 57 (1968). Specifically, the Senate version called for "(1) a study of present state and federal control of health hazards from electronic products radiation and other types of ionizing radiation; (2) a study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes; and (3) a study of the development and procedures for the detection and measurement of electronic product radiation from products manufactured or imported prior to the effective date of any applicable standard." *Id.* at 2057.

[64] *Id.* at 2057.

[65] *Id.* (internal quotations omitted).

[66] *Floor Action: Radiation Control*, 26 Cong. Q. 2725, 2732 (1968). Senator Scott explained that some components of electronic products may emit excessive radiation but that proper shielding in the completed product could eliminate the risk.

extended protection under the act to workers as well as consumers.[67] The final amendment by Senator Paul J. Fannin exempted electrical products used by licensed doctors, dentists, or hospitals. The amendment was believed to be needed to appease the medical profession.[68] This was not enough to appease the House, however. The House, which started a bill that was eventually backed by the President and that all of Congress seemed to agree was necessary, fell to strong lobbying efforts by the electronics industry.[69]

Representative Rogers adamantly opposed Senate language allowing the seizure of products found to be in violation, extending protection to workers on assembly lines, and allowing the Secretary of HEW broad discretion to inspect plants. The Senate conceded to Rogers to ensure passage of the bill before Congress adjourned. The final bill as passed was severely weakened. Inspections were allowed only in limited circumstances. Workers were no longer protected. Manufacturers were granted much more time to come into compliance with standards. The maximum civil penalty decreased from $400,000 to $300,000. Senate language requiring review of standards at least once every two years was dropped. Advisory standards for the licensing and training of x-ray technicians were dropped.[70] The House did accept a modified provision requiring manufacturers to repair or replace defective products and did drop the language granting exemptions to licensed physicians, dentists, or hospitals. The conference report was adopted by the House and Senate on October 11, 1968, though without the signature of Senator Yarborough, who believed the compromised bill was too weak.[71] Congress passed the bill on October 18, 1968.[72]

[67] *Id.*

[68] *Id.*

[69] *House-Weakened Radiation Control Bill Cleared*, 26 CONG. Q. 2971 (1968). The lobbying effort was financed by the Electronic Industries Association and led by former Postmaster General J. Edward Day.

[70] Senator Jennings Randolph pushed for years following enactment of H.R. 10790 to add this provision. He secured Senate committee approval of mandatory standards for training and licensing of x-ray machine operators several times. However, obstacles to enactment included anti-regulatory moods in Congress, House objections, and complaints of high cost by the American Medical Association, the ADA, and the Carter administration. One of Randolph's biggest complaints was that the Bureau of Radiological Health was not urging mandatory licensing when it was aware of the problems. *See* Elizabeth Wehr, *Senate Panel Backs Federal Standards for X-ray Operators*, CONG. Q. 2779, 2779 – 2781 (1980). Senator Randolph finally tucked the provision into a reconciliation bill in 1981. *See* Ann Pelham, *Health Spending Cut by 25 Percent*, CONG. Q. 1501, 1501 (1981).

[71] H.R. REP. NO. 90-1971 (1968). *See also House-Weakened Radiation Control Bill Cleared*, *supra* note 69, at 2981. Day's language was adopted nearly verbatim for the provision regarding plant inspections. *Id.* at 2972.

[72] Pub. L. No. 90-602, 82 Stat. 1173 (1968). The Radiation Control for Health and Safety Act has not undergone any

III. The Basic Workings of the Radiation Control for Health and Safety Act of 1968

The RCHSA is administered by the Secretary of Health and Human Services ("HHS")[73] through the FDA. The FDA's Center for Devices and Radiological Health ("CDRH") is charged with the responsibility of carrying out the provisions of the RCHSA.[74] The act applies to any electronic product, defined as "(A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits ... electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which in operation emits... such radiation."[75] This section begins by outlining the major provisions of the act, FDA actions pursuant to those provisions, and the scope of FDA authority under the act. It concludes by discussing the interaction of the RCHSA with other federal statutes later enacted.

A. The Major Provisions of the RCHSA

The RCHSA directs the Secretary to "establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation."[76] Specifically, the

major substantive amendments. It was recodified in 1990 as part of the Federal Food, Drug, and Cosmetic Act ("FDCA") and renamed the Electronic Product Radiation Control ("EPRC") provisions of the FDCA. It was originally codified as part of the Public Health Service Act at 42 U.S.C. 263c – 263n. 21 U.S.C. § 360hh – 360ss (2005). *See also* Bennett & Dormer, *supra* note 4, at 303 n.17; Peter Barton Hutt & Richard A. Merrill, Food and Drug Law 794 (2d ed. 1991). This paper will refer to the act by its original title.

[73] Formerly the Department of Health, Education, and Welfare. The department names are used interchangeably throughout this paper.

[74] Bennett & Dormer, *supra* note 4, at 303. *See also* Center for Devices and Radiological Health, *Electronic Product Radiation Control*, *at* http://www.fda.gov/cdrh/comp/eprc.html (last visited Mar. 29, 2006). The CDHR, then the Bureau of Radiological Health, was assigned to the FDA on May 17, 1971, and "thus became responsible for reducing unnecessary human exposure to man-made radiation in the use of electronic products and in the application of radiation in the healing arts." *Radiological Health Protection*, FDA Papers, Dec. 1971 – Jan. 1972, at 43, 43. CDRH also administers its program under the authority of the Medical Devices Amendments to the FDCA and the Mammography Quality Standards Act ("MQSA"). Center for Devices and Radiological Health, *The CDRH Radiological Health Program: Adapting to Current Public Health Needs: 2005 – 2010* 5 (2005), *available at* http://www.fda.gov/cdrh/radhlth/rhprogram.pdf [hereinafter "CDRH, *Adapting*"].

[75] 21 U.S.C. § 360hh(2) (2005).

[76] *Id.* § 360ii(a). "Electronic product radiation" is defined as "(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or (B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the

Secretary is directed to "prescribe performance standards for electronic products to control the emission of electronic product radiation;"[77] to "plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation;"[78] to "develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation;"[79] to refuse admission of electronic products offered for importation which fail to comply with the act;[80] and to inspect facilities when the "Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety . . . may not be adequate or reliable."[81] The major provisions of the act are discussed below.

1. Performance Standards

Radiation safety performance standards are the crux of the act. In setting the standards, the Secretary must consider "the latest available scientific and medical data in the field of electronic product radiation; the standards currently recommended by (i) other Federal agencies. . . and (ii) public or private groups with expertise in the field. . . ; and the reasonableness and technical feasibility of such standards. . . ."[82] The Secretary must also consult with the Technical Electronic Product Radiation Safety Standards Committee.[83] Standards may prescribe maximum radiation emission levels and require certification by the manufacturer that the product conforms to federal standards.[84] "Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment

operation of an electronic circuit in such product." 21 U.S.C. § 360hh(1) (2005). Ionizing radiation creates electrically charged ions capable of disrupting life processes. X-rays are an example. Though nonionizing radiation cannot create ions, it can adversely affect human health. Examples include microwaves and light. *See* De Vore, *supra* note 6, at 4.

[77] 21 U.S.C. § 360kk(a)(1) (2005).

[78] *Id.* § 360ii(a)(2).

[79] *Id.* § 360ii(a)(5).

[80] *Id.* § 360mm(a).

[81] *Id.* § 360nn(a).

[82] *Id.*

[83] *Id.* § 360kk(f). The Committee is composed of five members from governmental agencies, five members from affected industries, and five members from the general public, including one representative of organized labor. The Committee's Charter is available at www.fda.gov/cdrh/panel/charter/charter-teprssc.doc.

[84] Bennett & Dormer, *supra* note 4, at 304.

of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products."[85] Each regulation must take effect no sooner than one year and no later than two years after the date on which the standard is issued.[86] Judicial review of regulations is allowed in the federal courts of appeals.[87] The first four standards set by the FDA are discussed briefly below. Their progression and current statuses are discussed more thoroughly in Part IV.

The television receiver standard went into effect on January 15, 1970, and was carried out in three phases, with the third phase to conclude on June 1, 1971.[88] Testing on 259 televisions during the second phase revealed that all receivers had met the operating conditions required during that phase. This was a remarkable success, as evidenced by comparison to a study by the National Committee on Radiation Protection and Measurements ("NCRP") conducted between December 1967 and January 1968. NCRP tested 1,124 color televisions of various makes and models and found 268 to emit measurable levels of radiation. Two sets had radiation emissions exceeding the scale reading of the survey instrument. NCRP concluded that the absence of radiation emissions from more than three quarters of the televisions indicated that industry could, and for the most part was, manufacturing safe televisions.[89]

The microwave oven standard was issued on October 6, 1970, with compliance required by October 6, 1971. The setting of the microwave standard demonstrated the effectiveness of the bill. A 1967 Department of Defense survey found that twenty four out of thirty microwave ovens at Walter Reed Hospital leaked potentially hazardous radiation. One leaked radiation sufficient to produce eye cataracts. The Department estimated that 40,000 microwave ovens would be purchased that year, and that the total could eventually rise to half a million if development continued as anticipated.[90] A survey of 4,700 microwave ovens conducted in 1970

[85] 21 U.S.C. § 360kk(a)(1) (2005).
[86] *Id.* § 360kk(c).
[87] *Id.* § 360kk(d).
[88] De Vore, *supra* note 6, at 8.
[89] *See* National Center for Radiological Health, *A Survey of X-Radiation from Color Television Sets in the Washington, D.C. Metropolitan Area* 11 – 12, 20 (1968), *in 1968 House Hearings*, *supra* note 22, at 25.
[90] Sen. R. No. 90-1432 4 (1968).

revealed that ten percent of the ovens leaked radiation above the voluntary industry maximum. The industry voluntarily took corrective measures on the estimated 10,000 ovens believed to have a "strong potential" to exceed the industry maximum.[91] When the standard became effective, the FDA could state that microwaves were safe for consumers to use.

The third standard applied to electronic equipment used in high school and college science classes. Electron tubes used for demonstrations were found to leak radiation in excess of the recommended maximum for students under the age of eighteen. The sole manufacturer of the tubes agreed to stop sales of the tubes and to recall them from distributors. The manufacturer eventually redesigned two types of tubes and stopped making the third.[92]

The fourth standard applied to x-ray equipment, the hazards of which were thoroughly discussed in the hearings. The standard aimed to reduce both patient and operator exposure. Patient overexposure during examinations resulted primarily from the use of primary beams of x-ray that were larger than the film being used. The first x-ray standards, enacted on August 1, 1974, included over sixty performance specifications, including required use of a device that could restrict the x-ray beam to the size of the film being used.[93] The FDA helped manufacturers come into compliance by designing the device needed to restrict the x-ray beams.

Performance standards have now been issued for fluoroscopic equipment,[94] computed tomography (CT)

[91] *Radiological Health Protection*, *supra* note 74, at 45.
[92] De Vore, *supra* note 6, at 9.
[93] *X Rays: Focusing on Patient Protection*, FDA Consumer, June 1975, at 8, 9.
[94] 21 C.F.R. § 1020.32 (2005).

equipment,[95] cabinet x-ray systems,[96] laser products,[97] sunlamps,[98] mercury vapor lamps,[99] and ultrasonic therapy equipment.[100]

2. Research

The Congressional hearings demonstrated the clear need for a federal research program. The FDA was charged with controlling man-made radiation in electronic products and medical products, while environmental radiation and radioactive materials were regulated by the Environmental Protection Agency ("EPA") and AEC, respectively. In 1971, forty percent of the Bureau of Radiological Health's resources were transferred to the EPA. Of the remaining $10.3 million, $2.9 million was allocated to grants and contracts to support research and training and applied research.[101]

While the biological effects of high-dose ionizing radiation from such products as x-ray machines were well-known,[102] little was known about the effects of repeated low-dose radiation and of exposure to non-ionizing

[95] *Id.* § 1020.33.

[96] *Id.* § 1020.44. Cabinet x-ray systems include baggage x-ray machines at airports. Between 1968 and 1972, there were 147 attempted hijacks of U.S. aircraft, ninety one of which were successful. The President directed the Federal Aviation Administration ("FAA") to begin screening passengers. The original screening program was done by hand and relied on the screeners' determination that a passenger looked suspicious. When the use of x-ray systems became more common, states turned to the FDA for guidance on safety for screeners and passengers. The greatest concern was possible human exposure to the primary beam of radiation. Some of the systems in use at the time allowed operators to hold bags in the machines and to directly expose their hands. A secondary concern was damage to undeveloped photographic film. The FDA quickly issued recommended safety guidelines, which were soon adopted by all but four states. The remaining four states had already established more detailed and in some cases more restrictive requirements. The standard became effective on April 10, 1975. *See* Michael E. Shaffer, *X-Raying Baggage To Thwart Skyjackers*, FDA Consumer, July – Aug. 1974, at 16.

[97] 21 C.F.R. § 1040.10 (2005).

[98] *Id.* § 1040.20.

