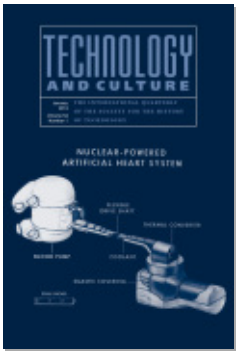
Negotiating Risk: The Failed Development of Atomic Hearts in America, 1967-1977



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Negotiating Risk

The Failed Development of Atomic Hearts in America, 1967–1977

SHELLEY McKELLAR

> *"If there's a chance, any chance at all, that problems caused by technology could outweigh the benefits, we should stop. Trouble is, I hardly know any scientists who will dare say, 'Stop.'"*
>
> **— Dr. William Bradfield, in *Heart Beat*, p. 319**

Heart Beat is a medical disaster novel, published in 1978, that foretells the perils of an atomic artificial heart. It is a story of Dr. William Bradfield's daring efforts to save the life of a dying patient through the implantation of a mechanical heart powered by plutonium. His patient, Henry Gray, survives the experimental procedure, makes an impressive recovery, and is discharged from the hospital to resume life with his fiancée. Both Bradfield and Gray enjoy their newfound celebrity status as guest speakers describing their experience with the radioisotope-powered artificial heart, and Bradfield goes on to implant more hearts with similar success. But then Gray is kidnapped by a madman who intends to remove and spray the hundred grams of plutonium that power the former's heart into the air, exposing thousands of people to dangerous levels of radiation. The FBI and local police begin a manhunt, while the National Heart Institute, government officials, and emergency-services personnel discuss contingency plans in the event that plutonium contaminates the area. A life-saving technology for one has now become a threat to society at large.

It is this issue of technology and risk rather than an endorsement of heroic therapies, skilled surgeons, or triumphs of medical science that the authors direct readers to reflect upon. Written by cardiovascular surgeon

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Eugene Dong and information officer Spyros Andreopoulos of the Stanford Medical Center, the book is an unlikely tale, yet it raises an intriguing question: Should technologies that pose society-wide risks be developed to save individual lives?[1] *Heart Beat* is fiction, but the technology it depicts is not. Between 1967 and 1977 medical researchers and engineers in two separate federally funded U.S. programs tackled the technological complexity of designing a radioisotope-powered mechanical heart, one in which the heat generated by radioactive decay, rather than fission, was the primary power source. When Dong and Andreopoulos speculated "what if" in *Heart Beat*, they reflected public anxiety about the risks associated with atomic power. In asking whether risky technologies could or should be developed in order to save lives, they invoked the classic conundrum of how to balance individual and collective good in a liberal society.

In a century replete with celebrated advances in science and technology, the 1970s emerged as a decade in which many individuals, as well as environmental groups, the consumer movement, and others speculated on the risks and unintended consequences for society that had resulted. Sociologist Dorothy Nelkin argues that the public's understanding of these risks came most often from journalists who had to "cope with complex and uncertain technical information and sort out conflicting scientific interpretations." Risk reporting was often sensational, confusing, and at times misinformed; it reflected the competing interests and disputed meanings that surrounded controversial technologies. According to Nelkin, many journalists tended to grant authority to scientists over others in their reporting of evidence and definitive solutions.[2] This led to science and technology news as predominantly good news, according to journalist Daniel Greenberg. In medicine, optimistic reporting of advances in disease understanding, cures, and devices tended to outnumber the stories that highlighted public dangers. Greenberg criticized the lack of scrutiny and minimal accountability that surrounded many federally sponsored, large-scale science and technology projects during this period, including the Apollo program and the Superconducting Super Collider project.[3] Yet the government maintained steadfast confidence in science and technology, bolstered by reports from the scientific community and its assertions of future benefits for Americans.[4] One such federally funded project was the development of atomic-powered artificial hearts.

1. Eugene Dong and Spyros Andreopoulos, *Heart Beat*.
2. Dorothy Nelkin, *Selling Science*, 54.
3. Daniel S. Greenberg, *Science, Money, and Politics*.
4. The "bolstering" of atomic hearts by project researchers can be seen in the University of Utah's Willem J. Kolff Collection, MS 654 (hereafter Kolff Collection 654), box 300, folder 10, "NHLI" press release (2 March 1972); and box 173, folder 11, "Biomedical Engineering Support final report" (15 June 1979). See also letter, E. W. Fowler to G. T. Seaborg, 4 December 1968, in U.S. Department of Energy, Atomic Energy Commission Secretariat Records, Office of History and Heritage Resources, RG 326 (hereafter USDOE-AEC 326), "AEC Commissioner G. T. Seaborg Office Files," box 206, file 6.

Most scholarship on the development of artificial hearts—including the work of sociologists Renee Fox and Judith Swazey, historians Barton Bernstein and Barron H. Lerner, and bioethicists George Annas, Arthur Caplan, and Albert Jonsen—passes over the development of atomic hearts and focus mostly on the sensational artificial-heart implant cases of the 1980s, highlighting issues of human experimentation, patient celebrity, excessive socioeconomic costs, and misplaced confidence in technology.[5] Yet comparable debates occurred years earlier with the development of atomic hearts. For example, scholars studying the 1980s cases describe the remarkable technological optimism and research zeal that supported the development of artificial hearts.[6] Earlier atomic hearts may also be characterized as such, with nuclear power fitting into Howard Segal's description of technological utopianism as a possible solution to many problems.[7] In both decades, queries from inside and outside the scientific community checked that zeal.

This case study explores the overlooked atomic heart that emerged from the ambitious U.S. Artificial Heart Program of 1964, highlighting the technological optimism of scientists and engineers, the intersection of science and government, and the broader context of public debates about risk and uncertainty going on at this time.[8] Medical researchers and engineers claimed that atomic hearts were feasible and practical and the technological complexities surmountable. But political and social apprehension challenged these medical assertions. During the late 1940s and the 1950s research into "atomic medicine" expanded, most notably the development of radio-isotopes as a replacement therapy for radium.[9] Yet by the late 1950s

5. The 1982 implantation of the Jarvik-7 artificial heart in Barney Clark, who lived 112 days with the device, was the most publicized and debated case of the decade. See Renee C. Fox and Judith P. Swazey, *Spare Parts*; Barton J. Bernstein, "The Misguided Quest for the Artificial Heart" and "The Pursuit of the Artificial Heart"; Barron H. Lerner, *When Illness Goes Public*, 180–200; George J. Annas, "No Cheers for Temporary Artificial Hearts"; Arthur L. Caplan, "To Mend the Heart"; and Albert R. Jonsen, "The Artificial Heart's Threat to Others."

6. Bernstein, "The Misguided Quest for the Artificial Heart" and "The Pursuit of the Artificial Heart"; Fox and Swazey, *Spare Parts*, 153, 193.

7. Howard P. Segal, *Technological Utopianism in American Culture*; see also Patrick Kupper, "From Prophecies of the Future to Incarnations of the Past."

8. On the expanding role of the government in scientific research and development programs, see Alfred K. Mann, *For Better or for Worse*; see also Robert Pool, *Beyond Engineering*.

9. In his famous "Atoms for Peace" speech on 8 December 1953 at the UN, President Eisenhower promoted a policy of peaceful nuclear-energy applications in health, industry, and agriculture; projects ranged from atom-smashing to space travel to desalination and irrigation projects. By 1951 cobalt-60 emerged as the first radioisotope to replace radium in cancer therapy. For general peacetime use of the atom, including health initiatives, see Richard G. Hewlett, *Atoms for Peace and War, 1953–61*; John Krige, "Atoms for Peace"; Martin Mann, *Peacetime Uses of Atomic Energy*, esp. chap. 9, "Atoms for Health," which includes the nuclear pacemaker and heart pump. For more detailed accounts of the use of radioisotopes, see Angela N. H. Creager, "Nuclear Energy in the Service of Biomedicine"; Soraya Boudia, "Radioisotopes 'Economies of Promises'"; Néstor

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and the 1960s medical scientists reluctantly began to acknowledge the limits of radioisotopes.[10] As Soraya Boudia argues, a combination of scientific and social discourse articulated the hazards of radiation and public anxieties surrounding the use of radioisotopes.[11] Such public concern regarding medical technologies and risk was not unwarranted. Litigation and publicity raised awareness of defective pacemakers, IUDs, and other medical devices in the late 1960s and the 1970s. The Medical Device Amendments passed in 1976 reflected political and public support for an increased federal role in protecting consumers against faulty devices, without negating the benefits of innovative medical technologies. The failed development of atomic hearts during this period was due to political and social concerns regarding the uncertainty and risk of radioisotopes in medicine within the broader context of faulty medical devices. Ultimately, such concerns trumped the scientific community's assertion of the atomic heart's safety and efficacy.

Developing Atomic Hearts: The Emergence of Competing Programs

In 1964, after much lobbying by cardiovascular surgeon-researcher Michael DeBakey, the U.S. Congress established the U.S. Artificial Heart Program (AHP) at the National Heart Institute (NHI), part of the National Institutes of Health (NIH) in Bethesda, Maryland.[12] Shortly thereafter NIH director James Shannon convinced surgeon Frank Hastings, who several years earlier had developed a crude mechanical-heart device, to join the institute to administer the new program.[13] The AHP was the NHI's first tar-

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tor Herran, "Isotope Networks"; Angela N. H. Creager, "Radioisotopes as Political Instruments, 1946–1953"; and Alison Kraft, "Between Medicine and Industry."

10. Technological uncertainty among scientists and engineers contributing to controversy and breakdown is also explored by Thomas R. Wellock, "Engineering Uncertainty and Bureaucratic Crisis at the Atomic Energy Commission, 1964–1973."

11. In the early 1960s the assessment of the medical application of radioisotopes was that "the great hopes that had become quickly widespread in the public on the therapeutic use of radioisotopes for cancer have been partly disappointed"; see Boudia, "Radioisotopes 'Economies of Promises,'" 255. See also Paul S. Boyer, *By the Bomb's Early Light*; Carolyn Kopp, "The Origins of the American Scientific Debate Over Fallout Hazards"; Joop van der Plight, *Nuclear Energy and the Public*; Catherine Caufield, *Multiple Exposures*; and J. S. Walker, *Permissible Dose*.

12. The National Heart Institute (NHI), created fourteen years earlier during the Truman administration, supported research and training into the causes, prevention, diagnosis, and treatment of diseases of the heart and circulatory system. Within the NHI the newly created Artificial Heart Program constituted a federally sponsored, large-scale research and development program and contributed substantially to the advancement of mechanical circulatory-support systems as it attracted researchers in both academia and industry to pursue this goal. For more on the history of the National Institutes of Health, see Victoria Harden, *Inventing the N.I.H.*; and National Institutes of Health, "Office of History."

13. Frank Hastings, William Potter, and John Holter developed a mechanical heart

geted, extramural (contract) development program, created to lure both academic and industry investigators to pursue development of mechanical circulatory-support systems. The NHI supported various lines of research related to design, materials, construction, blood interface and biocompatibility issues, energy sources, and control and driving systems, among other challenges. It was industry rather than academic researchers who first proposed to explore radioisotopes as energy sources.