[99] *Id.* § 1040.30. Mercury vapor lamps are more efficient and longer lasting than regular lamps. The lamp is surrounded by a hard borosilicate glass envelope to filter out shortwave radiation produced by the electrical current passing through the mercury-argon vapor. In December 1974, the FDA learned that eight people who had been playing volleyball in a school gym had suffered burns from ultraviolet radiation exposure. A mercury vapor lamp in the gym had been broken but continued to burn. Further investigation revealed at least eight other incidents. Annabel Hecht, *Shedding Some Light On Light*, FDA Consumer, Sep. 1976, at 10, 13. The current standards require that self-extinguishing lamps cease operation within fifteen minutes of breakage or removal of the outer envelope. 21 C.F.R. § 1040.30(d) (2005).

[100] 21 C.F.R. § 1050.10 (2005).

[101] *Radiological Health Protection*, *supra* note 74, at 43.

[102] Short term effects included nausea, anemia, fatigue, blood and intestinal disorders, and loss of hair. Long term effects included cancers and cataracts. Very high exposure was believed to cause injury to the central nervous system and possibly death. In children, small increases in ionizing radiation exposure were believed to increase the risk of leukemia. De Vore, *supra* note 6, at 5. For a detailed explanation of radiation and its effects as understood in 1979, see Bill Rados, *Primer on Radiation*, FDA Consumer, July – Aug. 1979, at 4.

radiation, such as microwaves and light. Because scientists had not identified a safe level of radiation, they believed that all forms of radiation included some risk to human health. The rise in use of electronic products such as microwave ovens, lasers, and ultrasound equipment further amplified the need for research on the biological effects of non-ionizing radiation. Early studies revealed that x-ray or ultraviolet light exposure increased the probability that certain cells would develop tumors.[103] Other studies involved the effects of microwaves on monkeys and on military occupations involving the use of microwaves.[104] A detailed discussion of specific studies and their use in setting standards is discussed in Part IV.

The Bureau's research also contributed technological devices to aid in the reduction of radiation emissions. The Bureau quickly developed instruments to help in the detection of radiation emissions from televisions and supported the development of a laser radiation detection monitor.[105] Different instruments were developed for testing in the factory and for use by television servicemen.[106] A separate meter was developed to detect radiation leakage from microwave ovens.[107] The Bureau also developed technology to aid in its research, such as a chamber capable of controlling animal research environments.[108]

CDRH was created in 1982 to combine the FDA's activities under the RCHSA and the Medical Devices Amendments. The centralization of the FDA's research programs has reduced inefficiencies, thus allowing for a more focused and effective research program.

3. Enforcement

The FDA's enforcement authorities under the RCHSA include recalls, seizures, and regulation of imports. If a manufacturer determines that its product is not in compliance with federal standards, it must notify the FDA.[109] The manufacturer must make the initial determination of the significance of risk associated with

[103] De Vore, *supra* note 6, at 5.
[104] *Radiological Health Protection*, *supra* note 74, at 46.
[105] *Id.*
[106] De Vore, *supra* note 6, at 9.
[107] *Id.*
[108] *Id.* at 5.
[109] 21 U.S.C. § 360ll (2005).

the defect. If it determines the risk is low, it can request an exemption from a mandatory duty to notify consumers.[110] Similarly, the FDA has a duty to notify a manufacturer if the FDA discovers a violation of its standards.[111] The manufacturer is provided a regulatory hearing in which it may explain why an exemption should be granted, but the hearing lacks procedural protections provided by a traditional trial.[112] If no exemption from public notification is granted, the manufacturer must correct the defect at its own expense or refund the purchase price.[113] The FDA may seize non-compliant products if a manufacturer fails to institute a recall.[114]

Historically, the FDA rarely instituted adversarial proceedings pursuant to the RCHSA. "A basic precept of FDA enforcement authority is the belief that a majority of persons desire to comply with the law and will comply voluntarily when given information as to what is required and what violations appear to exist."[115] The FDA and manufacturers developed a non-adversarial relationship early as they worked together to develop the standards. Almost all actions brought by the FDA settled before trial.[116] Manufacturers also rarely challenged the FDA's enforcement authority. Only two adversarial administrative hearings have occurred since enactment of the RCHSA.

The first adversarial hearing began in 1974 with routine testing of television sets. The FDA removed a component from a color television to simulate a failure and found that this caused excess radiation emission in violation of federal standards. Further testing of other models by the same manufacturer revealed that

[110] *Id.* § 360ll(a)(2).
[111] *Id.* § 360ll(e).
[112] Bennett & Dormer, *supra* note 4, at 306. The Commissioner of Food and Drugs appoints a presiding officer who is "free from bias or prejudice." Parties may present evidence and cross examine witnesses, but the manufacturers may not call agency staff as witnesses. The Federal Rules of Evidence do not apply, thus preventing manufacturers from challenging the authenticity and reliability of documents presented by the FDA. *Id.* For a more detailed discussion of the proceedings, see Ronald J. Greene, *Informal FDA Hearings*, Food Drug Cosm. L.J. 354 (1977).
[113] 21 U.S.C. § 360ll(f) (2005).
[114] Marie A. Urban, *The FDA's Policy on Seizures, Injunctions, Civil Fines, and Recalls*, 47 Food & Drug L.J. 411, 411 (1992).
[115] *Id.*
[116] Bennett & Dormer, *supra* note 4, at 307 – 308. From the 1968 enactment of the RCHSA to 1996, only thirty-two actions had been brought. Only three went to trial. It has been suggested, however, that the recodification of the RCHSA as part of the FDCA and the consolidation of the Bureau of Radiological Health into the more general Center for Devices and Radiological Health will end the non-adversarial relationship. *Id.*

300,000 to 400,000 color television sets posed the same risk. Matsushita Electric Company, J.C. Penney, and W.T. Grant, defined as manufacturers under the RCHSA, were granted an administrative hearing to challenge the FDA's findings. The companies sought an exemption based on their findings that a failure like the one the FDA had simulated had never occurred and was unlikely ever to occur. The companies stated that their quality control programs were sufficient to ensure this. The FDA rejected the claim for exemption.[117] The manufacturers chose not to seek judicial review and instead submitted the required corrective action plan in which they agreed to recall the televisions.[118]

The second proceeding involved 36,000 microwaves manufactured by GE. The FDA had determined that the microwaves leaked radiation in excess of the federal performance standard. GE sought an exemption from notification and corrective action. The hearing officer determined that GE had not proven that no person would or could be injured by the excess radiation, and GE eventually submitted a corrective action plan to repair the microwaves.[119]

In addition to seeking injunctions and requiring recalls and repairs, the FDA also relies on the imposition of civil penalties. The RCHSA authorizes a civil penalty of not more than $1000 for each product involved or for each act or omission in violation of the statute, with the maximum penalty for a single party for any related series of violations limited to $300,000.[120] The FDA's stated policy is not to warn manufacturers prior to considering penalties when it determines that "a violative product will cause serious adverse health consequences or death, or where responsible persons show intentional disregard for the law."[121] The FDA

[117] Walter E. Gundaker, *Getting the Picture On TV Recall*, FDA Consumer, Mar. 1975, at 8, 13.

[118] Bennett & Dormer, *supra* note 4, at 309.

[119] *Id.*

[120] 21 U.S.C. § 360pp(b) (2005). In 2004, the penalties were raised to $1,100 per violation and $330,000 maximum, in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990. U.S. Food and Drug Administration, Compliance Policy Guides Manual Sec. 390.300, 2004 WL 3363378 (updated July 29, 2004) [hereinafter "FDA, Compliance Policy"]. The FDA also has authority to impose civil penalties under the National Childhood Vaccine Injury Act of 1986, the Prescription Drug Marketing Act of 1987, The Safe Medical Devices Act of 1990, the Mammography Quality Standards Act of 1992, the Generic Drug Enforcement Act of 1992, and the Food Quality Protection Act of 1996. Marc J. Scheineson & Robert J. Kaufman, *FDA Lacks Authority to Impose Civil Monetary Fines*, Legal Backgrounder, Oct. 17, 2003.

[121] FDA, Compliance Policy, *supra* note 120. These actions include failure to notify the FDA of a known defect; the failure to submit required reports related to defective products; issuance of false certifications; refusal to permit entry or to allow inspection as required by the RCHSA; distribution of known non-compliant products; and refusal to initiate corrective action.

generally warns manufacturers before imposing fines for distribution of non-compliant products; refusal to notify purchasers; failure to implement an order to notify within a reasonable time; inadequate record keeping; and failure to implement an adequate recall due to inadequate distribution records. Fines will generally not be imposed for minor violations, defined as those that present little or no risk of injury or danger to health.[122] Because "manufacturer" is defined as "any person engaged in the business of manufacturing, assembling, or importing of electronic products,"[123] individuals can be held personally liable for the violations of the company. This allows the FDA to impose civil penalties on both the corporation and individuals for the same set of violations.[124]

The FDA also has the power to regulate importation of electronic products. The FDA may deny entry of products offered for importation that do not comply with federal standards. If the FDA believes that a product denied entry cannot be brought into compliance, the manufacturer must export the product at its own expense. Failure to export within ninety days grants the FDA the right to seize and destroy the non-compliant products.[125] The importation of multisystems is illustrative of the FDA's authority. Multisystems are televisions that can receive international broadcast systems. The FDA determined non-compliant multisystems did not pose a hazard to public health if sold in the United States because they were not designed to operate on standard United States power sources. They were allowed on the understanding that the importers would eventually sell the multisystems to consumers who were traveling or relocating overseas, referred to as an "import-for-export" exemption.[126]

By 1985, the FDA believed multisystems had become operable in the United States and required that all multisystems operable in the United States meet the television receiver standards. In 1988, the FDA issued

Id.

[122] *Id.*

[123] 21 U.S.C. § 360hh(3) (2005).

[124] *See* United States v. Hodges X-Ray, Inc., 759 F.2d 557 (6th Cir. 1985) (holding that the FDA had authority under RCHSA to fine both the company and the principle shareholder).

[125] 21 U.S.C. § 360mm (2005).

[126] K & K Merchandise Group, Inc. v. Shalala, No. 95 Civ. 10082, 1996 WL 183023, *1 – 2 (S.D.N.Y. Apr. 17, 1996).

an "import alert" that instructed FDA field inspectors to "detain all shipments of uncertified [multisystem] receivers until the importer establishes that the product in question is labeled for export only and cannot receive the [U.S.] NTSC 3.58 broadcast system."[127] The FDA remained concerned that multisystems were entering the United States market illegally, and in 1991 required that all multisystems, including those intended solely for export, meet the television receiver standard. In 1992, the FDA detained multisystems imported by K & K Merchandise Group ("K & K") for noncompliance with federal performance standards. K & K claimed that the FDA's policies regarding noncompliant imported electronic products constituted improper rulemaking. The court dismissed K & K's claim for lack of standing. The court held that K & K had alleged no concrete injury "because [K & K] has no legal right to import or sell its noncompliant multisystem television receivers in the United States."[128] The court affirmed Congress' intent that any noncompliant good qualifying for an exemption would be exported directly, not sold to U.S. distributors to later export.[129]

While K & K's troubles resulted from products that exceeded the maximum radiation emissions standards, the FDA also has the authority to seize products that meet the emission standards but violate other provisions of the RCHSA. In September 1991, the FDA placed a customs hold on 30,000 television sets manufactured by Goldstar due to irregularities in its testing methods at its Korean factory. Further investigation revealed similar problems at Goldstar's factory in Mexico, resulting in Goldstar's voluntary withholding of another 130,000 televisions from importation. While the test methods were determined acceptable, the instruments were not. The company was also found to have falsified x-ray test data and to have relabeled and reboxed televisions without proper quality control testing. Goldstar eventually submitted a corrective action plan and retested samples of its stock. On November 27, 1991, the FDA released the televisions from detention.

[127] *Id.* at *2.
[128] *Id.* at *3.
[129] *Id.* at *5.

This delay cost Goldstar tens of millions during the height of the selling season. None of the televisions was ever found to emit excess radiation, a problem the FDA had not seen in many years.[130]

Decreased funding has required the FDA to refocus its enforcement efforts, particularly regarding fieldwork. CDRH plans to emphasize inspections of manufacturers and conduct field and lab tests on a for cause basis only. Additionally, CDRH will increasingly use outside sources for data on adverse events and initiate enforcement actions accordingly.

B. Interaction with Other Statutes and Agencies[131]

In addition to the Radiation Control for Health and Safety Act, the FDA's regulation of electronic products also comes under the Medical Devices Amendments ("MDA") to the FDCA and the Mammography Quality Standards Act of 1992 ("MQSA").[132] The FDA shares its regulatory authority with the Consumer Product Safety Commission, the Nuclear Regulatory Commission ("NRC"), and the Environmental Protection Agency.[133] This section will briefly describe the role other statutes and agencies play in regulating electronic products.

Radiation emitting electronic products that are also medical devices, such as x-ray equipment, microwave diathermy, and surgical lasers, are also regulated by the Medical Devices Amendments of 1976.[134] The MDA was a response to the growing number and increasing complexity of medical devices. The FDA was required to classify all medical devices in terms of safety and effectiveness. The FDA was granted comprehensive con-

[130] *Goldstar Rocked by Obsolete X-Ray Rule*, Consumer Electronics, Feb. 17, 1992, at 9.
[131] This section is drawn largely from Bennett & Dormer, *supra* note 4, at 313 – 20.
[132] A diagram of the FDA's overlapping enforcement authorities can be found at http://www.fda.gov/cdrh/radhlth/pdf/overlap.pdf (last visited Apr. 9, 2006) [hereinafter "FDA Diagram"].
[133] Bennett & Dormer, *supra* note 4, at 318 – 20.
[134] Other electronic products regulated under the Medical Devices Amendment include diagnostic ultrasound, radiation therapy, MRI, ophthalmic instruments, sunlamps, and lithotriphter. FDA Diagram, *supra* note 132.

trol over the market introduction of medical devices. Congress also chose to enact special rules for specific devices.[135] While the RCHSA protects the public from unnecessary radiation from electronic products, the MDA ensures that marketed medical devices are safe and effective for their intended use. A product that violates the RCHSA is typically considered adulterated or misbranded under the MDA.[136]

The MDA was originally implemented by the Bureau of Medical Devices. Recognizing the interrelations of the MDA and RCHSA, HHS merged the agencies in 1982, forming the Center for Devices and Radiological Health. The conjunction of the acts grants the FDA more alternatives for enforcement. Under the MDA, the FDA can institute a suit to seize a device, a source of contention that the Senate lost on during the legislative hearings for the RCHSA. Other administrative actions pursued by the Senate during the hearings, such as detention of suspected non-compliant devices, are available under the MDA. The FDA can also pursue criminal penalties against manufacturers under the MDA.[137] The Safe Medical Devices Act of 1990 ("SMDA") provided the FDA with further regulatory authority. Civil penalties were made available, and the regulated entities were broadened to include facilities and device distributors in addition to manufacturers. The SMDA also eliminated the "state-of-the-art" defense to the refund, repair, and replace requirement for defective products, which aligned the SMDA with the RCHSA in this respect. The process for setting performance standards was relaxed in an attempt to allow the FDA to establish performance standards with the same relative ease as under the RCHSA. The FDA believes that the administration of the medical devices acts by the same agency that administers the radiation control act has minimized inconsistent and duplicative regulations. Though the standards for many medical devices are established by the RCHSA, the MDA essentially controls regulation of radiation emitting medical devices.[138]

[135] Hutt & Merrill, *supra* note 72, at 744 – 46.

[136] Bennett & Dormer, *supra* note 4, at 313 – 14. Bennett and Dormer note that an x-ray machine that failed to take x-rays of proper clarity would theoretically also be in violation of the RCHSA because patients would be exposed to radiation without any offsetting benefit. However, the FDA has not advanced this argument.

[137] *Id.* at 314 – 15.

[138] *Id.* at 315.

The Mammography Quality Standards Act of 1992 regulates mammography facilities and the use of mammography equipment "to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages."[139] Because mammography is a type of x-ray device, it is simultaneously regulated by the RCHSA. MQSA is part of the Public Health Services Act, where the RCHSA was codified prior to its move to the FDCA.[140] MQSA requires that all mammography facilities be certified by the FDA[141] and establishes quality standards for mammography equipment and personnel.[142] Facilities are subject to regular inspections[143] and sanctions including civil monetary fines.[144] The act was reauthorized in fall 2004 to extend to 2007.[145]

Mammography originally suffered from poor technique. High quality images and well-trained interpreters are needed to diagnose a breast tumor before a lump develops.[146] Improper film processing and improper use of image receptors resulted in poor images. Because the FDA had no authority to regulate procedures within a facility, the American College of Radiology began accrediting mammography facilities through a voluntary program. Medicare also required facilities that wanted to seek reimbursement to meet quality standards.[147] MQSA was needed to ensure mandatory participation in certification programs. Improvements in mammography equipment and techniques have made the process the most effective measure for early detection of breast cancer. Image quality has improved significantly, while radiation exposure is up to fifty times less today than it was twenty years ago.[148]

The Nuclear Regulatory Commission shares authority with the FDA for the regulation of radiation therapy

[139]U.S. Food and Drug Administration, *About MQSA*, *at* http://www.fda.gov/cdrh/mammography/mqsa-rev.html (last visited Apr. 9, 2006) [hereinafter "FDA, *About MQSA*"].
[140]42 U.S.C. § 263b (2005).
[141]*Id.* § 263b(b).
[142]*Id.* § 263b(f).
[143]*Id.* § 236b(g).
[144]*Id.* § 263b(h).
[145]FDA, *About MSQA*, *supra* note 139.
[146]Bennett & Dormer, *supra* note 4, at 316.
[147]Marian Segal, *Mammography Facilities Must Meet Quality Standards*, FDA Consumer, Mar. 1994, at 8, 11.
[148]U.S. Food and Drug Administration, *Frequently Asked Questions About MQSA*, *at* http://www.fda.gov/CDRH/MAMMOGRAPHY/cons-faq2.html#facilities (last visited Apr. 10, 2006).

systems. When the RCHSA passed in 1968, the AEC believed that the authority granted under the act did not affect the AEC. The Atomic Energy Act of 1954 had charged the AEC with the control of radiation hazards, but its authority was limited to responsibility for the "public health and safety in connection with construction and operation of nuclear facilities and the use of source, byproduct, and special nuclear material."[149] The AEC believed the definition of "electronic product radiation" limited authority under the act to radiation from products that used electronic circuits and therefore distinguished it from the radiation from nuclear sources that the AEC regulated. However, the AEC requested and was granted a provision stating that the act "shall not be construed as superseding or limiting the functions, under any provision of law, of any officer or agency of the United States."[150] The AEC fully admitted that the provision was intended to protect its authority.[151]

Technological advances have resulted in the use of special nuclear material in medical therapy, which implicates the NRC's authority. The NRC is charged with licensing physicians and facilities that use nuclear material in radiation therapy.[152] The NRC's stated objective is to "provide for the radiation safety of workers, the general public, patients, and human research subjects."[153] The requirements for licensing include maintenance of records;[154] the protection of human research subjects;[155] radiation safety aspects for medical use of byproduct material;[156] and notification.[157] Because radiation therapy systems are not considered electronic products, the FDA regulates them as medical devices under the MDA. The FDA and NRC generally share data on radiation hazards and knowledge of incidents of patient exposure through an informal process. Because the FDA has a broader range of regulatory options under the MDA, the NRC typically

[149] SEN. R. NO. 90-1432 33 (1968) (Letter of Glenn T. Seaborg).
[150] Pub. L. No. 90-602 sec. 4, 82 Stat. 1187 (1968).
[151] SEN. R. NO. 90-1432 31 (1968) (Letter of E.J. Bloch).
[152] 42 U.S.C. § 2134(a) (2005); Bennett & Dormer, *supra* note 4, at 319.
[153] 10 C.F.R. § 35.1 (2005).
[154] *Id.* § 35.5.
[155] *Id.* § 35.6.
[156] *Id.* § 35.12.
[157] *Id.* § 35.14.

defers to the FDA when regulatory action is needed. The agencies have entered into a Memorandum of Understanding "to coordinate existing NRC and FDA regulatory programs for medical devices, drugs, and biological products utilizing byproduct, source, or special nuclear material."[158]

The Consumer Product Safety Commission ("CPSC") regulates consumer products, including those that emit radiation but excluding medical devices. Products that come under the regulation of both the FDA and the CPSC include televisions and microwave ovens. The Consumer Product Safety Act ("CPSA") was enacted in 1972 in response to Congress' determination that an unacceptable number of consumer products distributed in commerce presented an unreasonable risk of injury and that existing federal, state, and local control was inadequate.[159] The CPSA was modeled after the RCHSA, resulting in enforcement authority that is essentially identical. This includes a repair, replace, or refund provision and the right to impose civil penalties. Unlike the RCHSA, however, the CPSA provides for criminal sanctions and seizure of noncompliant products. The CPSA typically defers to CDRH regarding radiation emissions, with deference becoming even more common with reductions in funding.[160]

The Environmental Protection Agency is "technically the lead federal agency in establishing federal policy on radiation."[161] It is charged to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States."[162] However, the EPA has typically deferred to the FDA and to CDRH regarding medical devices and electronic products to ensure that its actions do not conflict with the FDA's "responsibilities for developing product performance standards."[163]

[158] 58 Fed. Reg. 47,300 (Sep. 8, 1993); Bennett & Dormer, *supra* note 4, at 319.
[159] 15 U.S.C. § 2051 (2005).
[160] Bennett & Dormer, *supra* note 4, at 318.
[161] *Id.* at 319.
[162] *Id.*, citing Federal Radiation Council Authority, Pub. L. No. 86-373, 73 Stat. 688 (1959), transferred to EPA by Reorganization Plan No. 3 of 1970, as codified at 42 U.S.C. § 2021(h).
[163] Bennett & Dormer, *supra* note 4, at 320, citing 51 Fed. Reg. 27,318, 27,321 (July 30, 1986). Bennett and Dormer cite the EPA's proposed recommendations regarding public exposure to radio frequency radiation as an example. The EPA recognized CDRH's jurisdiction in this area and believed FDA performance standards could more readily control excess radiation exposure. The EPA proposed to exclude from its consideration exposure resulting from electronic consumer products.

The FDA remains the lead agency in radiation regulation.

IV. Major Electronic Products Regulated by the RCHSA

The effectiveness of the RCHSA can be seen best in the FDA's actions regarding studies and regulations of specific products. The FDA's actions include setting standards, conducting research, and educating manufacturers and consumers. The current status of electronic products considered possibly dangerous to human health in 1968 demonstrates the tremendous success of a federal regulatory program. While the granting of authority to enforce standards cannot be underscored in the success of the RCHSA, it is the extensive research program and the FDA's efforts at educating the public that have proved to be the true successes. During the congressional debates, witnesses repeatedly emphasized the lack of knowledge regarding the biological effects of radiation. The concern was not just for the lay consumers; it was also for the educated professionals who had repeated contact with radiation emitting devices. While scientists sensed that low-dose and non-ionizing radiation were toxic to human health, there was a complete lack of reliable evidence. The setting of enforceable standards indicated Congress' commitment to the elimination of unnecessary radiation. While some combination of concern for human health and the avoidance of adverse publicity would have led manufacturers to eliminate excess radiation to the extent feasible, the RCHSA undoubtedly accelerated the process. Congress' commitment to radiation protection extended not just to standard setting and enforcement, but also to a federally-funded research and education program. This section begins with a discussion of the products Congress identified as possibly dangerous in 1967 and 1968 to demonstrate the significant progress the RCHSA has made. It concludes with a discussion of cell phone regulation because it demonstrates the interaction of the FDA's obligations under the RCHSA with other federal statutes and

agencies and is the area with the least definitive research and, consequently, the most controversy today.