Thermo Electron Corporation of Boston proposed a radioisotopic power source for circulatory-support systems to both the NHI and the U.S. Atomic Energy Commission (AEC), hoping to tap into funding from both agencies.[14] The AEC, under Chairman Glenn Seaborg, was actively engaged in developing a series of isotopic power units, the most common of which, the radioisotope thermoelectric generator (RTG), produces electricity from the heat of radioactive decay, not fission. William Mott, chief of the AEC's Thermal Applications Branch, who would become the lead project coordinator for the AEC radioisotope-powered mechanical heart, explained: "we were always on the alert for new problems to match with our solutions."[15] Indeed, RTG was a solution looking for a problem, as industry sought applications beyond spacecraft and remote-navigation beacons. Both the NHI and AEC expressed interest in pursuing this research, although both rejected Thermo's bid, citing the proposal's lack of understanding of the complexity of artificial heart systems.[16]

Neither agency rejected the concept, however. The possibility of building an atomic heart appealed to the political aims of both agencies: the NHI sought to expand its fledgling AHP, building on the Johnson administration's interest in heart disease, while the AEC, typically involved with nuclear power, welcomed this project as contiguous to its work on radioisotope-powered space and medical applications and thus bolstering its role in development and regulation of all things nuclear.[17] Both agencies viewed

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device driven by a reciprocating fluid column at Miners Memorial Hospital in Harlan, Kentucky. It was a two-chambered diaphragm pump that was only implanted in a single dog, with unsuccessful results. See Hastings, Potter, and Holter, "A Progress Report on the Development of a Synthetic Intracorporeal Blood Pump."

14. The public information office of the AEC's Argonne National Laboratory in Illinois produced radio interviews with leading scientists titled "Let's Talk about the Atom" to inform the public about such projects. One such interview focused on the atomic heart. These interviews were made available to the author courtesy of the Department of Energy's Oak Ridge National Laboratory.

15. William E. Mott, "Nuclear Power for the Artificial Heart," lecture (17 October 1973), in Kolff Collection 654, box 168, folder 3.

16. Division of Isotopes Development, "Isotopic Engine for Circulatory Support Systems Report" (7 December 1966), in USDOE-AEC 326, "Secretariat Files, 1972–74," box 7740, file 5.

17. In 1964 President Johnson appointed Michael DeBakey as chair of the President's Commission on Heart Disease, Cancer, and Stroke. DeBakey had the ear of the president, and often there were photo ops of him showing President Johnson the newest

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the project as within its scope of activities: the NHI promoted heart-disease research and the development of cardiac devices, while the AEC supported the use of nuclear power (radioisotopes) and regulated its safety.

Over the next several years Seaborg and the NHI's director, Donald Fredrickson, worked collaboratively to explore the feasibility of a radioisotope-powered engine by sharing the cost of four separate conceptual-design studies. In 1967 they jointly funded Aerojet-General, Thermo-Electron Engineering, Westinghouse Electric, and McDonnell-Douglas to conduct parallel design studies of an isotopic engine that would power pumps to assist or replace functions of a diseased heart. Unlike RTG technology, which converted heat to electricity, the isotopic power source for the artificial heart heated a thermal engine that used the expanding action of a gas to drive a hydraulic blood pump. Both vapor-cycle and gas-cycle thermal engines had the potential for the efficiency, reliability, and compactness necessary for an artificial heart system. Other components of the engine included a heat exchanger using blood as the cooling medium, and a control system to regulate the power output of the engine. Each of the corporations involved proposed different engine designs. More importantly, each of the four studies stated that there was a sufficiently large population of potential recipients to justify a large-scale research effort; of the 700,000 deaths due to heart disease in 1963, approximately 12 percent of these would have been considered candidates for heart replacement. Each proposal declared the radioisotope-powered engine as the only possible energy solution for a completely implantable device. The ideal implantable device meant no external lines or connections from the patient to outside power sources and a ten-year reliability span. By comparison, conventional batteries required recharging multiple times each day from an external source and would need to be explanted from patients every two years. Of the difficult engineering problems with the atomic heart, most notably the weight and safety of a radioisotopic-powered engine for implantation in the human body, experts deemed these to be surmountable obstacles. Based on these favorable reports, the NHI and AEC described the prospect for developing a radioisotope engine for mechanical hearts as "good."[18]

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cardiac devices. DeBakey became a prominent medical spokesperson, with increasing political clout with the Johnson administration, and he lobbied continuously for increased funding for the development of the artificial heart. See U.S. Congress, House Committee on Appropriations, *Departments of Labor and Health, Education, and Welfare Appropriations for 1966*," 505. For more on the AEC, see Alice L. Buck, *A History of the Atomic Energy Commission*, 6; Richard G. Hewlett and Oscar Anderson, *The New World*; Hewlett and Francis Duncan, *Atomic Shield*; and Hewlett and Jack M. Holl, *Atoms for Peace and War*.

18. Isotope Powered Heart Prosthetic, AEC press release, "AEC Picks Four Firms for Design Studies of Radioisotope-Powered Heart Pump Engine" (12 May 1967), in National Archives and Records Administration, Joint Committee on Atomic Energy Records, RG 128 (hereafter NARA 128); Memorandum, Edward G. English to file, 13 March

However, the NHI and AEC collaboration ended before the next phase of the project was initiated. Despite instructions by the Joint Committee on Atomic Energy (JCAE)—a congressional committee that monitored atomic energy development, use, and control from 1946 to 1977—for the two agencies to negotiate an integrated, interagency plan for development of an atomic heart, both the NHI and AEC launched independent programs. The AEC's Isotope Development director, Eugene Fowler, detailed the NHI's lack of cooperation in a four-page report.[19] According to Fowler, the agencies could not agree on management jurisdiction or the approach for engine development, making a collaborative venture practically impossible. The NHI's new director, Theodore Cooper (who had succeeded Frederickson), proposed to develop the engine in two stages: first, a nonradioisotopic-powered device, followed by a radioisotopic engine. Since the first system would not be radioisotope-powered, Cooper asserted that the NHI was the appropriate agency to direct, as well as to fund, all heart engine development. In 1968 the NHI awarded contracts to five companies to develop different thermal engines, these firms reporting back only to the NHI AHP.[20] The NHI directed its contract recipients to produce a workable nonradioisotopic-powered device, which reflected the practical orientation of the AHP.

The AEC strongly disagreed with this approach, arguing that integrating radioisotope power into an engine designed to be powered otherwise would not be straightforward. Furthermore, NHI program priorities conflicted with the AEC's aim for this device: the NHI supported short-term heart assistance devices, while the AEC sought to develop an implantable, complete artificial heart to replace the diseased one on a long-term basis—a loftier, and more expensive, goal. Thus the AEC proposed a separate, parallel effort to develop a radioisotope engine for mechanical hearts.[21]

Being politically and scientifically motivated, neither the NHI nor AEC was willing to concede direction or management of atomic hearts. For the

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1968, in USDOE-AEC 326, "Secretariat Files, 1966–72," box 7740, file 5; Artificial Heart Assessment Panel, *The Totally Implantable Artificial Heart*, 38–39; Division of Isotopes Development, "Isotopic Engine for Circulatory Support Systems Report"; Letter, R. Hollingsworth to John T. Conway, 29 January 1968, in NARA 128.

19. Letter, Eugene Fowler to G. T. Seaborg, 11 September 1970, in NARA 128.

20. For example, the Thermo Electron Corporation worked on a tidal regenerator engine, the McDonnell-Douglas Corporation developed its proposed thermocompressor engine, and the Aerojet-General Corporation focused on its modified Stirling engine. Later contracts went to the Nuclear Materials and Equipment Corporation for its modified Rankine engine, as well as to Air Products for its high-pressure Stirling engine. See Lowell T. Harmison, "Totally Implantable Nuclear Heart Assist and Artificial Heart" (February 1972), in John Watson Papers, Acc. 2003-054 (hereafter Watson Papers), box 1, History of Medicine Division, National Library of Medicine, National Institutes of Health.

21. "Circulatory Support System Program Report" (12 September 1967) and Letter, E. E. Fowler to Chairman Seaborg, 21 November 1968, in USDOE-AEC 326, "AEC Commissioner G. T. Seaborg Office Files," box 206, file 6.

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NHI, the development of atomic hearts was one of various projects in its newly launched AHP, which represented its mandate of developing basic scientific knowledge about heart and cardiovascular disease, as well as transferring that knowledge to practical applications via pharmaceuticals, surgical techniques, and medical devices for the practicing physician. The AEC, on the other hand, welcomed various projects promoting the peaceful uses of nuclear energy, including, for example, the irradiation of sewage to reduce it to a sanitized solid for use as a building material, as well as atomic explosions to release trapped natural gas locked within rocks.[22] The prospect of developing an atomic heart constituted a much more dramatic peaceful use of nuclear energy. Early in his career, Seaborg had developed more than a hundred atomic isotopes, including the isolation of plutonium 238 as a fuel, hoping to find medical applications for these substances. Nuclear medicine, in its infancy during the 1960s, was an emerging medical specialty utilizing radioactive substances (ingested by the patient) to image the body to detect such problems as tumors, aneurysms, and irregular blood flow and to treat diseases like cancer.[23] Seaborg and others at the AEC were undoubtedly eager to contribute to this budding field of nuclear medicine by using their expertise on engine components and radioisotopes for atomic hearts, refusing to be squeezed out by the NHI.

The problem for the AEC in implementing its program was a lack of funds and the limited view of its role in this area of development.[24] In 1968 the U.S. Bureau of the Budget (renamed the Office of Management and Budget [OMB] in 1970) denied Seaborg's request for $1 million to continue work on a nuclear-power source for heart devices. The bureau, driven by Republican reappraisals of the value of federal research and development, deemed the NHI as the best agency to efficiently manage the development of an atomic heart and thus granted it jurisdiction over research on heart disease and related projects, reflecting the shift from the generous funding of 1960s science and technology positivism to tougher, new congressional oversight during the 1970s.[25] The AEC would maintain control over the

22. See "Various Atom Uses Explored by A.E.C."; Atomic Energy Commission annual reports for 1965 through 1970, in USDOE-AEC 326.

23. By the 1970s most organs of the body could be visualized using nuclear medicine procedures. Patients take radiopharmaceuticals (inhaled, injected, or taken orally), which emit gamma rays that are detected externally by special types of cameras. In 1971 the American Medical Association officially recognized nuclear medicine as a medical specialty. In 1972 the American Board of Nuclear Medicine was established. See the website for the Society for Nuclear Medicine, specifically its educational brochures on "What Is Nuclear Medicine?" available at http://interactive.snm.org/index.cfm?PageID=3106 (accessed 14 November 2011). See also Henry N. Wagner Jr., ed., *Principles of Nuclear Medicine*, 1–8.