A. Diagnostic X-Rays: Controlling the Main Source of Radiation Exposure

The regulation of x-ray machines represents perhaps the greatest success under the RCHSA. In 1968, medical and dental x-ray procedures represented ninety percent of human exposure to radiation.[164] Dr. Karl Z. Morgan acknowledged the great value of x-ray procedures but noted that better screening to determine when x-rays were appropriate and better designed devices could significantly decrease unnecessary human exposure.[165]

Following enactment of the RCHSA and growing public awareness of the possible dangers, patients began asking how safe x-ray exposure was. Like Dr. Morgan, the FDA was careful not to undercut the tremendous benefits of x-ray procedures. The Bureau acknowledged that "[t]ens of thousands of accident victims are saved every year because a physician can see on x-ray film exactly what is wrong," while "[o]thers would have died in childhood of heart defects or obstructed digestive tracts" without x-rays.[166] However, repeated exposure to low-dose ionizing radiation did pose a real threat. The Bureau believed that physicians and dentists had a duty to determine when x-ray diagnoses were actually needed and to use methods that produced the lowest possible exposure. By 1970, x-ray examinations had seen a ten percent per capita increase but had resulted in a drop in genetically significant dose. This indicated the ability to deliver "the best possible diagnostic information for the least possible x-ray exposure."[167]

The first set of standards aimed to reduce unnecessary x-ray exposure by requiring beam restricting capacities. All stationary devices were required to be able to restrict the beam to the film size. Bureau engineers designed a device, known as a collimator, to perform this task automatically. A feature to allow images to

[164] For an explanation of how medical x-rays work, see Robert T. De Vore, *Seeking the Safest X-Ray Picture*, FDA Consumer, Mar. 1979, at 24.
[165] *1967 House Hearings*, *supra* note 22, at 364.
[166] Robert T. De Vore, *Diagnostic X Rays: How Safe Are They?*, June 1973, at 4, 5.
[167] *Id.*

be reproduced was required to reduce unnecessary exposure from retakes.[168] As enacted on August 1, 1974, the standard contained over 60 performance specifications. The FDA devised a three-pronged approach to enforcement. First, the FDA intended to "evaluate[] reports on quality control and testing programs submitted by x-ray equipment manufacturers, and [to] supplement this information with factory inspections to verify that adequate testing was being conducted." Second, the FDA inspectors, with the aid of State inspectors, would inspect "hospitals, clinics, and other facilities to determine if the systems [had] been assembled and [were] performing in accordance with the standard." And third, the FDA would "test[] x-ray components and some fully assembled systems in its laboratory to check for compliance."[169] The FDA would notify manufacturers if their products failed this line of testing and would require that defective products be repaired or replaced free of charge.[170]

The first case to go to trial under the RCHSA involved a firm that assembled and installed medical x-ray systems. Walter Wilder, owner of X-Ray of Greenville, attempted to save $2500 per installation by using manual collimators rather than the automatic collimators required under FDA regulations. Automatic collimators sense the size and shape of the film being used and adjust the x-ray beam to limit the positive beam exposure. Wilder attempted to evade detection by not reporting the faulty x-ray machines to the FDA as required by law. He went so far as to prepare fictitious bills of sale claiming that the machines had been previously owned by physicians. This would allow him to avoid installing the expensive collimators under an exception allowing upgrading of old equipment. An inspection of a chiropractic clinic in February 1983 revealed that the unit did not have the proper safety features. The FDA sent a letter to X-Ray of Greenville and received no response, thus prompting a visit to Wilder's office. He refused access to his company's records, except the fictitious bills of sale. North and South Carolina state radiation control officials helped the FDA locate eleven systems installed by Wilder that had not been reported. A U.S. District Court mag-

[168] *Id.* at 5 – 7.
[169] *X-Rays: Focusing on Patient Protection*, *supra* note 93, at 8, 9.
[170] The current standards are available at 21 C.F.R. § 1020.30 (2005).

istrate found against Wilder on all counts. He was ordered to "provide [automatic collimators] on systems he had installed or to refund the purchase price to his customers; to give the FDA access to all sales invoices and other relevant business records; to file reports of assembly and certification for all units that he had installed but not reported; and to pay $6900 in civil penalties."[171]

Another FDA concern included decreasing the dangers of x-ray examinations in general by restricting dangerous products and by educating those who administered x-rays. In the early 1970's, the FDA discovered that an imported dental x-ray device sold as a 60,000-volt device was actually functioning at only 45,000 volts. The machines required at least five times as much exposure to produce a proper image. The FDA suspended sales of the machines and instituted actions for their replacement or correction. The FDA also helped institute training programs in medical and graduate schools and continued to conduct its own short courses on radiological health for health professionals.[172] The chief source of unnecessary radiation remained, however, the use of x-ray examinations that were not needed for meaningful diagnoses.[173] Widespread public education appeared to be the solution.

One of the Bureau's earliest actions involved public education regarding the proper use of x-rays. X-rays were commonly used in the 1940's and 1950's to screen for tuberculosis ("TB"),[174] but the development of the tuberculin skin test provided a safer alternative. The Bureau and the American College of Chest Physicians issued a joint statement in 1972 recommending that the use of mass chest x-rays for the detection of TB and other cardiopulmonary diseases be discontinued. The value of early detection of TB in the 1940's

[171] Carolyn Hommel & Richard C. Thompson, *X-ray Installation Scam Exposed*, FDA Consumer, June 1986, at 29.

[172] An example is the Radiological Health Sciences Learning Laboratory. Developed by the FDA and the University of California Medical Center at San Francisco, the Learning Laboratory is a comprehensive education system in diagnostic radiology. "It covers selection of patients for x-ray examinations, x-ray examination procedures, and interpretation of results... It provides the basic information to enable physicians to make sound judgments on the desirability of x raying a patient." The FDA also has a series, "Radiation Protection During Medical X-Ray Examinations," that teaches technologists how to protect themselves and their patients from unnecessary exposure. *X Rays: Focusing on Patient Protection*, *supra* note 93, at 11. As discussed in *supra* note 70, these training programs could not be made mandatory until 1981.

[173] De Vore, *supra* note 166, at 6. For example, x-rays were sometimes ordered to allay patients' fears or to provide physicians a record for malpractice suits, rather than when they were actually necessary for diagnosis.

[174] Community funds often made the x-ray screenings free to the public. Valerie Britain, *Mass Chest X Rays Are On The Way Out*, FDA Consumer, Feb. 1973, at 14, 15.

was believed to outweigh the risk. By 1973, however, the Bureau's research had identified five reasons to discontinue mass chest x-rays.[175] The once common practice soon ended.

A second public education concern was the advisability of x-ray examinations for pregnant women. During the initial House hearings, Dr. Morgan expressed his concern regarding the practice of some doctors to require pelvimetries as part of routine examinations of pregnant women.[176] FDA studies indicated that the risk of danger to the fetus from x-ray exposure was actually quite low and depended on many factors. X-ray procedures of areas other than the abdomen resulted in almost no radiation exposure to the fetus. A single, properly conducted x-ray examination of the abdomen was very unlikely to cause birth defects. Animal studies indicated a slight effect on intelligence and behavior, though scientists were unsure if diagnostic x-ray exposure would produce the same result. Still, several studies indicated that x-ray exposure did increase the risk of leukemia. Additionally, unusually high levels of exposure from repeated x-ray examinations over a short time period also posed a serious threat.[177] The FDA's education program sought to instruct physicians on the dangers of radiation to the human embryo, to encourage physicians to ask female patients routinely if they were pregnant, and to consult radiologists when considering abdominal x-rays on pregnant patients.[178] The FDA also encouraged women to be proactive in protecting their fetuses from unnecessary radiation by taking such simple measures as informing their doctors of possible pregnancies. The FDA continued to stress, however, that properly performed x-ray procedures were safe enough that they should not be avoided

[175] *Id.* at 15 – 16. First, the mass screenings were never really effective at detecting TB. More than ninety-five percent of infected people were detected through other means. Mass screening only detected TB in fewer than 1/20th of 1 percent. Second, TB was on the decline, which further decreased the likeliness that chest x-rays would detect an infection. Third, the tuberculin skin test served as a safer and more accurate screening device. Fourth, the x-ray screening exposed the population to unnecessary radiation when compared to the likelihood of detection. Fifth, the mobile devices often used for mass screenings tended to expose people to ten times more radiation than fixed x-ray units.

[176] *See 1967 House Hearings*, *supra* note 22, at 367. A pelvimetry uses x-rays to compare the size of the birth canal to the baby's head. It was originally used to determine if an irregular pelvis required delivery by Caesarian section. It later came to be used when physicians were considering Caesarian deliveries for other reasons. The usefulness of pelvimetries has also been questioned. First, small, trouble-causing pelvises are less common now. Second, babies' heads tend to "give" sufficiently for safe vaginal delivery, and pelvimetries cannot predict the amount of "give." Third, other diagnostic techniques such as ultrasound can determine the need for Caesarian section without the use of x-rays. Roxanne Smith, *X-rays For Childbirth: Risky, Costly, Not Always Helpful*, FDA Consumer, Feb. 1982, at 21, 21 – 22.

[177] James L. Morrison & Mark Barnett, *X Rays And Pregnancy*, FDA Consumer, May 1977, at 24, 24 – 25.

[178] *X Rays: Focusing on Patient Protection*, *supra* note 93, at 11.

if doctors determined them to be necessary.[179]

By 1979, the Bureau of Radiological Health believed that x-rays were still over-prescribed. John C. Villforth, director of the Bureau, believed that as many as thirty percent of the 278 million diagnostic x-rays performed in the previous year may not have been necessary.[180] Villforth explained that the FDA's concern about overuse of x-rays was motivated by both health and cost concerns. He estimated that medical and dental x-rays cost the American public as much as $6 billion each year.[181] He also noted that "nonradiologists . . . who provided their own x-ray services used those services almost twice as often as physicians who referred patients to consulting radiologists," and believed that physicians and dentists did not fully appreciate the risks they were imposing on their patients.[182] The federal government, however, did address the concerns articulated by Villforth. A presidential directive instructed Federal agencies to reduce unnecessary diagnostic x-rays. On May 29, 1980, the Public Health Service asked all of its agencies, HHS, and twenty-eight other federal departments and agencies to "review their current procedures, eliminate chest x-ray screening not supported by the guideline, and justify any screening that would be continued."[183] The result was the elimination of approximately 150,000 formerly required chest x-rays and savings of approximately $4 million a year.[184]

Villforth also noted that the advances in mammography demonstrated technology's ability to meet changing needs. Mammography was recognized as an effective tool for early detection of breast cancer. A low energy x-ray beam is used to get a good contrast between normal tissue and a lump or mass in the breast. The process results in less radiation reaching the film and more being absorbed by the body. Prior to the

[179] Morrison & Barnett, *supra* note 177, at 25.
[180] John C. Villforth, *The X Raying of America*, FDA Consumer, Dec. 1979 – Jan. 1980, at 13.
[181] *Id.*
[182] *Id.* at 15 – 16.
[183] *X'ing Out Unneeded X Rays*, FDA Consumer, Apr. 1981, at 19.
[184] *Id.*

Bureau's involvement, radiation exposure from mammography varied widely among hospitals and clinics. Improper techniques and equipment further exacerbated the already high levels of radiation produced by mammography.[185] With FDA support, better x-ray films and intensifying screens were developed that provided "a sharper, clearer, more defined image on the film at a much lower dose of x rays to the patient than previously had been possible."[186] While such technology would have been developed eventually, Villforth believed the widespread concern from physicians and consumers about the dangers of unnecessary radiation dose in mammography accelerated the process.[187]

The progress of x-ray radiation control is remarkable. While many in Congress were disappointed that the FDA had not pushed for more authority to regulate x-ray use,[188] the concerns that arose during the legislative hearings were successfully addressed because the FDA developed a broad radiation control program that encompassed not just enforcement of the RCHSA but also a public education program. Some patients may still demand unnecessary procedures, but the vast majority of the public and the medical profession recognize the inherent dangers of excess radiation exposure. The combination of widespread education and better technology has produced a society much less likely to be exposed to excessive x-ray radiation.

B. Microwave Ovens: Space-Age Cooking Devices

Microwaves were experiencing a significant increase in popularity at the same time the RCHSA was being passed. While Dr. Russell Morgan's statement about the lack of evidence of biological effects from microwaves may have been technically correct,[189] the FDA believed the absence of proof did not indicate that microwaves were actually safe. The FDA's research indicated that many microwaves were leaking radiation

[185] *See* Annabel Hecht, *Using X Rays To Detect Breast Cancer*, FDA CONSUMER, Apr. 1976, at 14.
[186] Villforth, *supra* note 180, at 15.
[187] *Id.*
[188] *See supra* note 70.
[189] *See supra* note 43.

above the voluntary industry recommendation.[190] The first microwave oven standard went into effect on October 6, 1971, and was set well below the lowest level known to cause biological effects.[191] That did not satisfy *Consumer Reports*, however, which found "'measurable radiation leakage' in 15 leading models and warned the public not to purchase those ovens."[192] Dr. Milton Zaret testified before Congress that several years of such exposure could lead to the development of cataracts.[193] *Consumer Reports* claimed that no amount of leakage could be considered acceptable.[194]

The FDA and the Association for Home Appliance Manufacturers disputed that assessment. The FDA indicated that common consumer goods such as shavers, food mixers, vacuum cleaners, and other appliances with electric motors would have to be banned under a zero-radiation policy.[195] The FDA also criticized *Consumer Reports'* erroneous interpretation of the FDA's policy for causing unnecessary concern among the public. The FDA claimed *Consumer Reports* inappropriately compared the FDA's microwave *emissions* standards to the Soviet Union's microwave *exposure* standards in concluding that the Soviet Union's standards were 500 times lower than the American standard. The emission level at the source was very different from the actual exposure received.[196] The Bureau assured the public that a properly manufactured and operated microwave oven was safe for human use, and that the Bureau would continue to test microwaves in homes, commercial establishments, and on dealer and distributor premises to ensure compliance with

[190] *See supra* note 91 and accompanying text.
[191] Robert T. De Vore & Albert Van De Griek, *The Microwave Oven Safety Debate*, FDA Consumer, Apr. 1973, at 25.
[192] *FDA Actions: Microwave Ovens*, 31 Cong. Q. 850 (1973).
[193] *Id.*
[194] De Vore & Van De Griek, *supra* note 191, at 25.
[195] *Id.*
[196] *Id.* The Soviet standard was for whole body exposure for a working day of eight hours or more. If a microwave emitted radiation at the maximum allowed level, "one could stand within four feet of it for over eight hours per day or within 14 inches for two hours a day without reaching Russian exposure limits." Additionally, if a microwave leaked from multiple points, then fewer points of the human body would be exposed to radiation, further reducing the danger to humans. *Id.* at 26. *Consumer Reports* refused to acknowledge the inaccuracies in its April 1973 report and instead declared in August 1973: "Microwave Ovens: Still Not Recommended." Thomas V. DiBacco, *Microwave's Generation: America Begins Cooking to a Different Beep*, Wash. Post, May 31, 1990, at T28.

federal standards.[197] The Association of Home Appliance Manufacturers asserted that all leakage cited in the *Consumer Reports* article was "'well within the limits' set by the government."[198]

The FDA continued to adjust its microwave standard to protect the public. The FDA proposed amendments to its standards in 1973 to require ovens to shut off automatically if the safety interlocks that prevented the ovens from operating when the door was open had failed. By October 3, 1975, manufacturers were required to attach permanent labels warning users how to avoid exposure to excessive microwave energy.[199] In issuing the labeling requirement, the FDA assured the public that it reflected the FDA's belief that a safe product as manufactured could pose a risk to consumers if used or serviced improperly. The FDA emphasized that there had been no documented cases of injuries associated with microwave ovens that complied with federal standards. The FDA confirmed, however, that extra precautions were necessary because of the uncertainties about possible radiation effects.[200] The standards are now a mix of performance standards and warnings through labels and instruction manuals for consumers and repair personnel.[201]

Despite fears of uncertainty, these "space-age" cooking devices became commonplace as prices dropped. The first models were priced at $1500. By 1968, the price had dropped but was still very high at $995. About 100,000 ovens were sold in 1971, when the first standards were enacted. In April 1973, when *Consumer Reports* warned consumers not to buy microwave ovens, sales were predicted to reach 800,000. By 1981, forty-five companies were manufacturing microwaves. Two years later, one in every four American homes

[197] De Vore & Van De Griek, *supra* note 191, at 26. The Bureau also assured that it carefully monitored manufacturer quality control and test procedures and would use its authority to withhold non-compliant microwave ovens from the market.

[198] *FDA Actions: Microwave Ovens*, *supra* note 192.

[199] Valerie A. Britain, *Microwave Oven Labeling*, FDA Consumer, July – Aug. 1975, at 16. The current labeling requirement remains the same: "Precautions for safe use to avoid possible exposure to excessive microwave energy. DO NOT attempt to operate this oven with: (a) object caught in door, (b) door that does not close properly, (c) damaged door, hinge, latch, or sealing surface." 21 C.F.R. § 1030.10(c)(6)(i) (2005).

[200] Britain, *supra* note 199, at 16. In particular, microwave radiation can cause heating within the body without activating temperature sensors on the skin. While these sensors can warn users of dangers from gas or electric ovens, they may not always function when exposed to microwave radiation.

[201] *See* 21 C.F.R. § 1030.10 (2005).

owned a microwave, now priced at just $399. By 1990, seventy-five to eighty percent of American homes had microwaves, which were now manufactured to fit every individual's needs.[202] Currently, as many as ninety-five percent of American homes owns a microwave.[203]

The generally accepted safety of microwave ovens changed the focus of the FDA's concerns from radiation emission to the contents of microwave-packaged foods, the materials used in the packaging, and the proper techniques for microwave cooking. Microwave packaged food sales had risen from $53 million in 1983 to $3 billion in 1992. When packaging materials were first regulated as passive or active indirect food additives, the FDA did not consider the possible effects high temperature could have on the migration of components of the packaging material. In 1987, FDA scientists noticed that the heat-susceptor[204] portions of microwavable popcorn bags would burn through. Further investigation indicated that the heat-susceptors helped, rather than prevented, the migration of components into foods. The FDA was unsure of the health effects of such migrations but used the opportunity to urge safe use of microwaves. While the FDA repeated safety measures outlined in instruction manuals, the U.S. Department of Agriculture issued its instructions on proper microwave cooking of meats.[205] The current trend in FDA regulation of microwaves is a significant advance from the days when people thought microwave cooking made the food radioactive.

C. Sunlamps and Sunbathing: There Is No Such Thing as a Safe Tan

The FDA also expended great effort in public education concerning sunlight and sun tanning. While scientists in the 1970's agreed that the sun was the leading cause of skin cancer, the public was not so informed.

[202] Di Bacco, *supra* note 196, at T28. Note, however, that many still questioned the safety of microwave ovens. Joanne Barron of CDRH stated that the department still received two to twenty complaints of radiation leakage each year. Most turned out to be false alarms. The real problems were often due "to abuse of the oven or improper servicing." Dixie Farley, *Keeping Up with the Microwave Revolution*, FDA Consumer, Mar. 1990, at 17, 18. *See also* Jane Clarke, *Radiate a Little Goodness*, Times London, Features, Apr. 19, 2005 (noting that a major objection to microwave ovens is a safety concern regarding the use of radiation to heat food).

[203] *Cornell Researchers Explanation Why Some Microwaved Foods Explode Could Revolutionize Microwave Cooking and Sterilization*, Cornell News, June 23, 1998, *at* www.news.cornell.edu/releases/June98/microwave.ift.ssl.html (last visited Apr. 29, 2006).

[204] "[H]eat-susceptor packaging is usually metalized polyethylene terephthalate (PET) film laminated to paperboard with adhesive. This metalized film absorbs the microwave energy in the oven and, with most of the microwaves absorbed, the package becomes a little 'frying pan' that actively participates in the cooking." Dixie Farley, *supra* note 202, at 19.

[205] *Id.* at 20.

Sunbathing and the use of sunlamps were rather common, with little notice paid to the estimated 6,500 to 7,500 deaths in the United States annually from skin cancer.[206] The FDA sought to educate the public about the dangers of ultraviolet radiation, particularly because it was believed that a ninety-eight to one hundred percent cure rate was possible with consumer awareness and early detection.[207]

The concerns about ultraviolet radiation were similar to the concerns about microwave radiation: both are invisible and cannot be felt at the time of exposure. Biological effects appear later and may include eye injury, sunburn, skin eruptions, premature aging of the skin, and skin cancer. The short wavelengths of ultraviolet radiation emitted by some sunlamps were believed to be highly dangerous to cell structure.[208] Repeated exposure to ultraviolet radiation, even when a person never burns, was believed to be damaging in the long run. While people under twenty rarely develop skin cancer, the rate of skin cancer increases until about the age of seventy five. Dermatologists strongly advised against excessive sunbathing, believing that many sunbathers relied on inaccurate assumptions to justify their actions.[209] The use of sunlamps further increased the potential for damage.

The FDA published its first proposed standards for sunlamps on December 30, 1977.[210] Sunlamps were being used primarily for tanning, though they were also used to treat acne and other skin problems. At the time the standards were first proposed, thousands were treated annually for injuries from sunlamps, which typically occurred when users failed to follow instructions. Many fell asleep under the lamps, failed to use timers or goggles, or tried exposures that were too long. The proposed regulations would require sunlamps to have timers that shut the lamp off automatically after ten minutes or less. Sunlamp bulbs

[206] Robert T. De Vore, *Sunbathing and Skin Cancer*, FDA Consumer, May 1977, at 15.

[207] When the FDA began promoting public awareness, ninety-five percent of skin cancer patients were fully cured. Skin cancer differs from other cancers because "it can be seen [and] can almost always be detected and treated in an early stage." *Id.*

[208] *Id.* at 16. The FDA noted that the ozone layer filtered most of the dangerous short wavelengths from the sun, but the severe ozone depletion since the 1970's has renewed concerns about such exposure.

[209] The FDA cited two common justifications. First, the sun stimulates vitamin D production. Experts countered that a proper diet provided sufficient vitamin D. Second, sunscreen lotions allowed tanning without burning, and therefore was safe for the skin. The experts countered that a "tanned skin is a damaged skin." Even in the absence of burning, ultraviolet radiation can damage DNA. *Id.*

[210] *Sunlamps: Putting Safety First*, FDA Consumer, Mar. 1978, at 16, 19.

that fit into conventional sockets would not be allowed to ensure that they could only be used with timers. Sunlamps would not be allowed to emit excessive short wavelengths of radiation. Protective eyewear would be required. Finally, better warning labels and instructions would be required.[211] The FDA also suggested safety precautions for those who insisted on using sunlamps.[212] The first sunlamp standards went into effect on May 7, 1980.[213]

As the FDA was researching the dangers of sunlamps, tanning booths and huts in salons began to grow in popularity, particularly in sunny states where bronzed skin was equated with wealth.[214] The new tanning booths were using ninety-five percent UV-A radiation and only five percent UV-B radiation, leading to claims that tanning booths were a safer alternative.[215] While UV-B radiation was believed to be the cancer-causing radiation, the FDA did not support the safety claim. At the time, UV-A radiation was known to penetrate deeper into the skin and was believed to cause aging and skin sagging, but no direct connection to cancer had been established. The FDA was certain, however, that some chemicals increased sensitivity to UV-A radiation and could cause damage. The FDA also rejected the claim that goggles were not needed. Both types of radiation could cause eye burning and other corneal irritations and could increase the risk of cataracts. Additionally, the amount of light provided by the booths was as high as "10 times the irradiance of noon summer sunlight." In other words, there was enough radiation to serve as a "successful experimental tool for generating skin cancer in animals."[216]

By 1987, the FDA believed the first generation to understand the risks of too much sun had arrived. The problem remained, however, that tanning was becoming more popular than ever. While only one in 1,500

[211] *Id.*

[212] These precautions included makeshift options that reflected the concerns addressed in the proposed standards, such as using loud kitchen timers when a sunlamp does not have an automatic one and using some form of eye protection. Practical precautions included not using sunlamps if a person has fair skin and only using sunlamps as recommended in the instructions. A surprising precaution was not to use sunlamps after a shower or sauna because natural oils that can absorb some of the ultraviolet rays have been washed off. *Id.*

[213] The current standards are at 21 C.F.R. § 1040.20 (2005).

[214] Harold Hopkins, *Tan Now, Pay Later?*, FDA Consumer, Apr. 1982, at 9, 11.

[215] *A Careful Look Into Tanning Booths*, FDA Consumer, Oct. 1980, at 20, 23.

[216] *Id.*

persons in the United States was expected to develop melanoma in 1930, the expected rate in 1980 was one in 250. Scientists estimated that it could rise as high as one in 100. The FDA also determined that the assertion that UV-A tanning booths were safer than UV-B sunlamps was wrong.[217] UV-B radiation was originally believed to be more dangerous because it burned the skin faster, but research indicated that the effects of UV-A radiation were just as harmful. The effects of UV-A radiation were merely delayed because the radiation penetrated deeper into the skin.[218] Following its duty to protect the public, the FDA prohibited manufacturers and sunlamp operators from making such health claims as "improves immunity" and "treats disease." "No harmful rays" and "no harmful effects" were also prohibited. The FDA used its seizure and enforcement authority to intercept imported sunlamps because they lacked required safety features. The FDA also seized installed equipment and shut down salons for unsafe equipment and operation. State and local governments developed their own regulations requiring tanning salons to properly inform and protect customers.[219] The 1978 requirement of the "sun protection factor" ("SPF") indicating the degree of protection a sun-blocking agent supplied had led to a growth in the sun products industry, suggesting some success.[220]

Yet despite the FDA's efforts at public education and the availability of sunscreens, skin cancer rates continued to grow. A University of Florida study found that ninety percent of those surveyed knew the basic harms of sunlight and understood the SPF system. However, only half used sunscreen regularly, and most still insisted that a "tan is healthy."[221] The FDA began to publish regularly its recommendations against sunlamps and tanning booths and its suggestions for protecting against sun exposure.[222]

[217] Richard C. Thompson, *Out of the Bronzed Age*, FDA Consumer, June 1987, at 21, 22.

[218] Scientists debate whether UV-A radiation is actually more harmful because it damages the dermis – "the inner layer of skin that contains the blood vessels, hair follicles, and nerve endings." Alexandra Greeley, *No Safe Tan*, FDA Consumer, May 1991, at 16, 19.

[219] Thompson, *supra* note 217, at 22.

[220] The cosmetics industry quickly picked up on the SPF trend and began applying these numbers to their products. *Id.* at 23.

[221] *Id.*

[222] *See, e.g.*, Greeley, *supra* note 218; Paula Kurtzweil, *Seven Steps to Safer Sunning*, FDA Consumer, June 1996, at 6; Michelle Meadows, *Don't Be in the Dark About Tanning*, FDA Consumer, Nov. – Dec. 2003, at 17; Carol Rados, *Teen*

The trend in recent years has been the use of sunless spray tans. Some credit designer Coco Chanel with starting the tanning craze by returning from her yachting vacation with a tan. Tanned skin was soon equated with great wealth, leisure time, social status, and high fashion, a complete departure from the previous association of tanned skin with outdoor laborers.[223] When celebrities began turning to sunless tans as a safer and easier alternative, the public followed. Many salons now offer spray tans that look a bit unnatural but are much safer.