24. Memorandum, Seymour Shwiller to file, 10 July 1970, in NARA 128.

25. I thank Matthew Eisler for this information. See Greenberg, *Science, Money, and Politics*, 172–76.

radioisotope fuel, while the NHI would manage the atomic heart project, although the bureau assumed that the NHI would seek the AEC's assistance and collaboration in the development of an isotopic engine. Because of the NHI's plans to develop a nonisotopic, intermediate-stage device, the agency refused to transfer funds to the AEC. Cooper hoped that the AEC would readily supply medical-grade radioisotopes for related NHI research on heat dissipation and radiation emissions (which the AEC in fact did), but otherwise the AEC would not be consulted until the intermediate-stage device successfully advanced to the stage of incorporating a radioisotope. Seaborg complained about the NHI's lack of cooperation, but Cooper asserted that the cooperation between the two agencies was adequate.[26]

A frustrated Seaborg made a case for the AEC's continuing involvement in this research before the JCAE. Citing the agency's previous experience in power sources and engines, as well as its broad authority for nuclear applications of all kinds, Seaborg argued for the appropriateness of the AEC's involvement in the atomic heart project. He also argued that the NHI was "going down a dead-end road," because it supported a hardware-oriented program with in vivo studies (animal implants) to provide physiological-effects data that could be fed back into the program to produce more hardware. In contrast, the AEC team proposed an analytical evaluation that would assess the practicality of a nuclear-powered artificial heart without having to "bend tin" or produce hardware.[27]

Seaborg argued to the JCAE that the idea of an isotopic engine was technically feasible: an isotopic heat source would generate heat, which would then increase the temperature of a gas or generate steam; gas heated to the proper temperature could operate a Stirling engine or steam could run a Rankine cycle; and finally, such engines could operate a blood pump for use in humans. But was it practical? Applications of these basic ideas differed by duty cycles, load profiles, or varying power demands. A radar set, an automobile, and the human body each possess different power demands, including intermittent calls for power. How flexible or controllable was nuclear energy for its use in a mechanical heart implanted in a human? According to AEC expert Mott, the key issue was whether a completely implantable, radioisotopic-powered artificial heart was practical: Could a device of the requisite weight, volume, shape, performance, isotope inventory, reliability, durability, and cost be developed within a reasonable time and at reasonable expense? Reflecting its practical concerns, the AEC proposed

26. Letter, Charles J. Zwick to Clinton P. Anderson, 22 March 1968, in USDOE-AEC 326, "Secretariat Files, 1972–74," box 7740, file 5; Letters, Jim Ramey to Ed Bauser, 17 September 1970, and Elliot L. Richardson to John O. Pastore, 27 March 1972, both in NARA 128.

27. "Circulatory Support System Program Report"; Letter, Clinton P. Anderson to Charles J. Zwick, 23 February 1968, in USDOE-AEC 326, "Secretariat Files, 1972–74," box 7740, file 5; Memorandum, Shwiller to file.

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conceptual designs modeling these challenges, culminating in one design for production as a working model for bench testing. There were no AEC plans for in vivo studies at this stage.[28]

In addition to the AEC's criticism of the NHI's premature animal implants, the former's project members challenged the latter's two-stage approach. The AEC team maintained that the radioisotope fuel and its containment and conversion system needed to be developed together with the device from the outset. Furthermore, it argued, only the AEC possessed the unique expertise and capability required. Countering this, Cooper and his NHI team contended that they should be responsible for total system development because of as yet poorly understood physiological factors affecting it. Consequently, AEC–NHI collaboration meetings always ended in impasse, and hence Seaborg pleaded with the JCAE to allow his team to lead its own development program.[29]

Initially, Cooper and his NHI team had no intention of altering their development program despite this AEC criticism and the decision by Seaborg for the AEC to pursue a different approach. In mid-1970 the NHI, now renamed the National Heart and Lung Institute (NHLI), softened its position.[30] After reviewing the AEC's critical assessment of its nuclear-powered AHP, the NHLI team conceded, granting the expediency of an independent AEC development program. Fowler, who was one of the leaders of the NHLI team, reported that the NHLI would no longer oppose an AEC program because "the proposed AEC work would neither duplicate NHLI's ongoing in vivo test program nor depend upon it." In fact, the NHLI later came to regard the AEC's work as complementary to its own. However, Fowler suggested that this new position represented less an "appreciation" of the proposed AEC work than an NHLI strategy to end a shaky collaboration. In early 1971 the OMB, per the recommendation of the JCAE, acknowledged the irreconcilable differences between the two agencies and released $800,000 to the AEC, as well as additional funds to the NHLI for its program.[31]

28. Letter, William E. Mott to Edward J. Bauser, 6 March 1972, in USDOE-AEC 326, "Secretariat Files, 1972–74," box 7844, file 7; Memorandum, Shwiller to file.

29. Letter, E. E. Fowler to Chairman Seaborg, 22 May 1970, in USDOE-AEC 326, AEC "Commissioner G. T. Seaborg Office Files," box 206, file 8.

30. In November 1969 the National Heart Institute was renamed the National Heart and Lung Institute to reflect its expanding functions.

31. Letter, E. E. Fowler to Chairman Seaborg, 2 July 1970, and Letter, Fowler to Seaborg, 11 September 1970 in USDOE-AEC 326, AEC "Commissioner G. T. Seaborg Office Files," box 206, file 8; Memorandum, Seymour Shwiller to file, 13 January 1971, in NARA 128.

The AEC Atomic Heart

After securing its funds the AEC awarded contracts to Westinghouse Electric and TRW to conduct parallel analytical studies for a radioisotope-powered thermal converter, a device that would convert thermal energy to mechanical energy. Upon evaluating many thermal energy-conversion alternatives, each firm submitted a design of an artificial heart system with their preferred thermal converter. Each company asserted that their system design, if developed, would lead to a practical and fully implantable ten-year device to replace the human heart. Only intending to fund the development of one artificial heart system, the AEC selected Westinghouse's Stirling mechanical converter because its approach had a better-understood and -developed technological basis. The Stirling mechanical converter was the most efficient in the size range desired, had greater potential reliability due to a reduced number of rubbing seals and bearings, and required the least nuclear-energy wattage. The AEC then awarded Westinghouse another contract to develop a complete radioisotope-powered artificial heart system.[32]

Over the next two years Westinghouse completed additional theoretical and experimental work and then coordinated the fabrication of a realistically sized bench model of the full system.[33] The envisioned prototype of the AEC–Westinghouse nuclear-powered artificial heart system consisted of two main subsystems: the thermal converter or power supply, and the blood-pump mechanism (fig. 1). The work of fabricating the AEC–Westinghouse artificial heart necessitated the expertise of both engineers and medical scientists. Westinghouse subcontracted the construction of the thermal converter to the engineering firm of Philips of North America, which was the leading expert in the Stirling engine.

The thermal converter produced by Philips was a gas-driven Stirling cycle engine, powered by sixty grams of plutonium-238, or Pu-238 (a thirty-three-watt nuclear-energy source), that was triply encapsulated in high-strength, high-temperature-bearing metal alloys (platinum-rhodium, tantalum, and Pt-20 Rh) for safety and durability[34] (fig. 2). After considering such radioisotopes as promethum-147 and thulium-171, Philips chose

32. The Westinghouse engine required twenty-six watts of nuclear energy, in comparison to the TRW engine that required forty watts to power its particular blood-pump model. See Watson Papers, box 17; and memorandum, Clarence Dennis to file, 8 August 1973, in Clarence Dennis Papers, History of Medicine Division, National Library of Medicine, National Institutes of Health (hereafter Dennis Papers).

33. "Atomic Energy Commission Annual Report for 1971," 153, in USDOE-AEC 326; letter, Seymour Shwiller to Edward J. Bauser, 6 December 1971, in NARA 128; Watson Papers, box 17; memorandum, Clarence Dennis to file, 13 September 1973, in Dennis Papers.

34. Mott, "Nuclear Power for the Artificial Heart"; L. Smith et al., "Development of the Implantation of a Total Nuclear-Powered Artificial Heart System."

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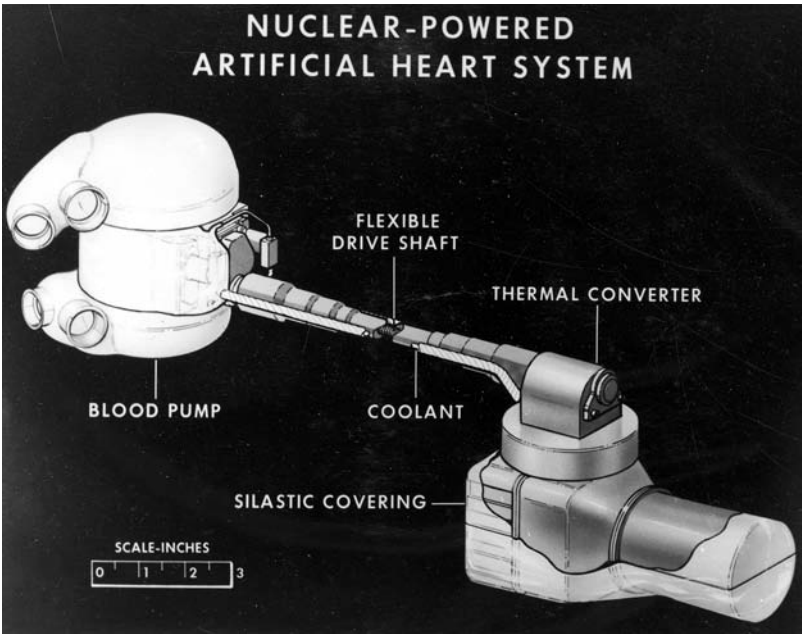

FIG. 1 AEC–Westinghouse atomic heart, developed by Westinghouse under contract from the AEC in the early 1970s. (Source: Willem J. Kolff Collection, box 5, book 5, folder 4, P0343, in Special Collections, Marriott Library, University of Utah, Salt Lake City. Reprinted with permission.)

Pu-238 due to its low radiation-emission rate with high power density, long half-life of 87.7 years, and availability. Recognizing the toxicity of Pu-238, Philips's engineers designed durable encapsulation and containment of the radioisotope, and provided sufficient thermal insulation for the converter to reduce heat dissipation (and hence tissue damage) in the body.[35] To assemble the blood-pump mechanism, Westinghouse worked with the artificial heart team of Willem Kolff at the Institute for Biomedical Engineering at the University of Utah.[36] Westinghouse's Astronuclear Laboratory built the mechanical portions of the pump, while Kolff's research team focused

35. Pu-238 is primarily an emitter of alpha particles, which have high energy but very low penetrating power and can be stopped by a thin piece of paper or even skin. Pu-238 also emits penetrating gamma and neutron radiation, but engineers argued that this radiation could be readily shielded from recipients by good capsule and engine design. The heat from the isotope capsule was to be stored and released as required (although no specifications offered how in relation to the human duty cycle) to power the thermal engine.

36. Due to his artificial heart experience, early device success, and bioengineering approach, Kolff was the ideal medical researcher with whom Westinghouse could contract for its nuclear-powered artificial heart project. For more on Kolff's career, see Shelley McKellar, "Limitations Exposed."