Sunless spray tans contain the color additive dihydroxyacetone ("DHA"), which interacts with skin cells to darken the skin color. The FDA approved DHA for use in tanners in 1977, though it was used at that time only in over-the-counter lotions and creams. Doctors now encourage teenagers to use self-tanners as opposed to sunbathing or sunlamps.[224] Excessive sunbathing remains a problem, however. While sunless tanning is growing in popularity, it also indicates that Americans still associate tanned skin with good health and wealth. The federal standards ensure that tanning booths are as safe as possible, but the FDA's efforts in changing people's mindsets have yet to succeed.

D. Lasers: Disco Fun and Medical Wonder

Lasers are composed of concentrated beams of visible light, which distinguishes them from other forms of radiation like microwaves and ultraviolet light that can cause cancer and genetic damage. The high concentration, or coherence, of the light waves in laser beams makes them potentially dangerous despite the absence of cancer causing properties.[225] The nature of lasers allowed them to be used in a wide variety of areas in the early years of the RCHSA. Lasers had been used as highly accurate surveying tools; as tools to perform delicate surgical procedures of the eye and throat; as supermarket checkout scanners; and as

Tanning Hazards, FDA Consumer, Mar. – Apr. 2005, at 8. Carolyn J. Strange, *Thwarting Skin Cancer With Sun Sense*, FDA Consumer, July – Aug. 1995, at 10.

[223] *See* Greeley, *supra* note 218, at 17.

[224] Rados, *supra* note 222, at 9.

[225] Center for Devices and Radiological Health, Laser Light Show Safety: Who's Responsible? 5, 7 (rev. ed. 1986), *available at* http://www.fda.gov/cdrh/radhlth/pdf/llsgde01.pdf [hereinafter "CDRH, Laser Light Safety"].

tools for drilling, cutting, and welding materials. Other popular uses included "communications, fingerprint identification, pollution detection, cell measurement, [and] tailoring."[226]

The first laser standard went into effect on August 1, 1976. Lasers were classified into four categories depending on their ability to injure people and the intensity of the radiation from the beam. Class I lasers are known to have no biological effects. Class II lasers can produce eye damage from long, direct exposure. Class III lasers can injure tissues after short, direct exposure. Class IV lasers can cause injury from reflected light and after the beam has scattered.[227] Lasers used for demonstration purposes were generally in Class I or Class II, but the growing popularity of laser light shows, which require Class III or even Class IV lasers to be effective, concerned the FDA.

The first laser light show was introduced in Los Angeles in 1973 and was immediately successful. Just five years later, laser light shows became popular in planetariums in at least twenty cities in the United States, Canada, Britain, and Japan. Additionally, rock bands and discotheques began using laser light shows to entertain patrons.[228] While lasers at planetariums posed little threat to patrons, reports of uncontrolled or unsafe use by rock bands were common. One performer directly sprayed the audience with laser beams from a device on his wrist. Another show involved beams bounced from mirrored walls and mirrored balls. One report stated that a rock band's laser was so powerful that a stagehand used it to light a cigarette.[229] The FDA repudiated the belief that quick moving lasers were safe. Rather, lasers can strike a shiny surface at any time and reflect into the eyes of patrons, causing serious vision impairment. The shows were being designed by people who had little knowledge of the dangers of lasers, and the shows were virtually unregulated. The FDA began an investigation into who the producers of the shows and the manufacturers of the equipment were, and into what the specific hazards were. The FDA interpreted "manufacturer" to include persons who

[226] Annabel Hecht, *Entertainment Lasers: Approach With Care*, FDA Consumer, Sep. 1978, at 20, 22.
[227] 21 C.F.R. 1040.10(b) (2005).
[228] Hecht, *supra* note 226, at 20.
[229] *Id.* at 23.

receive compensation from laser light shows, who sell services as an assembler of such shows, or who create the show and perform in the show. Laser light shows were technically required to seek variances, though guidelines established situations in which variances were unnecessary.[230] The FDA required variances for Class III-b and Class IV lasers beginning in 1985.[231] To provide substance to the guidelines, the FDA does inspect shows when possible.[232]

The guidelines also regulate outdoor laser shows that may affect airline pilots. The FDA originally believed the chance of harm was very low,[233] but by 1993, that view had changed. High-powered outdoor laser light shows had become extremely popular in Las Vegas as a means of attracting tourists. Late that year, a pilot was treated for corneal irritation after laser lights interfered with his vision on take-off. By late 1995, the FAA reported to the FDA a total of fifty-two incidents of aircraft illuminations from laser light shows, eleven of which resulted in temporary blindness of the flight crew members, and twenty four of which took place during critical flight times. The temporary blinding of an airline pilot on October 30, 1995, was so severe that his captain had to take control until the pilot regained his eyesight. Investigations revealed numerous violations of FDA standards, including operating without a variance, failing to employ spotters to warn of incoming and outgoing planes, failing to maintain documented quality control procedures, and failing to provide certificates of proper operator training. In December 1995, the FDA declared a temporary moratorium on laser light shows in Las Vegas.[234] In July 1999, the FDA completed a memorandum of understanding with the FAA to coordinate their programs and research on laser light displays.[235]

[230]Hecht, *supra* note 226, at 24. The guidelines required that the radiation exposure to the audience be no greater than a Class I laser. Lasers must be operated at least three meters above where the audience may stand. Equipment was required to have a shut off mechanism. Notification to the FDA was required. The FDA retained the right to inspect the shows and to impose civil fines up to $300,000. A detailed explanation of the guidelines can be found in CDRH, Laser Light Safety, *supra* note 225, at 17 – 20.

[231]CDRH, Laser Light Safety, *supra* note 225, at 18.

[232]Rebecca D. Williams, *Non-Medical Lasers: Everyday Life in a New Light*, FDA Consumer, July – Aug. 1991, at 32, 34.

[233]*See* CDRH, Laser Light Safety, *supra* note 225, at 20.

[234]Paula Kurtzweil, *Laser Light Shows Nixed Until Fixed*, FDA Consumer, May 1996, at 31.

[235]Memorandum of Understanding Between the Food and Drug Administration and the Federal Aviation Administration, 64 Fed. Reg. 40603 (July 27, 1999).

The predominant use of lasers remains in the medical field. The FDA's authority to regulate medical uses of lasers comes under both the RCHSA and the Medical Devices Amendments. Lasers provide benefits in medicine that traditional tools cannot. Lasers have the potential to vaporize or mend tissue with minimal scarring.[236] They can cut through tissue with minimal bleeding because they actually help coagulate the tissue. They reach parts of the body that a doctor with a scalpel cannot reach. Selection of wavelengths allows doctors to target specific tissues without affecting others.[237] Technology has since allowed lasers to be used for a variety of other purposes. The FDA has approved the use of lasers by dentists for soft tissue surgery, an option favored by many patients because recovery is less painful.[238] A laser to treat tooth decay has also been approved.[239] Laser eye surgery can correct myopia, hyperopia, and astigmatism with minimal pain and minimal recovery time.[240] Cosmetic uses include skin resurfacing, a controlled burning of the skin to remove wrinkles, lines, scars, and superficial growths,[241] and hair removal.[242]

The increasing popularity of lasers among consumers has added to the FDA's concerns, particularly for children. The decreasing price of lasers allowed for their greater use by teachers and lecturers, but the FDA feared the promotion of lasers as toys.[243] The Laser Institute of America reported that some mothers bought lasers for their children to simulate Star Wars characters.[244] The availability of lasers on the internet further exacerbated the situation. High-powered green lasers were being modified to emit radiation far in excess of the FDA's standards and were being used for such activities as aiming at airplanes in flight. The FDA

[236] Williams, *supra* note 232, at 32.
[237] Alexandra Greeley, *Cosmetic Laser Surgery: A High-Tech Weapon in the Fight Against Aging Skin*, FDA Consumer, May – June 2000, at 34, 36.
[238] *See* Ricki Lewis, *Lasers In Dentistry*, FDA Consumer, Jan. – Feb. 1995, at 15.
[239] *Laser Treatments OK'd For Tooth Decay, Astigmatism*, FDA Consumer, July – Aug. 1997, at 2. Laser treatment was found to be just as effective as traditional drilling and required the use of less anesthetics. *See also* Paula Kurtzweil, *Dental More Gentle with Painless Drillings and Matching Fillings*, FDA Consumer, May – June 1999.
[240] *See* Carol Lewis, *Laser Eye Surgery: Is It Worth Looking Into?*, FDA Consumer, July – Aug. 1998, at 32.
[241] *Greeley*, *supra* note 237, at 35.
[242] *See* Marian Segal, *Hair Today, Gone Tomorrow*, FDA Consumer, Sep. 1996, at 21.
[243] U.S. Food and Drug Administration, *FDA Issues Warning on Misuse of Laser Pointers* (1997), *available at* http://www.fda.gov/bbs/topics/NEWS/NEW00609.html.
[244] Linda Bren, *Illuminating Facts About Laser Pointers*, FDA Consumer, May – June 2005, at 18.

issued a warning to consumers that lasers purchased over the internet might not comply with federal safety regulations and that illegal lasers from outside the United States could be denied entry.[245] Unlike other devices regulated by the FDA, lasers are dangerous for contradictory reasons: people are either unaware of the dangers, or they are aware and exploit their knowledge. In addition to educating the public about the true dangers of lasers, the FDA must seek to control their availability.

E. Cell Phones: Renewed Radiation Concerns

The proliferation of cellular telephones and other wireless electronic devices has renewed concerns about dangerous radiation emissions. Similar to the concerns about microwave ovens, the public was aware that some form of radiation was emitting from cell phones but was unsure of just how dangerous the radiation was. Cell phones emit radiation in the form of non-ionizing radiofrequency ("RF") energy, the same type of energy used in microwave ovens. RF energy can be harmful at high levels because it can heat living tissue and cause biological damage. RF energy from cell phones comes mainly from the antenna and dissipates quickly with distance. Many experts believe that the six tenths of a watt of power emitted from cell phones cannot possibly affect human health. "[F]rom the physics standpoint, biological effects from mobile phones are 'somewhere between impossible and implausible.'"[246] Extensive research has been conducted to verify this assumption and in response to lawsuits and general public concerns.

The FDA has collaborated with the Federal Communications Commission ("FCC") in its research and public education program.[247] The results of studies have been conflicting. Proving a cause-and-effect relationship in epidemiological studies is difficult because of the many variables involved in a person's life. Brain cancers

[245] U.S. Food and Drug Administration, *Important Information to Consumers on Internet Sales of Laser Products*, *at* http://www.fda.gov/cdrh/comp/internetlasers.html (last visited Apr. 6, 2006).

[246] Tamar Nordenberg, *Cell Phones & Brain Cancer: No Clear Connection*, FDA CONSUMER, Nov. – Dec. 2000, at 19, 19 – 21.

[247] The Environmental Protection Agency and the Occupational Safety and Health Administration also have a regulatory duty regarding cellular telephones. U.S. Food and Drug Administration, *Wireless Phones: Additional Information*, *at* http://www.fda.gov/cellphones/additional.html#1 (last visited Apr. 6, 2006).

can also take years or even decades to develop, while lifestyle factors such as the position in which a person holds the phone create additional difficulties. Animal studies are easy to control, but correlating animal-testing results to human health effects is difficult. In addition, researchers in animal studies tend to use animals genetically altered to be predisposed to cancer and expose the animals to much more radiation than is consistent with normal cell phone use.[248] The FDA admits that some test results may warrant further investigation,[249] but no studies have demonstrated a clear connection between cell phone radiation exposure and biological health effects.[250] A concern exists, however, because the studies averaged three years of phone use and therefore cannot make credible predictions of long-term effects.[251]

Cell phone regulations and standards are set by the FCC.[252] After the passage of the National Environmental Policy Act, the agency adopted guidelines for electromagnetic radiation emissions.[253] As an agency without expertise on health and safety matters, the FCC relied on standards promulgated by the American National Standards Institute ("ANSI"), an organization also consulted by the FDA in setting its standards. The final standards, however, were established based on consultations with the FDA regarding the FDA's obligations under the RCHSA. The FDA advised the FCC to decline ANSI's recommendation to exempt wireless phones and other low-power devices from federal RF standards, and the FCC deferred to the FDA's expertise. This resulted in the FDA's characterization of the RF requirements as "a significant step towards achieving a

[248]Nordenberg, *supra* note 246, at 21. Scientists note the difficulty of correlating nearly continuous, whole body RF exposure of rats predisposed to develop cancer with the much briefer, head-only radiation typical of normal human cell phone use.

[249]In one study, tumor patients reported that the tumor developed on the side they tend to hold their cell phones, but researchers believed the recollections were biased by knowledge of which side the tumor was on. A different study found no association between cell phone use and a type of brain cancer called glioma. However, there appeared to be an increase in one rare type of glioma. Researchers believed this was due to chance because the risk tended to decrease with greater cell phone use. A cognitive function test in which participants were exposed to simulated phone signals indicated no impairment in cognitive skills. People exposed to the signals actually responded more quickly in one of the tests. *Id.* at 23.