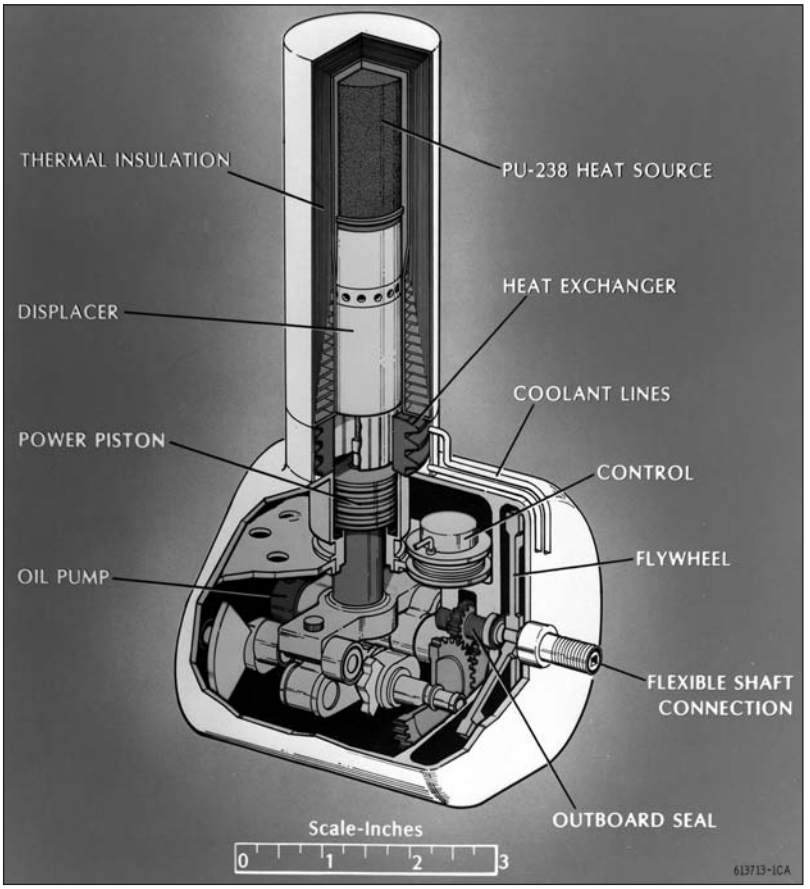

FIG. 2 Cutaway diagram of the AEC–Westinghouse atomic heart's thermal converter, fabricated by the engineering firm Philips of North America under subcontract to Westinghouse. (Source: Willem J. Kolff Collection, box 5, folder 21, P0343, in Special Collections, Marriott Library, University of Utah, Salt Lake City. Reprinted with permission.)

on its blood-handling portions, and they collaborated on the interconnecting flexible draft shaft that transmitted rotational mechanical power from the thermal converter to the pump. Their blood pump consisted of two ventricles, which received and flushed out the body's blood by the compression of a roll-sock diaphragm on pusher plates attached to a Scotch-yoke mechanism. The blood pump's drive mechanism took the rotating drive-shaft output of 1,800 rpm from the Stirling mechanical converter, and through reduction gearing and the Scotch-yoke mechanism actuated the pump diaphragms at 120 beats per minute. Blood came in

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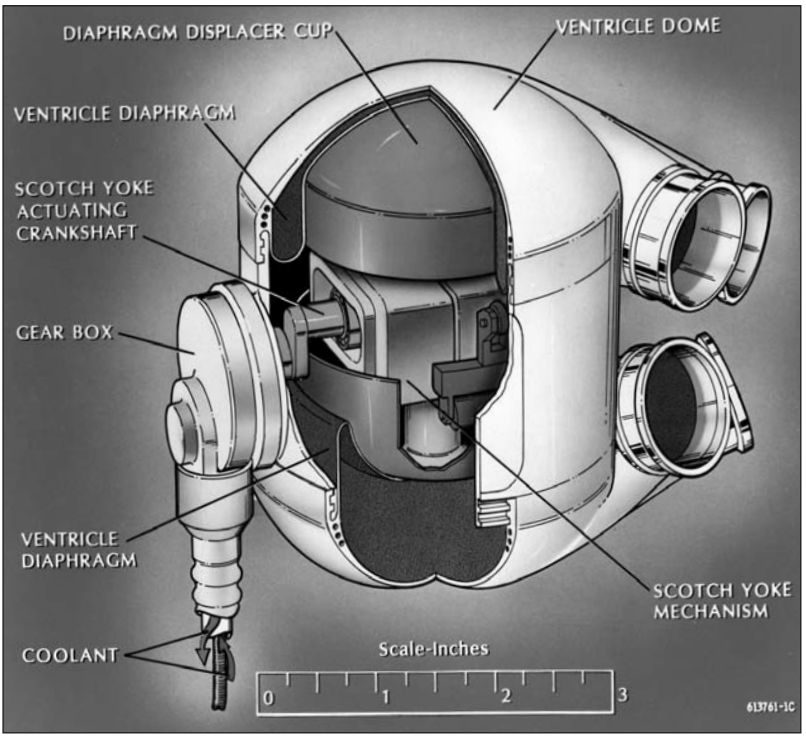

FIG. 3 Cutaway diagram of the AEC–Westinghouse atomic heart's blood pump, fabricated at Westinghouse's Astronuclear Laboratory in collaboration with Willem J. Kolff's artificial heart research team at the University of Utah. (Source: Willem J. Kolff Collection, box 5, folder 21, P0343, in Special Collections, Marriott Library, University of Utah, Salt Lake City. Reprinted with permission.)

contact with the silastic rubber ventricles, which, coated in Dacron fibrils, reduced blood clotting[37] (fig. 3). This mechanical blood pump would be fitted orthotopically in the chest (after removal of the diseased biological heart) and connected via the flexible draft shaft to the thermal converter implanted in the abdomen.

During this period Philips's engineers, Westinghouse's Astronuclear Laboratory researchers, and Kolff's scientific team managed a coordinated and cooperative effort, capitalizing on their respective expertise and producing encouraging results. For example, medical researchers at the University of Utah supplied Philips with suggested practicability criteria, such as power and control requirements for a blood pump and surgical-implan-

37. Mott, "Nuclear Power for the Artificial Heart"; Smith et al., "Development of the Implantation of a Total Nuclear-Powered Artificial Heart System."

tation factors that facilitated successful component integration for the device.[38] But in 1972 the AEC–Westinghouse artificial heart was far from ideal because both the Philips converter and Kolff's blood pump needed reduction in size and weight and improvement in efficiency and reliability, as well as greater system responsiveness to the needs of the body (called the load profile). Nevertheless, Westinghouse officials were encouraged and they committed the next several years to improved fabrication and testing of the entire system, with eventual animal implants scheduled for 1974.[39] Their optimism and confidence in the atomic heart, however, was exceeded by that of NHLI officials, who beat their rivals to the punch. The first animal implantation of a nuclear-powered artificial heart system did not happen with the AEC–Westinghouse device, but instead with an assist device developed by the NHLI program.

The NHLI Atomic Heart

In February 1972 cardiac surgeon John Norman, of Harvard Medical School's Surgical Laboratories and Boston City Hospital, implanted into a calf an NHLI-sponsored heart assist system powered by Pu-238, which operated successfully for eight hours until a kinked inflow tube terminated the experiment (figs. 4 and 5). The ventricular assist pump attaches to the natural heart to assist in the pumping of blood into the body's circulatory system. Norman was the first to test an atomic heart (albeit an assist pump) in an animal. NHLI director Cooper issued a press release to announce the achievement, and the story was front-page news nationwide, including images of the nuclear-powered assist device and photos of the implanted calf.[40]

There were key similarities and differences between the AEC-sponsored and the NHLI-sponsored nuclear-powered hearts at this time. Like the AEC–Westinghouse device, the NHLI's assist system consisted of two main parts: the thermal converter or nuclear engine, and the blood-pump mech-

38. Westinghouse also subcontracted specific tasks outside of Philips and the University of Utah. One of these included Yuki Nosé's team at the Cleveland Clinic that studied the surgical fit of the proposed device in order to provide dimension limits to both Philips and Kolff. The most significant outsourcing of production surrounded radioisotope Pu-238. This required the cooperation of the Savannah River Laboratory (where Pu-238 was produced), the Los Alamos National Laboratory (where the powder from Savannah was purified and formed into a solid cylinder), the Mound Laboratory (where the cylinder was encapsulated), and the TRW Systems Group (where the encapsulating materials were fabricated). See Mott, "Nuclear Power for the Artificial Heart."

39. "Annual Report (to AEC)—Biomedical Engineering Support" (15 July 1972), in Kolff Collection 654, box 164, folder 2; Mott, "Nuclear Power for the Artificial Heart."

40. D. A. Hughes et al., "Nuclear-Fueled Circulatory Support Systems XII," 741; John C. Norman et al., "An Implantable Nuclear-Fueled Circulatory Support System"; "NHLI" press release (2 March 1972), in Kolff Collection 654, box 300, folder 10. Some examples of this news coverage include: Robert Reinhold, "Nuclear Heart Pump"; Frank Carey, "Atomic Booster"; and "Atomic Engine Developed for Artificial Heart."

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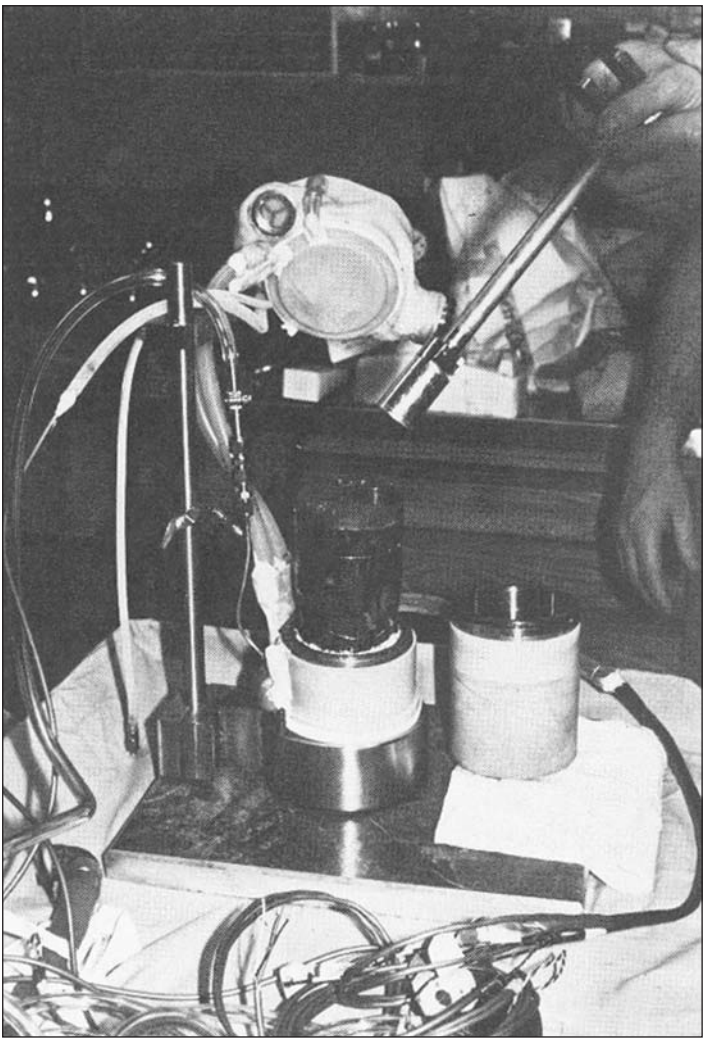

FIG. 4 The NHLI atomic heart. This nuclear-powered heart assist system consisted of two main parts: (1) the blood pump or Model VIII assist pump (top), which is attached via hydraulic drive lines to (2) the thermal converter or nuclear engine (bottom). This photo shows the system being held in an assembly stand during the insertion of the plutonium-238 fuel capsule (center) into the engine prior to implantation. (Source: John C. Norman et al., "An Implantable Nuclear-Fueled Circulatory Support System," *Annals of Surgery* 176, no. 4 [October 1972]: 497. Reprinted with permission.)

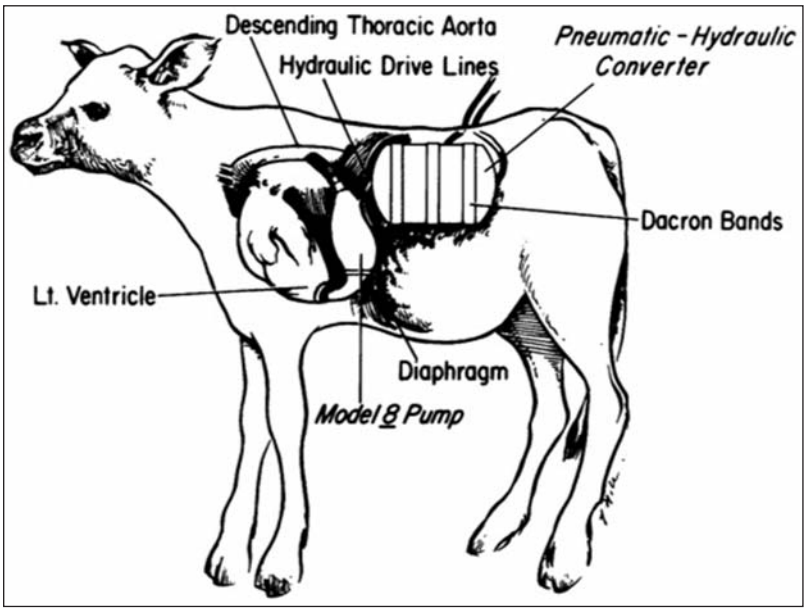

FIG. 5 The NHLI atomic heart functioning in a calf. The device consists of a converter (fueled by plutonium-238) attached via hydraulic drive lines to the Model VIII heart assist pump, which in turn connects to the natural heart. (Source: John C. Norman et al., "An Implantable Nuclear-Fueled Circulatory Support System," *Annals of Surgery* 176, no. 4 [October 1972]: 500. Reprinted with permission.)

anism. But there were significant design differences with these two systems. Most obviously, the NHLI system used an assist device—the Model VIII Left Ventricular Assist Pump—and not a complete replacement device for the heart. The Model VIII pump connected to the left ventricular apex of the heart and to the descending thoracic aorta, thereby assisting the left side of the heart to pump oxygenated blood into the greater heart vessels for circulation throughout the body. Like the AEC–Westinghouse pump, Model VIII was made of silastic and the blood moved through the bladder by action of a pusher plate. Also like the AEC–Westinghouse pump, the blood surface areas of Model VIII contained Dacron fibrils to produce a smooth lining and prevent blood-clot formation. The pump bladder was clamped in stainless-steel housing, and this pump unit was hydraulically driven from the attached six-pound cylinder (situated in the abdomen) that contained a miniature thermal engine with a nuclear heat source.[41]

41. Norman et al., "An Implantable Nuclear-Fueled Circulatory Support System"; see also "Medical Devices Applications Report" (1972), in Watson Papers, box 13.

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The thermal converter of the NHLI's heart assist system was developed by the Thermo Electron Corporation, an NHLI contractee, and it differed from Philips's thermal converter in its mechanics and need for double the amount of plutonium. The Thermo converter was a tidal-regenerator engine, or a regenerative gas-cycle engine, that combined the advantages of the Rankine engine with those of the Stirling engine. It was a thermodynamic machine in which heat was converted to work by means of a cyclic process whereby the working fluid was vaporized and condensed. The familiar steam engine is an example of a vapor-cycle engine. (Interestingly, in his comparison of the AEC and NHLI devices, Mott reminded his team that they had evaluated and eliminated both the thermocompressor and tidal-regenerator engines in favor of the Stirling mechanical converter during their Phase I Thermal Converter Practicability Study.) In contrast, NHLI supporters of the tidal-regenerator engine argued that the few moving parts of this system—it had no valves or sliding seals—constituted an advantage in comparison with other nuclear engines under development. Like the AEC–Westinghouse device, the Thermo engine employed a Pu-238 fuel capsule, triply encapsulated; however, it required 120 grams of Pu-238 to generate fifty-two watts of energy of converted hydraulic power to drive the pump, which was twice the amount of plutonium required as the AEC–Westinghouse device.[42]

The NHLI embraced the timing of Norman's reported success to release a status report on its nuclear-powered heart program. AHP acting chief Lowell Harmison (who succeeded Frank Hastings after his sudden death in 1971) wrote a sixty-three-page report outlining the "substantial progress" in both nuclear-engine development and blood-pump systems as a result of five years of NHLI-funded research. Most likely, this report was designed to reassure senior management and public officials due to its simplified presentation of contributions, pronouncement of successes, and confident tone of overcoming the remaining challenges. Written for lay rather than scientific consumption, the report was dismissed by many in the field as a political document. Moreover, for many scientists and engineers, it also smacked of conflict-of-interest issues concerning its author, who, as an NHLI researcher (who had only recently moved into administration) was very much involved in the development of the H-TAH (Harmison-TECO Assist Heart) and Model VIII Left Ventricular Assist Pump that was currently being used (and promoted) in the NHLI atomic heart system.[43]

42. Norman et al., "An Implantable Nuclear-Fueled Circulatory Support System," 494 and 499; William E. Mott, "Comparison of NHLI and AEC Nuclear-Powered Artificial Heart Systems" (29 March 1972), in Kolff Collection 654, box 332, folder 8; "Medical Devices Applications Report."

43. Harmison, "Totally Implantable Nuclear Heart Assist and Artificial Heart"; T. C. Robinson, S. S. Kitrilakis, and L. T. Harmison, "The Development of an Implanted Left Ventricular Assist Device and Rankine Cycle Power Systems"; Norman et al., "An Implantable Nuclear-Fueled Circulatory Support System."

Many of the scientific and technological gains declared in the report as NHLI "successes" were hardly unique to NHLI's nuclear-powered heart program. First, blood-pump development had certainly improved by 1972, with advancements in device mechanisms and biomaterials reached by many in the field. The NHLI report attributed its "flocked" interface of Dacron fibers bonded to blood-contacting surfaces of these pumps as an important contribution to controlling the problem of blood clotting, and the reduction of blood damage (hemolysis) when using its positive-displacement pumps. The AEC–Westinghouse device also incorporated positive displacement and similar blood-interface design and materials. Second, research on the effects of radioisotope heat and radiation in dogs and primates supported scientific claims that the body could tolerate prolonged exposure with minimal effects. Again, AEC-funded research at Cornell University presented similar results. Last, the NHLI reported on its various nuclear-engine systems. Whereas the AEC program concentrated on one design—a standard pattern of a Stirling engine with a Scotch yoke–type of crankshaft, a flywheel, and a mechanical delivery of power from the engine to the actuator of the pump—the NHLI program supported multiple engine designs: a tidal-regenerator engine, a modified Rankine engine, a thermocompressor engine, a modified Stirling engine, and a high pressure Stirling engine. But rather than offering a comparative analysis of these different engines, the report simply described the independent work completed to date by each contractee. All engines were "technically feasible," but their size, weight, and coupling to the blood-pump systems needed refinement before achieving a functional circulatory-support system. Nevertheless, the overall message of the NHLI report was clear: five years of NHLI-sponsored research had culminated in the "successful" development of a nuclear-powered artificial heart system.[44]

The AEC's artificial heart researchers and other critics of the NHLI program challenged the announced success of the NHLI-sponsored nuclear-powered heart assist system, noting that the results were overstated. An NHLI atomic heart was not nearing clinical use, nor was any other such device. One anonymous critic (possibly Mott) denounced the NHLI statement as "full of deceit" and delivered for the purpose of obtaining funding from Congress. AEC researchers like Fowler feared that it might threaten their own congressional support; they warned Congress not to be misled, because the NHLI engine technology showed no major advancement since last reviewed in June 1970. According to Mott, the NHLI report was "the greatest piece of technology charlatanism that has come down the pike in a long time." He pointed the finger at Lowell Harmison, who "operated un-

44. Clarence Dennis, "The Program on the Development of an Artificial Heart: An Evaluation" (29 November 1974), in Dennis Papers, box 6, folder 18, "The Program on the Development of an Artificial Heart, 1974 Nov."; Harmison, "Totally Implantable Nuclear Heart Assist and Artificial Heart."

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checked, without knowledgeable peers and superiors." Indeed, Harmison had exaggerated the research innovation and performance of the NHLI's nuclear-powered artificial hearts. In response to all this criticism, the NHLI released another statement conceding the "technical bugs" in its system, admitting to the problems of engine overheating and the clotting reaction of blood in the pump. After only four animal implants in early 1972 Norman stopped his testing until mechanical modifications improved device efficiency and reduced heat losses in the surrounding tissue. In 1973 and 1974, Norman implanted another eleven calves, but according to him, while "significant progress has been made, many problems remain to be solved."[45] Obvious technical problems aside, media reports and lawsuits against faulty medical devices currently in commercial use also contributed to researchers' reluctance in announcing premature statements on artificial heart devices' readiness for patient use.

Defective Devices and New Medical-Device Legislation

Faulty medical devices contributed to more than 700 deaths and 10,000 injuries during the 1960s in the United States, according to the Study Group on Medical Devices, chaired by NHLI director Cooper (it was also known as the Cooper Committee).[46] Consumer advocates reported on anesthesia machines bursting into flames, cardiac pacemaker malfunctions, and ineffective emergency respirators as only "the tip of the iceberg" of defective medical equipment "needlessly killing" Americans. The Cooper Committee consulted extensively with doctors, manufacturers, engineers, trade associations, and consumer groups, reporting alarming cases of contaminated intraocular lenses that had caused patients' vision loss, unsafe intrauterine contraceptive devices that caused infection, sterility, or death for thousands of women, as well as hearing aids that had resulted in further hearing damage. Heart-valve failures caused hundreds of deaths and radiation equipment resulted in thousands of injuries, as did a variety of prosthetic and orthopedic devices, dental equipment, sutures, syringes, and

45. "Artificial Hearts" news release (6 October 1972), in Kolff Collection 654, box 300, folder 10; Letter, M. T. Johnson to E. E. Fowler, 5 April 1972, in USDOE-AEC 326, "Secretariat Files, 1966–72," box 7844, file 7; William E. Mott, "Comments on NHLI Announcements of March 2, 1972" (15 March 1972), in Dennis Papers, box 7, folder 23; Hughes et al., "Nuclear-Fueled Circulatory Support Systems XII," 742.

46. President Richard Nixon mandated the Department of Health, Education, and Welfare to study the standards and pre-clearance aspects of medical-device regulation based on hospital surveys reporting that up to 40 percent of their equipment proved defective when checked. Other accounts of therapeutic misadventures associated with medical devices were also brought to the president's attention. The numbers of 700 deaths and 10,000 injuries due to faulty medical equipment are cited in U.S. Congress, House Committee on Interstate and Foreign Commerce, Subcommittee on Health and the Environment, *Medical Device Amendments of 1975*, 199.

heating pads and blankets. "Medical device problems too often are related to faults in the design and manufacture," the committee's report asserted. It stated its "distress by the lack of data in many areas related to the interaction of medical devices with the human body, and by the seeming unquestioning acceptance of claims for medical device safety and performance unsubstantiated or inadequately supported by scientific fact."[47] The report also acknowledged that some of the problems were caused by improper use, but this factor was downplayed. The Cooper Committee concluded that the medical-device hazards problem related mainly to problems of design and manufacture, areas that legislation could ameliorate.[48]

In 1970 the committee submitted seventeen recommendations to Congress intended to shape new medical-device legislation. The most significant recommendations addressed the process of pre-market evaluation, provided an inventory and classification of current medical devices, and created device standards. Most importantly, the committee recommended that medical devices needed a different regulatory approach than drugs and, given the breadth and diversity of such devices, that regulation should be carefully tailored to the type of device involved.[49] It proposed that medical devices be classified according to their comparative risk and regulated accordingly, suggesting a three-tiered classification that the Food and Drug Administration (FDA) could use for medical devices: Class III devices of high risk (such as artificial hearts) requiring expert review prior to mar-

47. Richard D. Lyons, "Faulty Devices Linked to Deaths"; "Parley Backs Medical Devices Law"; Theodore Cooper, "Device Legislation," 170; U.S. Department of Health, Education, and Welfare, *Medical Devices*.