[250]The studies that demonstrate a possible connection have suffered from design defects. *See supra* notes 248 – 249 and accompanying text; *infra* note 271.

[251]U.S. Food and Drug Administration, *Questions and Answers about Wireless Phones*, *at* http://www.fda.gov/cellphones/qa.html#25 (last visited Apr. 6, 2006).

[252]*See* 47 C.F.R. §§ 1.1307(b), 2.1091, 2.1093 (2005).

[253]In re Wireless Tele. Radio Frequency Emissions Products Liab. Litig., 216 F. Supp. 2d 474, 484 n.6 (D. Md. 2002), *rev'd sub nom.* Pinney v. Nokia, Inc., 402 F.3d 430 (4th Cir. 2005), *cert. denied* Nokia, Inc. v. Naquin, 126 S.Ct. 551 (2005), *and cert. denied* Cellco P'ship v. Pinney, 126 S.Ct. 552 (2005).

consensus guideline on RF exposure which will have the support of the federal agencies responsible for protecting the public from nonionizing radiation injury."[254]

The FDA's and FCC's assertions regarding the safety of cell phones have not stopped the proliferation of law suits, however. In 2000 neurosurgeon Chris Newman filed an $800 million lawsuit against Motorola alleging his brain tumor was caused by nine years of cell phone use. Motorola's response echoed the assertions of the FDA:

> Since 1992, we have seen this same issue raised in a limited number of other cases. One by one, these have been dismissed by the courts or withdrawn by the plaintiffs. This trend reflects a fundamental reality: the claim of a link between wireless phone use and adverse health effects is groundless and unsupported by a substantial amount of scientific knowledge accumulated from decades of research related to the possible health effects of radio waves.[255]

Newman stirred public concerns about cell phone safety, but his claim eventually failed.[256] The district court rejected his expert witnesses for failing to meet the requirements for reliability under *Daubert v. Merrell Dow*.[257] The court cited the vast array of studies published in peer-reviewed journals that all found no reliable link between cell phones and brain tumors.[258] Newman's expert witnesses, on the other hand, relied on "reasoning, theories, and methodology [that] have not gained general acceptance in the scientific community."[259] While Motorola presented established and highly-credentialed experts, Newman presented witnesses who appeared to manipulate the results of their own research to provide the desired result. No one had replicated or validated their studies, while most outright rejected them. Other expert witnesses proffered by Newman were deemed irrelevant.[260]

The result was hardly unexpected. A Florida district court had rejected a wrongful death case against a

[254] *In re Wireless*, 216 F. Supp. 2d at 486.
[256] Newman v. Motorola, Inc., 218 F. Supp. 2d 769 (D. Md. 2002), *aff'd* 78 Fed.Appx. 292 (4th Cir. 2003).
[257] 509 U.S. 579 (1993).
[258] *Newman*, 218 F. Supp. 2d at 773 – 74.
[259] *Id.* at 783.
[260] *Id.*

cell phone company for the same reason five years before Newman filed his suit.[261] The plaintiff alleged his wife had died of a brain tumor either caused or accelerated by the use of a cell phone. The plaintiff's expert witnesses had misrepresented the conclusions of the studies on which they had relied. Summary judgment was granted for the defendants for lack of evidence.[262]

A district court acknowledged the importance of the RCHSA in *Schiffner v. Motorola, Inc.*, when it rejected the plaintiff's argument on federal preemption grounds.[263] The plaintiffs' causes of action included failure to warn consumers of risks associated with cell phone use and false pronouncements of proven safety. The court held that the RCHSA preempted state regulations despite the fact that the FDA was not affirmatively regulating cell phones. Allowing states or courts to set standards would usurp power granted to the FDA by Congress under the RCHSA and could create conflicts between federal and state standards.[264] This holding has been called into question by *Pinney v. Nokia, Inc.*[265] The Fourth Circuit held that a well-pleaded complaint could avoid the substantial federal question doctrine.[266] The court stated that FCC standards were merely evidence to be considered in determining if a product was defectively designed; a ruling for either side would not question the FCC's decisions. The dissenting judge stated that "the case cannot be resolved without proving that the FCC's RF radiation emission standards are too high to protect the consuming public."[267] Rejecting the majority's assertion that all claims could be proven without reference to the FCC's standards, Judge Kiser characterized the case as a "thinly-disguised attack on the validity of the FCC standards [that] raises a substantial federal question."[268] While federal preemption was not a proper affirmative defense to raise in the removal hearing, the majority did reject a similar argument couched as a

[261] *See* Reynard v. NEC Corp., 887 F. Supp. 1500 (M.D. Fla. 1995).
[262] *Id.* at 1508.
[263] Schiffner v. Motorola, 697 N.E.2d 868, 870 (Ill. App. 1 Dist. 1998).
[264] *Id.* at 873.
[265] 402 F.3d 430 (4th Cir. 2005).
[266] *Id.* at 446 – 47.
[267] *Id.* at 459 (Kiser, J., dissenting).
[268] *Id.*

federal question issue.[269]

For the most part, however, cell phone law suits eventually fail, primarily due to the lack of scientific evidence establishing a link between cell phone use and brain cancer. While other mass tort claims have succeeded despite the lack of evidence, cell phone suits have not. It has been suggested that the absence of any evidence of a cover up of by the cell phone industry of alleged fault may account for the difference.[270] While research thus far has failed to find a link, the research continues, particularly concerning the long-term effects of cell phone use.[271]

V. The Accomplishments of the RCHSA

The Radiation Control for Health and Safety Act has been exceedingly successful in remedying the concerns addressed during the 1967 and 1968 congressional hearings. During the hearings, witnesses consistently pointed to a lack of research and general knowledge of radiation risks as a driving force behind the failure to protect the public. The absence of federal authority to regulate was of course a problem, but Congress admitted upon passage of the act that more research was needed before enforceable standards could be set.

[269] *Id.* at 448. The court did consider the question of complete federal preemption, in which Congress "so completely preempt[s] a particular area that any civil complaint raising th[e] select group of claims is necessarily federal in character." The court held that the FCA did not establish the exclusive claim for alleging cell phone injuries. *Id.* at 449, quoting Metro. Life Ins. Co. v. Taylor, 481 U.S. 58, 63 – 64 (1987).

[270] Benjamin J. Wolf, *"Can You Hear Me Now?": Cellular Phones and Mass Tort Litigation After Newman v. Motorola, Inc.*, 14 Alb. L.J. Sci. & Tech. 267, 272 – 73 (2003).

[271] In April 2006, Dr. Lennart Hardell, the expert witness discredited by the court in *Newman v. Motorola*, released a study finding a correlation between cell phone use and increased risk of brain cancer. His study was reported by major news outlets and is raising concerns similar to those raised during Dr. Newman's suit. The FDA stated that it planned to convene a meeting to evaluate the study, but its initial review of the study revealed many defects that have led to past rejections of Hardell's research. In particular, the research relied on mailed questionnaires and a few follow-up interviews conducted by telephone. Hardell failed to make statistical adjustments for all confounding factors other than time of diagnosis. He also lacked an established mechanism of action and supporting animal studies. The FDA again noted that Hardell's study was contrary to other published studies of long-term cell phone use and brain cancer. U.S. Food and Drug Administration, *Use of Wireless Communications Devices and the Risk of Brain Cancer*, *at* http://www.fda.gov/cdrh/wireless/braincancer040606.html (last visited Apr. 6, 2006).

The FDA currently has standards for 12 categories of electronic products, and manufacturers for the most part comply with these standards. The act also resulted in increased public awareness and a strong public education program that helped drive a change in behavior, so much so that other countries cite the act as the model to follow in protecting their citizens from radiation.[272] This section discusses the accomplishments of the act but in doing so also acknowledges areas where results have not been quite as successful.

A. Research and Standard Setting

A physician who testified during the congressional hearings urged that the RCHSA be limited to only ionizing radiation, as that was the only type of radiation known to cause biological damage. That statement was questionable at the time and has since been soundly rejected. In addition, the dangers of long-term or low-dose ionizing radiation exposure, a little explored area in the 1960's, are now much more established. The FDA's radiation research program, first through the Bureau of Radiological Health and now through the Center for Devices and Radiological Health, in conjunction with other federal safety statutes and regulatory agencies, has supported extensive research and contributed greatly to scientific knowledge. The commitment to research has allowed standards to be set at levels that the FDA can say is truly protective of human health. Before enactment of the RCHSA, electronic products were regulated loosely by the states and by voluntary standards from professional groups. The absence of federal enforceable standards required consumers to rely on companies' self-policing. As evidenced by the GE television recall, self-policing does work because companies are concerned about their reputations. However, the lack of enforceable standards at the manufacturing and market entry stages led to excessive radiation exposure for consumers. In addition to serving a preventative function, enforceable standards were able to serve as a technology-forcing device. Innovation occurs over time, and televisions unquestionably would have become safer in the absence of federal standards. While rogue players will always exist,[273] most manufacturers will design safe consumer devices, if

[272] *See* Vanguard, *Consumer Protection: The Right of Every Nigerian*, Africa News, Jan. 14, 2004 (stating that Nigeria should follow the FDA's lead and protect its citizens by regulating radiation-emitting products, particularly cell phones).

[273] *See, e.g.*, the X-Ray of Greenville case, discussed *supra* Part IV(A).

not to protect consumers, then at least to protect their reputations. When the safety measures are relatively low-cost and can be passed to consumers, manufacturers have little incentive to produce a slightly cheaper but dangerous product, particularly when their competitors are producing safe products. Hard deadlines quicken this process. The GE television recall occurred in 1967. The public awareness of radiation emissions from televisions persuaded the government to recommend that viewers sit at least six feet from their sets. By 1971, when the final phase of the first television standard was enacted, the government believed it was safe to watch television from any distance.[274] Limiting emissions proved to be quite easy and cheap.[275] Consequently, violations of the emissions limits are uncommon. The 1974 Matsushita television recall was based on possible radiation emissions should part of the circuit board fail. While the FDA rejected its defense, Matsushita claimed that no similar failure had ever occurred, nor was one likely to occur.[276] The 1991 Goldstar violations were due to poor testing procedures. Everyone agreed that no Goldstar televisions had ever been found to emit excess radiation.[277]

In addition to standards setting, the RCHSA required the FDA to support research. This included both the dangers of radiation exposure and the innovations needed to reduce radiation. Research under the RCHSA has alerted the scientific community and the public to the dangers of microwave radiation, ultraviolet light from the sun, and laser lights directed towards the eyes, all non-ionizing forms of radiation previously thought to have negligible harms. However, research has also contributed to the development of safer products, the primary goal of the RCHSA. The Bureau of Radiological Health quickly developed devices to study the effects of the radiation, but it also designed cheap and effective tools to be used in the field to detect radiation emission.[278] The Bureau's research also directly improved the safety of radiation emitting products. One

[274] De Vore, *supra* note 6, at 9.

[275] "[S]pecial voltage hold-down circuits were put into use in all color sets, causing them to fail rather than exceed [the] specified level; picture tube shielding was improved, and, coincidentally, sets went solid state, removing [the] power tube as a possible radiation source." *Goldstar Rocked by Obsolete X-Ray Rule*, *supra* note 130.

[276] Gundaker, *supra* note 117, at 11.

[277] *Goldstar Rocked by Obsolete X-Ray Rule*, *supra* note 130.

[278] De Vore, *supra* note 6, at 7. The meter to check microwave ovens for radiation leakage was designed using parts readily

example is the automatic collimator.[279] Unlike the detection devices and the television modifications, the collimator was comparatively expensive to install.[280] However, its ability to reduce excess radiation exposure in the source that provided ninety percent of Americans' overall exposure led to its inclusion in the x-ray standards.[281] While manufacturers' lobbying efforts succeeded in weakening the bill in 1968, consumer safety, not cost-benefit analysis, remains the primary goal of the RCHSA.

Enforcement actions for violations of RCHSA standards are rare. While this is certainly due to the traditional cooperation between the FDA and the manufacturers, it must also be related to the fact that violations are not common. Certainly some violations go undetected, but the cost of compliance, particularly after the technology has been developed by manufacturers and by the FDA, is low compared to the cost of being found in violation. Both the Matsushita and Goldstar violations were detected during routine inspections. For Goldstar, the money saved by lax recordkeeping and improper on-site testing resulted in the loss of tens of millions of dollars in sales when its products were kept off the market during the peak sales season. Goldstar was also required to implement a Corrective Action Plan, which required it to redesign its quality control program and retest samples of its stock.[282] The imposition of civil fines on companies and on individuals for violations by the company further reduces any financial gain a company may seek. The FDA's trend towards combining enforcement under the RCHSA with other safety acts adds the possibility of criminal prosecution. These penalties assume companies care only about the bottom line and leave out the possibility that manufacturers also recognize the dangers of radiation and understand their duty to produce safe products. Whatever the reasons, the combination of extensive research and standards enforceable

available to oven servicemen. The Bureau's device cost $150, while commercial microwave measuring instruments at the time cost $800. A similar x-ray detection instrument was designed as an "easy-to-use" and inexpensive device for television servicemen for use on home receivers.