48. The FDA possessed authority over medical devices well before the beginning of artificial heart research. Early federal acts had defined the term "drug" to include medical devices. Then the 1938 Food, Drug, and Cosmetic Act defined "devices" as distinct from drugs and enabled the FDA to police and remove fraudulent devices from the marketplace. Under the 1938 act the agency successfully used the courts to remove such fraudulent devices as the Relaxicisor (an electric machine to help make people slim), the Micro-Dynameter (a string galvanometer to detect stomach ulcers, epilepsy, cancer, tooth infection, diabetes, and insanity), and the Halox Therapeutic Generator (a generator that emitted chlorine gas for the respiratory treatment of arthritis, sinusitis, and other ailments). However, as noted by Margaret Harris, in "Legislation to Regulate Medical Devices," legal actions were costly and time-consuming. By the 1960s medical devices had grown to a $3–5 billion industry, about half the size of the pharmaceutical industry. Developments in electronic miniaturization, biomedical engineering, and plastics contributed to the increasing number of new and sophisticated medical devices, from surgical implants to intensive-care monitoring equipment. The enactment of the Kefauver-Harris Amendments in 1962, spurred by the thalidomide tragedy, strengthened the FDA's regulation of the drug industry. However, there were no provisions relating to medical devices. For more on this, see the Food and Drugs Act of 1906; Peter Barton Hutt, "A History of Government Regulation of Adulteration and Misbranding of Medical Devices"; and Harris, "Legislation to Regulate Medical Devices."

49. Hutt, "A History of Government Regulation of Adulteration and Misbranding of Medical Devices."

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keting; Class II devices of moderate risk (such as powered wheelchairs) for which standards could be established to protect public health and safety; and Class I devices of low risk (such as tongue depressors) requiring neither standards nor expert pre-market testing. At the time, no such inventory of medical devices in clinical use existed. The Cooper Committee also recommended that the government establish or encourage development of device standards and compliance testing for all new instruments or machines, with FDA authority to audit manufacturers to ensure compliance. It was hoped that new regulation would protect patients from faulty devices, while still fostering the continued development of new devices.

Less than one month after the submission of the report, U.S. Representative Paul Rogers (D-Fla.) introduced a bill that incorporated almost all of the committee's recommendations. While politicians wrangled over its language and contents, the FDA immediately began compiling an inventory of medical devices on the U.S. market. It cataloged a staggering 8,000 devices produced by about a thousand manufacturers and, with the help of appropriate experts, classified each device according to the proposed three-tiered system. The FDA's activity kept pressure on Congress not to bury the bill. More importantly, however, publicity from defective device mishaps underscored the need for increased regulation.[50]

Public outrage over deaths and injuries from defective heart valves, pacemakers, and intrauterine devices (IUDs) rallied support for the passage of medical-device legislation. Many patients reported heart-valve problems caused by poor surgical implantation and flawed device design.[51] At the same time, several manufacturers, including Medtronic, General Electric, Cordis, Biotronik, and Vitatron, initiated a series of pacemaker recalls based on a variety of causes, such as premature battery failure, moisture seepage into the pacemaker's case, and faulty leads that stopped transmitting electrical current to the heart. These problems resulted in some deaths, including among children.[52] Garnering even greater media coverage, thousands of women sought damages through the courts after experiencing excessive bleeding, uterine perforation, septic abortions,

50. Cooper, "Device Legislation," 171–72; David M. Link, "Cooper Committee Report and Its Effect on Current FDA Medical Device Activities," 626.

51. Although the FDA could offer no firm numbers, in numerous instances a break occurred in the supporting strut that held the valve in place. Typically, only patients suffering from severe heart disease received mechanical heart valves, so their underlying illness complicated the risk of death to which the defective valve may or may not have contributed. See U.S. Congress, *Medical Device Amendments of 1975*, 220; and Harold M. Schmeck Jr., "Law on Faulty Health Devices Urged."

52. U.S. Congress, House Committee on Government Operations, Intergovernmental Relations Subcommittee, *Regulation of Medical Devices (Intrauterine Contraceptive Devices)*, 188; and U.S. Congress, *Medical Device Amendments of 1975*, 220; Lawrence K. Altman, "Pacemaker Users Affected by Recall Are Notified"; David Burnham, "G.A.O. Assails FDA Over Pacemakers" and "Safety Lag Seen on Pacemakers."

and pelvic infection from faulty IUDs.[53] Battling thousands of lawsuits, the manufacturer of the Dalkon Shield IUD withdrew it from the market in 1974 and eventually went bankrupt.[54] Increased litigation fueled public pressure for the federal government to safeguard the health of Americans, but without denying them the benefits of new technologies.

In response to these court cases, Congress held hearings to discuss the need for increased federal regulation of medical devices. It was, as noted by health policy analyst Susan Foote, a period of strong consumer activism during which women's groups, the elderly, Ralph Nader's Health Research Group, and others pressured the government to protect consumers. They argued that the burden of proof to establish products as unsafe should not lie with the FDA, but rather with manufacturers to demonstrate their products' safety and effectiveness. These consumer activists suggested that increased regulation fostered a "preventive approach" to ensure the quality of products and reduce malpractice suits. But medical professionals and manufacturers warned that their own judgments would be eliminated in the bureaucratic process and their expertise hamstrung by inflexible procedures. They argued that increased regulation could stifle innovation and hamper development, delaying the entry of valuable devices into the marketplace, and pleaded with the government to refrain from safety "overkill" and bear in mind that the majority of imperfect heart valves and pacemakers had extended many lives. Surgeon Arthur Beall stressed the risk–benefit ratio of new devices: "although about 500 people have died from imperfections in artificial valves, over 200,000 are alive who would have died without the artificial valves." Researchers and manufacturers bristled at the intervention of the federal government and its concomitant burden of meeting new regulations. Both disliked the added pre-clinical scientific testing and burdensome recordkeeping being proposed for FDA approval, stating, for example, that self-regulation by manufacturers of pacemakers led to their voluntarily modifying their devices in order to accommodate the American Heart Association's recommendations for standardizing leads and instru-

53. During the early 1970s the IUD emerged as one of the most popular forms of birth control, with an estimated three million American women using this device. Dozens of IUD varieties flooded the market; one of the top sellers was the Dalkon Shield, which was claimed by its manufacturer A.H. Robins to be the most effective. IUDs were not new, but physicians regarded them as dangerous to women's health. Women's groups and Planned Parenthood clinics also warned IUD users of the associated health risks. However, with the introduction of the contraceptive pill and the availability of inert plastics that caused fewer tissue reactions, contraception researchers retooled the IUD for commercialization. See Susan Foote, *Managing the Medical Arms Race*, 117–18; Jane E. Brody, "Pressure Grows for U.S. Rules on Intrauterine Devices"; "Birth Curb Group Acts on IUD Risk"; and "FDA Links Rise in Deaths to Birth Device."

54. For more on the criticism of the Dalkon Shield and its manufacturer, see U.S. Congress, *Regulation of Medical Devices (Intrauterine Contraceptive Devices)*. See also Morton Mintz, *At Any Cost*; Susan Perry and Jim Dawson, *Nightmare*; and Nicole J. Grant, *The Selling of Contraception*.

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ment specifications.[55] Manufacturers also reminded Congress that unsafe use of their devices was part of the problem; professional training and user education needed to be part of the solution as well. At this time, however, the medical-device industry was an unorganized collection of large and small groups who could do little to stop the momentum toward increased federal regulation; their arguments against regulation were overshadowed by the publicity surrounding faulty devices and patient risk.[56]

President Gerald Ford enacted the Medical Device Amendments of 1976, which contained many of the recommendations in the Cooper Committee's report. The new legislation established a complicated regulatory scheme. Congress, siding with consumer groups, wanted to ensure the FDA's authority to regulate medical devices and therefore outlined the agency's responsibilities and actions therein. The intention was to strike a balance between protecting the public and promoting research and development of innovative lifesaving medical devices. Risk would be contained without delaying the benefits of new medical technology to Americans in need. Some medical researchers disagreed, contending that the regulations would discourage clinical investigation and ruin the innovative small manufacturer, who with limited resources would be unable to meet the FDA's new requirements. FDA personnel are "well meaning and intense young people," described one physician, but they "were inherently suspicious of private enterprise and somewhat crusading in their approach." Furthermore, the critics contended that the legislation would force many U.S. device manufacturers abroad for their initial clinical trials, where less rigid European oversight was more attractive both financially and administratively. They predicted that the new federal regulations would neither improve the scientific database nor noticeably decrease the risk of high-technology devices.[57]

Under this legislation, atomic hearts were classified as high-risk Class III devices, and new safety and efficacy standards for patient use would have to be met later while seeking the commercialization of the device. Yet it was the faulty-device reports and political discussions leading up to the passage of the regulations that were more significant for the future of atomic hearts,

55. Foote, *Managing the Medical Arms Race*, 120; U.S. Congress, *Regulation of Medical Devices (Intrauterine Contraceptive Devices)*, 214–15, cited in Harris, "Legislation to Regulate Medical Devices," 267–68; Kirk Jeffrey, *Machines in Our Hearts*, 194.

56. No overarching trade organization represented the industry as a whole until, in direct response to increased regulation, the creation of the Health Industry Manufacturers Association (HIMA) in 1976. As a national trade association representing manufacturers of medical devices, diagnostics, and health information systems, it represents the industry before Congress and regulatory agencies like the FDA on issues of interest to members. See Jeffrey, *Machines in Our Hearts*, 192–93; and Foote, *Managing the Medical Arms Race*, 120.

57. Harold M. Schmeck Jr., "FDA to Control Medical Devices"; Patricia E. Weil, "From Toothbrush to Pacemaker"; Foote, *Managing the Medical Arms Race*, 121; Richard E. Clark, "Medical Device Regulation," 298–99.

because they underscored both public and scientific concerns surrounding the exposure of patients and society to risky medical technologies. With the public becoming somewhat disenchanted with medical technology, questions of acceptable risk and unintended consequences captured its attention. Atomic heart supporters found themselves situated within a milieu of risk awareness or consciousness; that is, as scholars Anthony Giddens and Ulrich Beck argue, modern society seemed fixed upon managing or containing risk during this era.[58] Politicians, bioethicists, journalists, and others became more directly involved in shaping the development of atomic hearts.

Should Atomic Hearts Be Built?

Even if experts resolved the technological problems, were nuclear-powered artificial hearts desirable? Were the risks acceptable given the potential medical benefits? And who should make these judgments? Experts, government officials, and bioethicists alike began to ask these kinds of questions in the wake of controversies over medical-device safety.[59] Individuals working in both the NHLI and AEC programs anticipated this line of questioning. As Mott commented: "Without question a plutonium-238 powered heart, regardless of its technological assets, will stir many more emotions and evoke much stronger criticism than would a heart powered by any other means." By the early 1970s the critiques of large-scale government-funded science and technology projects by anti-nuclear and environmental groups made nuclear-energy projects increasingly difficult to justify. Political scientist Robert Duffy points out that by the 1970s discussions of nuclear power had shifted to the potentially harmful effects associated with its use due, in part, to "outsiders" or nonscientists emphasizing the political and social dimensions of the technology.[60] Likewise, in matters of clinical research, bioethicists raised political, economic, and social questions associated with medical

58. Anthony Giddens, *Runaway World*; Ulrich Beck, *Risk Society* and *World Risk Society*.

59. During this period the development and use of the radioisotope-powered pacemaker utilizing Pu-238 raised similar issues of safety and risk, and again medical and public opinions were divided. Cardiac surgeon Victor Parsonnet implanted the first U.S.-built Numec atomic pacemaker in a patient in New Jersey in 1973. Later in the decade the introduction of the lithium-powered pacemaker, which matched the longevity of the atomic pacemaker at less cost and risk, ended the use of atomic pacemakers. Significant technological differences between atomic pacemakers and atomic artificial heart systems make this a problematic analogy: the most obvious being that atomic artificial hearts take more than a hundred times the amount of plutonium in comparison to the atomic pacemaker. For more on atomic pacemakers, see Victor Parsonnet et al., "Thirty-One Years of Clinical Experience with 'Nuclear-Powered' Pacemakers," 195; and Jeffrey, *Machines in Our Hearts*, 115–17.

60. Mott, "Nuclear Power for the Artificial Heart"; Robert J. Duffy, *Nuclear Politics in America*, 49–80; Caufield, *Multiple Exposures*.

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innovation. David Rothman calls the emergence of bioethics at this time a "movement," or a shift to collective rather than individual decision making. Bioethicists aimed to ensure that researchers assessed risks and benefits to human subjects in ways that were not self-serving, and that physicians reached critical medical judgments that were not idiosyncratic.[61] In this environment of reform exotic new technologies like atomic hearts concerned bioethicists, consumer groups, politicians, and others.

The NHLI attempted to lead this debate by convening a mixed panel of medical and laypersons to examine the broader, ethical aspects of its Artificial Heart Program. The agency deemed this move prudent because of the approaching clinical use of mechanical hearts, the unresolved moral and legal implications of heart transplants that were evident from recent experiences, and the need to understand the consequences of technology, specifically nuclear power.[62] In July 1972 the NHLI's Artificial Heart Assessment Panel explored the social, ethical, legal, and economic implications of the development and use of artificial hearts in humans. Its discussions were not limited to the atomic heart, although this figured prominently in the panel's resulting report. The panel consisted of three physicians (a cardiologist, an internist, and a psychiatrist), two economists, two lawyers, one sociologist, one priest-ethicist, and one political scientist. No members were artificial heart specialists or engineers; in fact, most of the panel admitted to knowing very little about the medical and technical requirements of artificial hearts. This, however, did not deter the panel from asking about the medical need for such hearts and the present state of artificial heart technology. Panel members met with the NHLI's and AEC's Artificial Heart Program

61. Bioethics emerged in the 1960s as an interdisciplinary field of academic study in response to advancements in medical science (for example, the availability of new technologies such as in vitro fertilization) and cultural change (including challenges to authority and the rise of patient rights). Whereas traditional medical ethics guided doctors in their individual relationships with patients, bioethics sought to provide guidelines relating to broader socioeconomic issues and incorporate greater public involvement and control over medical care and treatment. Bioethicists study the thorny social, economic, ethical, and political factors associated with medical problems and therapies, such as organ transplantation, reproductive technologies, kidney dialysis, end-of-life care, and health-care justice, among other issues. Their goal is to guide patients, doctors, lawyers, hospitals, government agencies, policymakers, and society in managing many of the dilemmas surrounding medical advancement. The two most important books to review are David J. Rothman's *Strangers at the Bedside* and Albert R. Jonsen's *The New Medicine and the Old Ethics*. Historian M. L. Tina Stevens challenges these accounts and argues that bioethics developed from earlier social criticisms and the tradition of ambivalence more generally. She finds its modern roots in the responsible science movement that emerged following detonation of the atomic bomb. According to Stevens, bioethics has served more as a "midwife" to new medical research and technologies than as a critic. See Stevens, *Bioethics in America*. Many scholars, however, disagree with Stevens's account, including Robert Baker in "Bioethics in America," 432–34.

62. Artificial Heart Assessment Panel, *The Totally Implantable Artificial Heart*, 1.

directors, as well as with numerous artificial heart researchers; they also consulted with individuals from the Institute of Society, Ethics, and the Life Sciences in New York (later renamed the Hastings Center), the Kennedy Institute for Bioethics at Georgetown University, and the Health Policy Program at the University of California, San Francisco.[63]

Nearly two years later the panel submitted a 250-page assessment of NHLI's AHP, recommending that research on all types of mechanical circulatory-support systems should continue with NHLI funding and concluding that artificial hearts (if successful) would contribute to a healthier population. The report covered issues of access, including potential shortfalls in supply; cost; and quality of life. It identified larger issues, but these were discussed only superficially: namely, the relationship between experimentation and therapy, and the conditions for human experimentation and informed consent. The report concluded that the nuclear-powered approach to artificial hearts was the better technological option compared to biological fuel cells, which were decades away from practical use, and battery systems, which tended to overheat, required multiple rechargings daily from an external energy source, and had a limited lifespan of only two years. A plutonium fuel capsule would provide a reliable source of energy for a period of ten years, with no dependence on external sources of energy. In short, "the nuclear system is far more advantageous to the recipient in terms of his sense of well-being and personal convenience."[64]

However, the panel was uneasy about the toxicity of the plutonium, the possibility of accidents or criminal acts relating to the device, and the radiation exposure to recipients, their families, and the public at large.[65] This latter issue of radiation raised the most serious concerns, since there was little scientific data about the biological effects of continuous exposure to low doses. In 1971 the National Council on Radiation Protection and Measurements (NCRP) recommended a maximum exposure of 0.5 rem as safe for individuals. Atomic heart recipients would be exposed to 55 rem of radiation annually, and their spouses risked annual exposures ranging from 0.7 to 9 rem, depending on whether recipient and spouse slept in the same bed. This constituted a significant increase and range of radiation exposure

63. Participants included John Norman, William Kolff, Michael DeBakey, and Tet Akutzu, among others. See ibid. The first centers devoted to the study of bioethical questions were the Hastings Center in New York, founded by philosopher Daniel Callahan and psychiatrist Willard Gaylin in 1970, and the Kennedy Institute of Ethics, which opened at Georgetown University in Washington, D.C., in 1971. More bioethics centers and academic units emerged thereafter, in part due to the emergence of controversial new medical technologies like the artificial heart. See Rothman, *Strangers at the Bedside*; and Jonsen, *The New Medicine and the Old Ethics*.

64. Artificial Heart Assessment Panel, *The Totally Implantable Artificial Heart*, 104–7, 194–96.

65. Ibid., 107–12.

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when considering that typically the average person received about a hundred millirems of cosmic-background radiation per year.[66] Medical personnel performing implants faced exposure to more than the occupational limit of 5 rem annually. According to the recommendations of the NCRP, the estimated combined exposure of the plutonium implant itself and the recipient's life thereafter was too high, causing individuals to be at risk for sterilization and development of leukemia or other cancers, among other possible health problems. The panel acknowledged, however, that recipients and their families might choose to accept these risks rather than face certain death.[67]

The End of Atomic Heart Research Programs

The Artificial Heart Assessment Panel attempted to balance the aggregate benefits to society of this technology against the aggregate risks. It agreed that 1) the benefits of an atomic artificial heart appeared to outweigh its low or acceptable risks; 2) the possibility of accidents or criminal acts involving patients with atomic hearts was remote; 3) the radiation exposure could be lowered; and 4) the regulation and licensing of Pu-238 would contribute to controlled management of this potentially harmful material. Still, some members had serious reservations about whether the panel's risk–benefit analysis was an ethically appropriate measurement tool. Despite concluding that atomic power was the superior energy source for the device and that its aggregate benefits outweighed its risks, the panel recommended that the radioisotope-powered artificial heart not be implanted in humans until it was scientifically established that there would be no significant risk of injury involuntarily imposed upon individuals other than recipients. The panel coupled this recommendation with a plea for greater efforts to develop alternative energy sources—specifically, better battery technology.[68]

Atomic heart researchers like Kolff contested the panel's recommended ban. Investigators experimenting with animals fully expected to move forward to human implants, contending that human tests could supply data

66. National Council on Radiation Protection and Measurements, *Basic Radiation Protection Criteria*, cited in Dennis, "The Program on the Development of an Artificial Heart: An Evaluation"; Helen Caldicott, *Nuclear Power Is Not the Answer*, 44.

67. At that time, allowable levels of whole-body exposure were 5 rem per year for nuclear workers and 0.5 rem per year for the general public. A rem (an acronym from roentgen equivalent man) is the dose of ionizing radiation that will produce a biological effect approximately equal to that caused by one roentgen of X-ray or gamma-ray radiation. See also National Council on Radiation Protection and Measurements, *Basic Radiation Protection Criteria*; Artificial Heart Assessment Panel, *The Totally Implantable Artificial Heart*, 111–17.

68. Artificial Heart Assessment Panel, *The Totally Implantable Artificial Heart*, 121–23.

that were impossible to obtain from animal experiments. The panel members were not persuaded; here they drew the line: continue with animal experiments, but no human implants. They pointed to the danger of a "slippery slope": namely, more widespread use of atomic systems could not be controlled once human implants, experimental or otherwise, began. The AEC's Mott, shocked by what he considered the panel's baseless conclusions, challenged its members' technical competence and commented that they were "preoccupied with the nuclear system and its risks."[69] Indeed, the panel was uneasy about the nuclear system, questioning the AEC's and NHLI's scientists' claims that the nuclear fuel capsule was indestructible. Since this assertion was not grounded in actual experience, the panel chose to err on the side of caution.

Administrators, government officials, and the public seemed to agree. The latter was especially apprehensive about radiation exposure during this period—whether from nuclear power plants, other atomic-energy applications, and even medical and dental X-rays.[70] Acceptability of atomic hearts by recipients and their families with no other options was one thing, but acceptability by the general public was quite another. When the Artificial Heart Assessment Panel asked members of the Subcommittee on Somatic Effects of the NAS-NRC Advisory Committee on the Biological Effects of Ionizing Radiation about the risk of a radioisotope-powered artificial heart, one scientist replied: "My main worry about a Pu-238 powered heart pump is that one day on a Trans-Pacific flight, economy class, I will be seated between two of them." As sociologist Lee Clarke has pointed out, the public is often more tolerant of risks when exposure is regarded as voluntary, instead of involuntary.[71] The panel anticipated that the public would not find the risks associated with a radioisotope-powered artificial heart acceptable; it decided therefore to limit experimental implants to animals, hoping that safer nonnuclear energy sources would be forthcoming soon, thus rendering the nuclear option moot.