[279] De Vore, *supra* note 166, at 5 – 6.

[280] In the X-Ray of Greenville case, Wilder saved $2500 by foregoing the use of automatic collimators in favor of manual collimators, a decision that was both in violation of the standards and potentially dangerous. *See* Hommel & Thompson, *supra* note 171.

[281] 21 C.F.R. § 1020.30(h) (2005).

[282] *Id.*

through inspections, forced recalls, and fines has resulted in much safer consumer products and has met the goals Congress set for the RCHSA.

B. Education and Behavior

While public education is not technically required by the RCHSA, the FDA's radiation control program has always included an effort to educate consumers and users to achieve the goals of the act. Public awareness of the dangers of radiation emitting products is essential in reducing unnecessary exposure. CDRH has four goals for its radiological health program:

> (1) A public able to make informed choices about their own exposure to radiation-emitting products in the medical, occupational and home setting;
>
> (2) Users of radiation-emitting products able to minimize their own exposures and those of people they expose;
>
> (3) Manufacturers of radiation-emitting products able to understand their responsibilities and sensitive to radiation risk issues; and
> (4) FDA and State radiation control programs that actively encourage and assist users in minimizing radiation exposure and risk.[283]

Public disclosure has the potential to lead to greater fears regarding previously unknown risks, but it can also allay fears created by popular press or other unreliable sources. It can also change behavior. Behavior does change in the absence of federal regulation, but change is often slower or, as in the case of the fluoroscope, is in response to a really bad practice. A fluoroscope is "an x-ray device that provides images of internal body parts as they move."[284] It requires high levels of radiation exposure, and often for longer periods of time, to produce useable images. Fluoroscopes were common in doctors' offices during the 1950's because they were very effective diagnostic tools. When they were first developed, however, they were considered novelties that drew in people's attention and consequently were used for rather impractical reasons. Shoe stores used them to see the bone structure in customers' feet. Customers, particularly children, liked seeing the bones in their feet move when they wiggled their toes, and shoe stores liked the increased business. The use was quickly

[284]Lewis, *supra* note 1, at 18.

discontinued when scientists discovered the potential harm.[285] The correct decision for human health was made before anyone ever considered a radiation control bill.

A fairly bad practice that was remedied by the RCHSA was the excessive use of x-ray diagnoses. The value of x-ray technology was never questioned, but as discussed in Part IV(A), the technology was being used in unwarranted situations. Mass chest x-rays to detect tuberculosis[286] or as part of routine government physicals[287] were common, as were pelvimetries of pregnant women in some parts of the country.[288] Patients often demanded x-ray examinations as further assurance of their good health, while doctors commonly provided x-rays to establish evidence in the event of a malpractice suit.[289] X-ray procedures expose patients to radiation but are justified on the basis of their diagnostic value. When medical diagnoses can be made effectively without the use x-rays, the use of such procedures represents nothing more than unnecessary and excessive radiation exposure. Informing the public that excessive x-ray exposure posed long-term risks was not difficult. However, the FDA was then faced with a public fearful of all x-ray examinations. The FDA had to convey that properly prescribed x-ray examinations provided benefits that far outweighed the risks, and that no one x-ray examination would cause cancer.[290]

One method of reducing fears was to educate both patients and physicians regarding the measures that can be taken to reduce potential risks. The scientific community generally recognized that radiation that posed almost no risk to adults could have a much greater biological effect on individual reproductive cells and on developing fetuses. A mutation in a single sperm or egg cell later used in reproduction can cause genetic

[285] *Id.* at 18 – 19. Note, however, that some doctors continued to use fluoroscopes despite awareness of the high radiation emissions and potential risks. Technology to allow lower doses was not developed until the 1960's, and it was not until the 1990's that cameras and computers could enhance images to further reduce exposure. Even today, while the radiation doses have decreased, the lengthy time of exposure for proper diagnosis remains a concern. *Id.* at 20. For an explanation of the current state of fluoroscope technology, see Paula Price, *Equipment Safety and Risk Management*, 75 RADIOLOGIC TECH. 197 (2004).

[286] *See* Britain, *supra* note 174, at 15.

[287] *See X'ing Out Unneeded X Rays*, *supra* note 183, at 19.

[288] *See* Smith, *supra* note 176, at 21.

[289] *See* De Vore, *supra* note 166, at 6.

[290] *See id.* at 5.

defects that can pass for generations,[291] while a single mutation in the cells of a fetus' developing organs can lead to birth defects.[292] Both risks are unlikely, but simple measures such as using gonad shields to cover male and female reproductive organs and informing doctors of possible pregnancies would further reduce the already minimal risks. The FDA stressed that patients should ask their physicians why x-rays are necessary and about protective measures that can be taken.[293] Radiation exposure was further reduced by better technology that allowed for safer x-rays, and by the development of other medical imaging devices that did not use ionizing radiation.

Another interesting education program involves the dangers of sun tanning, discussed in Section IV(C). FDA regulations have made sunlamps and tanning booths as safe as possible, and the public appears well aware of the risks, but it continues to regard tanned skin as a sign of good health. The FDA maintains a webpage entitled "The Darker Side of Tanning" that warns consumers of the dangers of UV-A and UV-B radiation. [294] Consumers' behavior in this area appears quite irrational but might be explained by the fact that the harms of UV radiation appear much later in life. Most skin cancers are also curable if detected early, which may lead people to believe that skin cancer is not that dangerous. The FDA also had to contend with manufacturer and tanning salon claims that tanning beds that used UV-A radiation were safer than natural sunlight. While such claims are no longer allowed, their effects remain.[295] Self-tanners were often rejected because they looked unnatural, but the proliferation of self-tanning by celebrities wanting a safe, year-round tan has rejuvenated that market. The FDA's challenge will be to convey to the public that pale skin is healthy skin.

[291] James Morrison & Mark Barnett, *Reducing Genetic Risk From X Rays*, FDA Consumer, Feb. 1977, at 16, 17.
[292] Morrison & Barnett, *supra* note 177, at 24.
[293] Weck, *supra* note 2, at 27.
[294] Center for Devices and Radiological Health, *The Darker Side of Tanning*, *at* http://www.fda.gov/cdrh/consumer/tanning.html (last visited Apr. 12, 2006).
[295] *Id.*

The area of perhaps greatest interest is the effects of RF emissions from cell phones. As the number of cell phone users grew, so did the concerns about new sources of radiation. In 2002, the FDA established a website entitled "Cell Phone Facts" that explained RF emissions, federal regulatory standards, and the current research demonstrating the safety of cell phone use.[296] While all credible research has indicated that cell phones emit too little radiation to cause biological harm, cell phone companies have continued to face lawsuits regarding the alleged dangers of their devices. This is complicated by the lack of sufficient long-term studies, a result of the relatively recent phenomenon of cell phone technology and regular cell phone use. Additionally, the media has hampered the FDA and FCC's efforts at properly informing the public. The media has jumped on the various lawsuits and created concern that has no basis in fact. After Dr. Newman's suit was filed, Larry King had an "expert" on his show defending Newman's claim and telling the public that cell phones caused brain tumors.[297] Newman's suit was determined by the court and by well-established scientists to be based on inconsistencies and questionable witnesses whose research techniques had been rejected by the scientific community. The researcher rejected in Newman's suit released a study in April 2006 that purports to prove that long-term cell phone use increases the risk of cancer. The FDA immediately posted a notice to consumers on its cell phone website stating that it would evaluate Dr. Hardell's conclusions but also informing consumers of the flaws it detected in Dr. Hardell's methods. However, the story reached the public not through the FDA's considered statement on its website, but through the popular media that reported Hardell's conclusions without evaluating his methods. Consequently, cell phone risks are now a renewed concern despite the vast amount of evidence indicating a lack of danger. This hardly means an end to cell phone use, but it can lead to more law suits and potential plaintiff success.

[296] U.S. Food and Drug Administration, *Cell Phone Facts*, *at* http://www.fda.gov/cellphones/ (last visited Apr. 12, 2006). *See also* Federal Communications Commission, *FDA-FCC Cellular Phone and Radiofrequency Energy Website Posted for Public Use and Comment*, 2002 WL 920836 (May 8, 2002).

[297] Nordenberg, *supra* note 246, at 19.

The FDA's education program historically relied on publications to communicate with manufacturers and consumers, while health care professionals were provided with instructional courses. The internet now provides the easiest and most effective tool to communicate the FDA's research and policies. CDRH's electronic product radiation website provides the regulations for each electronic product regulated by the FDA, basic information about each product, answers to frequently asked questions, forms for manufacturers, and updates on research. The challenge will be to alert the public that this credible resource exists. Collaboration with the popular media, perhaps by having the media refer the public to the FDA's website for further information on their stories, may provide the public with the most complete information and avoid repeats of the Larry King cell phone misinformation.

VI. Conclusion

The Radiation Control for Health and Safety Act succeeded because the federal government was committed to understanding the effects of radiation and protecting the public from it. The Bureau of Radiological Health was dedicated to determining safe levels of radiation emissions and establishing enforceable standards that reflected its research. Similarly, manufacturers understood the importance of working with the FDA in establishing standards and developing techniques to meet the standards. Radiation-emitting electronic products are now considered safe, which has shifted the FDA's concerns from product design to misuse of products by consumers. Over the years, however, the FDA has seen a reduction in federal funds earmarked for radiation control activities.

In light of the different circumstances in which CDRH finds itself, it has reconfigured the goals of the radiation control program. Included in these goals are the acknowledgement of "the availability of national and

international voluntary standards"; an awareness of radiation emitting products; the dissemination of useful public health information to industry, users, the public, and regulators; and continued research to address radiation risks.[298] Specific changes are proposed for each of the five major program elements: standards, monitoring, education, research, and program management. While CDRH will maintain its existing standards, it believes a move toward voluntary consensus standards for other products may be necessary, and it is seeking "legislative changes to allow adoption and enforcement of voluntary consensus standards."[299] CDRH plans to change its monitoring program to devote resources to inspections of manufacturers rather than product testing. It also plans on reducing the content of required reports from manufacturers.[300] The education program will rely on the World Wide Web to deliver user-friendly radiological health messages. CDRH will also train "State and Federal personnel who can deliver critical radiological health messages to users and the public." Research will focus on high priority radiological health activities, as determined by the Science Prioritization Oversight Committee. CDRH believes the success of its program requires "endorsement and active participation by [the Office of Regulatory Affairs] and the States."[301]

The criticisms the FDA faced in the 1970's have been resolved over the years. The RCHSA does not grant the FDA authority to require pre-market approval of radiation-emitting products, so while the early standards involved known dangerous products, the later standards arose as responses to problems. Since enactment of the RCHSA, Congress has enacted several other consumer safety statutes that provide more extensive authority to the FDA and other agencies. Consequently, dangerous products are generally prevented from entering the market. As an agency with expertise, the FDA has administered the act as well as any other agency could have. This is evidenced by the deference agencies such as the EPA and the FCC have granted to the FDA in the setting of standards. While some may disagree with the allocation of funds within the

[298] CDRH, *Adapting*, *supra* note 74, at 5.
[299] *Id.* at 7.
[300] Extensive recordkeeping was considered necessary in the early years of the act in the event of a recall, but the general safety of products today reduces the need to maintain this expensive practice.
[301] CDRH, *Adapting*, *supra* note 74, at 8 – 10.

FDA, the fact remains that electronic products are now safe, scientists understand the biological harms of all types of radiation, and consumers understand the general hazards of excess radiation.

All major devices that emit radiation are now regulated by the federal government, either through the RCHSA or another federal act. When accidents happen, people become concerned that federal regulation is insufficient to protect the public.[302] However, the radiation standards were set so far below the known dangerous levels that variation from the standards may not actually endanger human health. Additionally, the FDA has established a system that strongly encourages manufacturers to comply with the regulations and to cooperate with the FDA in remedying violations. Though the FDA rarely resorts to adverse proceedings, it retains that authority. The Senate certainly wanted a stronger bill in 1968, but the FDA's achievements under the compromised bill have sufficiently addressed Congress' concerns as it debated the bill. The budget cuts may force the FDA to allocate its resources to what it considers more pressing matters, but that certainly does not mean the RCHSA will cease to be important. While some companies will cut corners, it would be illogical to think that these companies would completely abandon their obligations to the consuming public and begin producing dangerous products. A more reasonable concern is that technology allows for the rapid development of increasingly complicated and potentially hazardous electronic products, and the FDA may not be financially equipped to conduct research and establish new standards. Hopefully, the FDA will discover the most appropriate manner in which to exploit the mass communications market to convey its knowledge, policies, and concerns to manufacturers and to the general public.

[302] *See* Bennett & Dormer, *supra* note 4, at 310 (noting Senator John Glenn's concerns following a case in which a radioactive tip broke off a radiation therapy device and resulted in the death of the patient due to extreme radiation exposure).