The Artificial Heart Assessment Panel's report influenced both the NHLI's and AEC's atomic heart projects. The NHLI responded immediately to almost all of its recommendations, discontinuing support for the atomic heart and redirecting its attention to other energy sources. By this time, unsatisfactory animal testing of three different agency-sponsored thermal engines with various ventricular assist devices resulted in a discouraging outlook for nuclear-powered devices. Norman had implanted a total of fifteen calves with plutonium between 1972 and 1974 with survival rates

69. Ibid., 123; Letter, William E. Mott to W. J. Kolff, 8 May 1973, in Kolff Collection 654, box 168, folder 3.

70. See Boyer, *By the Bomb's Early Light*; Spencer R. Weart, *Nuclear Fear*; and Caufield, *Multiple Exposures*.

71. Artificial Heart Assessment Panel, *The Totally Implantable Artificial Heart*, 132; Lee Clarke, "Explaining Choices among Technological Risks," 23.

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measured in hours, not days. The average animal lived less than forty-eight hours until various technological problems with both the pump and the engine, including device leaks, breaks, and thermal exposure to the animal, terminated the tests. Mechanical modifications made after each animal implant demonstrated improved system efficiency and reduced heat losses to the surrounding tissue, but many problems remained to be resolved.[72]

Clarence Dennis, who had succeeded Harmison as chief of the NHLI's AHP, moved to stop the "unproductive, extravagant experiments" linked to the atomic heart. Dennis stated that

> [i]n contrast to the AEC, which in 1970 embarked upon development of a single thermal engine, the NHLI Program was launched without sufficiently thorough investigation and funded several contractors and designs. . . . The multiple approach with insufficient prior investigation has resulted in a funding of patterns of thermal drives which should have been rejected outright on the basis of the physiological implications.

The NHLI's atomic heart program's budget was four times that of the AEC's. It awarded contracts to six different engineering companies, totaling $14,320,177, in comparison to the AEC's one contract to Westinghouse for the sum of $3.5 million. Calling for a return to basic science, Dennis advocated ending the NHLI's atomic heart program and redirecting funding toward the development of alternative energy sources.[73]

Likewise in 1974, incumbent AEC chairman Dixy Lee Ray announced that the AEC would phase out the development of its atomic heart over the next three years. AEC officials admitted that the questions raised regarding public acceptability by the Artificial Heart Assessment Panel partly influenced this decision, as did general uncertainty about the ultimate success of the program.[74] A 1974 review of the AEC's atomic heart program by a group of seven independent engineers and research physicians criticized the device as "immensely complicated with more than a dozen gears and heaven knows how many bellows and bearings. It is difficult for most to conceive of such a device working successfully for ten years without service."[75] They also expressed concern over the device's radiation levels. Contributing to this pes-

72. Hughes et al., "Nuclear-Fueled Circulatory Support Systems XII," 741–42; memorandum, Clarence Dennis to file, 20 November 1974 and "General Correspondence, 1974 Oct–Dec," in Dennis Papers, box 2, folder 2.

73. Dennis, "The Program on the Development of an Artificial Heart: An Evaluation."

74. Letter, John A. Hill to Hon. Frank E. Moss, 30 December 1974, in Kolff Collection 654, box 171, folder 7.

75. Letter, Clarence Dennis to William E. Mott, 7 June 1974, in Dennis Papers, box 6, folder 10. Review panel members included Clarence Dennis (NHLI), Adrian Kantrowitz (artificial heart researcher), John Storer (Oak Ridge National Laboratory), J. W. Poston (Oak Ridge National Laboratory), Peter Mansfield (cardiovascular researcher), H. M. Paynter (engineer), and Glen Newby (engineer).

simism was the budget crunch of the mid-1970s. Many government officials deemed the atomic heart program too long-term and costly to continue, and thus drastic budget cuts seemed imminent.[76] Meanwhile the AEC, under public pressure because of its perceived conflict between dual missions to promote and regulate nuclear power, split into two new agencies: the Energy Research and Development Administration (ERDA), which directed all research and development programs, and the Nuclear Regulatory Commission (NRC), which assumed all regulatory functions.[77] Atomic heart researchers now working for the ERDA fought to keep their program alive, arguing that they had developed a successful thermal-energy-conversion system, but it was too late. Mott, a key AEC/ERDA project coordinator, left the program after being reassigned to a different area and Donald Cole took over as project coordinator. Senior AEC administrators commented that they were reviewing "future directions and priorities within the program," which meant transferring the atomic heart program to the NHLI.[78]

Having invested heavily in the AEC atomic heart, Kolff lobbied politicians and pleaded with the Joint Committee on Atomic Energy to reinstate ERDA's program, thus prompting another review of it. Expert bioengineers and medical researchers recommended that ERDA continue funding its AHP, arguing that the advantages of the plutonium source outweighed its risks, making plutonium the energy source of choice. Yet the OMB allocated no money to the ERDA for continued research on the artificial heart during the next fiscal year, thus effectively terminating the program.[79]

In his final report a disappointed Kolff defiantly declared the AEC–Westinghouse artificial heart a success, although it had never been tested with plutonium. Denied access to plutonium, Kolff replaced the Stirling engine with a small electromotor on the pump and implanted this device in calves, of which one survived for thirty-five days. But like the NHLI's heart assist systems, Kolff's artificial heart also wrestled with problems re-

76. Letter, James Liverman to Senator Jake Garn, 14 March 1975, in NARA 128, box 81, "General Correspondence Files 1956–1975"; memorandum, Clarence Dennis to file, 1 November 1974, in Dennis Papers, box 2, folder 2, "General Correspondence, 1974 Oct–Dec."

77. In 1977 the ERDA was reorganized, along with other activities, into the Department of Energy. Many AEC scientists working on the artificial heart were reassigned to other projects. For more on the reorganization of the AEC, see Duffy, *Nuclear Politics in America*, 103–22; and Glenn T. Seaborg, *The Atomic Energy Commission under Nixon*.

78. Letter, Robert W. Wood to W. Kolff, 9 May 1975, in Kolff Collection 654, box 169, folder 7.

79. Letter, W. J. Kolff to Mayor E. J. Garn, Salt Lake City, 22 November 1974, in NARA 128, box 81, "General Correspondence Files 1956–1975"; letters: W. Kolff to J. V. Tunney, 13 February 1975 (folder 8); Allan T. Howe to W. Kolff, 2 May 1975 (folder 7); and W. Kolff to Robert W. Wood, 2 June 1975 (folder 7), in Kolff Collection 654, box 169; "Final Report—ERDA Artificial Heart Program Review" (August 1976), in Watson Papers, box 1; Letter, W. J. Kolff to G. McKay, E. J. Garn, O. Hatch, D. Marriott, and F. Church, 15 March 1977, in Kolff Collection 654, box 170, folder 3.

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garding biocompatibility and device performance. The NHLI's Dennis commented that "one might say that AEC has suffered from putting all eggs in one basket while the NHLI has suffered from trying to carry too many baskets at one time." In a 1977 review of the NHLI's AHP, scientific assessors identified numerous remaining bioengineering challenges of current blood-pump designs, including the threat of thrombosis and embolization (blood clots leading to strokes), problems of hemocompatibility with pump materials (suitable blood-interface materials), and infections with percutaneous air-drive lines. Yet for all of these challenges, the many problems of nuclear power as an energy source appeared greater.[80] By 1977 institutional support for atomic heart programs ended.

Conclusion

Medical scientists and engineers did not develop atomic hearts beyond limited animal testing. Despite their assertions that the technological complexity of this device was surmountable, public concern and political responses to the uncertainty and risks associated with medical devices in general, and the use of radioisotopes within the body in particular, contributed to the government's decision to withdraw funding, effectively ending this line of investigation. From 1967 to 1977, as the public was beginning to demonstrate greater consciousness of risks in medical technologies, the development of atomic hearts vacillated between being a potentially positive and valuable nuclear-powered product or a medical device that was risky to the wider public. Laypersons, such as bioethicists, journalists, consumer groups, politicians, and others, became more vocal, calling attention to the broader political, economic, and social issues surrounding complex medical technologies. Society and the state—outsiders, as opposed to predominantly scientific experts—influenced how the boundaries around artificial heart research would be constructed. The concerns raised by bioethicists and other laypersons and the FDA both increased federal management of the risks associated with medical devices and effectively ended the scientific research on atomic hearts.[81]

To be sure, the ambitious pursuit of developing the atomic heart expe-

80. See the supporting documentation, in the Willem J. Kolff Collection, National Museum of American History, box 1, folder 10; and "Final Report, 1979," in Kolff Collection 654, box 173, folder 9; Letter, Dennis to Mott, 7 June 1974; "Mechanically Assisted Circulation—the Status of the NHLBI Program and Recommendations for the Future: Report of the Cardiology Advisory Committee" (May 1977), in Watson Papers, box 15.

81. Researchers continue to explore and debate the use of radioisotopes as an implantable energy source for artificial hearts, but the issues of economic cost and risk to society still appear to trump the technological feasibility. See Victor Poirier, "Will We See Nuclear-Powered Ventricular Assist Devices?" and Vakhtang Tchantchaleishvili et al., "Plutonium-238: An Ideal Power Source for Intracorporeal Ventricular Assist Devices?"

rienced significant technological difficulties during the period studied here. Two major bioengineering obstacles in constructing these artificial hearts concerned finding a viable surface or biomaterials that prevented blood clotting and hemolysis (blood damage) and developing an implantable power source. Most researchers, such as Kolff, remained steadfast in their view that, given time, these technical problems could be overcome. Yet multiple factors complicated the situation, consequently reducing the authority of these researchers. Work was done by two agencies' competing programs, which probably hindered rather than enhanced the development of a functioning atomic heart and perhaps contributed to the public's skepticism. The scientific community was not unified in its support of either the development of an atomic heart or the role of outsiders in assessing research programs. Moreover, a discernible political shift in the NHLI's AHP promoted attention to alternative technological solutions, including greater support for the development of left ventricular assist devices instead of complete mechanical hearts and nonnuclear power sources for implantable devices. Declining congressional financial support accompanied this change in program orientation.[82] The fact that atomic heart research continued for ten years (1967–1977) is testimony to the commitment of a handful of researchers, including Kolff, to develop the technology.

Despite the attempts of many individuals during the late 1960s and the 1970s to explore avenues in which atomic energy might be used in a positive way, radioisotope-powered artificial hearts did not fulfill these hopes. The risk scenarios surrounding atomic hearts, such as damaging radiation exposures and stolen plutonium incidents, never had the opportunity to become reality, remaining fictionalized in the novel *Heart Beat*. Despite abandoning the nuclear power source, work on the artificial heart did continue, benefiting from earlier research on biomaterials, pump mechanisms, and other aspects of the device. Kolff, for example, achieved better clinical results with a pneumatically driven, rather than a radioisotope-powered, artificial heart in the early 1980s.[83] Political and social concerns arising in the context of a heightened sense of risk awareness in the 1970s ultimately played the biggest role in shutting down the atomic heart programs, as strong public support for increased government control of both atomic energy and medical devices overrode scientific assertions that further development could produce a safe and efficacious atomic heart.

82. M. J. Strauss, "The Political History of the Artificial Heart," 335.

83. Kolff returned to air-powered hearts, a simple power source that had been used since 1957, with his first successful animal implant. His more promising devices were both pneumatically driven: the Kwan-Gett artificial heart (1967–77) and the Jarvik artificial heart (1972–90), which was implanted in Barney Clark in 1982. See McKellar, "Limitations Exposed."

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