The Pediatric Circulatory Support Program (PCSP) of the National Heart, Lung, and Blood Institute (NHLBI) was established to fund the development of novel circulatory support devices for children with medically refractory heart failure. Before this, developers of circulatory support devices found little incentive to enter the pediatric market because of the small patient numbers that are generally insufficient to justify the significant costs required to develop these devices. As a result of the lack of availability of new devices for circulatory support of pediatric patients, extracorporeal membrane oxygenation (ECMO), which first had been used clinically in the 1960s, remained the most commonly used modality to support these critically ill children during the next 40 years. The most attractive feature of ECMO for pediatric circulatory support is its ability to be used in even the smallest infants and neonates. However, ECMO support is characterized by thromboembolic complications and sepsis in a significant percentage of patients. Perhaps most importantly, ECMO has generally only been suitable for short-term support, limiting its usefulness as a bridge to transplantation, and the size and extracorporeal configuration of the system components usually limit its use to the intensive care unit setting and preclude ambulation and rehabilitation during support.

In recognition of the limitations of the existing devices for pediatric mechanical circulatory support and the limitations for the entry of device companies into the pediatric market, the NHLBI established the PCSP to “perform basic and applied research to develop novel circulatory assist devices or other bioengineered systems for infants and children with congenital and acquired cardiovascular disease who experience cardiopulmonary failure and circulatory collapse.” Because the PCSP was a development program for new devices to address a broad goal (circulatory support for pediatric heart failure) rather than for a specific design, and because funding various promising approaches would improve the chances of successfully achieving the objectives of the program, proposals were solicited under a Broad Agency Announcement. Broad Agency Announcements are used, as in this case, when proposals with varying scientific or technical approaches are anticipated. After receipt, review, and assessment of the proposals submitted in response to the Broad Agency Announcement, contracts totaling >$20 million were awarded by the NHLBI in the spring of 2004 to 5 contractors to develop a family of pediatric circulatory support devices (Table 1). Funding support for the PCSP concluded in 2009. In 2006, a summary report was published that described these devices and the development goals of their respective programs as the PCSP was initiated. The PCSP was a development program involving different devices, the design processes, the in vitro and in vivo tests and analyses, and the goals for those tests varied between contractors. However, to make the most of the program, contractors participated in monthly conference calls, attended and presented their progress at annual meetings, and shared quarterly progress reports. These activities provided a means for each of the contractor teams to learn from and leverage the progress made by the other contractors and, as appropriate, to modify their approach and improve their device. The present report provides a summary of progress for each of the contractors at the conclusion of this program, including a sampling of some of the test results and analyses. The report concludes with the plans for achieving clinical application of these and other promising pediatric circulatory support devices.

The PediaFlow Pediatric Ventricular Assist Device (University of Pittsburgh)

A consortium led by the University of Pittsburgh undertook an ambitious program that relied on fundamental bioengineering principles to develop, de novo, a miniature blood pump specifically intended for the youngest heart failure patients. Through the PCSP, the consortium produced the PediaFlow PF3, a miniaturized magnetically levitated blood pump (Figure 1). With a flow rate range between 0.3 and 1.5
L/min and a volume approximately that of an AA cell battery (Table 2), the clinical PediaFlow ventricular assist device (VAD) has been developed to meet the goal of the PCSP to provide circulatory support for neonates, infants, and children weighing /H11021/25 kg who experience cardiac failure and circulatory collapse due to congenital and/or acquired cardiovascular disease.

The first 2 designs (the PF1 and PF2 models) focused on demonstrating feasibility and improving the hemodynamic characteristics, particularly increasing the peak flow rate to 2.0 L/min against a pressure head of 80 mm Hg. This was accomplished by the development of an optimized 4-pole motor that provided the required torque. Operation was demonstrated to be stable at pump outputs between 0.25 and 2.0 L/min against a pressure load of 80 mm Hg. Progress was also made in reducing the size, profile, and weight of the PediaFlow pump. Through design optimization, the PF2 pump occupied approximately half of the volume (35.5 mL) associated with the housings for the PF1 pump (63.6 mL). As designed, the PF2 pump would be implantable in patients weighing ≈10 kg but would be problematic for implantation in the smallest patients.

The PF3 design represents the latest enhancements of the PediaFlow VAD. The system overcame size limitations of the earlier PF1 and PF2 designs by being uniquely configured for supercritical operation at rotational speeds beyond those associated with resonance frequencies. This modification resulted in dramatic size reduction, and therefore the PF3 system takes less than half of the volume of the previous versions. As a result, the PediaFlow pediatric VAD is capable of full implantation in the left upper quadrant behind the left rectus abdominus muscle in the smallest patients (<5 kg).

During the program, 9 in vivo ovine PediaFlow implantation studies ranging from acute (6 hours) to chronic (30 days

Table 1. National Heart, Lung, and Blood Institute Pediatric Circulatory Support Program Contractors and Devices

<table>
<thead>
<tr>
<th>Program</th>
<th>Device</th>
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<tbody>
<tr>
<td>University of Pittsburgh</td>
<td>PediaFlow pediatric ventricular assist device</td>
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<tr>
<td>Cleveland Clinic</td>
<td>PediPump</td>
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<tr>
<td>Enson, Inc</td>
<td>Pediatric Cardiopulmonary Assist System</td>
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<tr>
<td>Jarvik Heart, Inc</td>
<td>Pediatric Jarvik 2000</td>
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<tr>
<td>Penn State University</td>
<td>Pediatric ventricular assist device</td>
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Figure 1. The family of devices developed under the Pediatric Circulatory Support Program. A, The PediPump ventricular assist device showing application for biventricular support; B, PediaFlow ventricular assist system; C, Penn State infant pediatric ventricular assist device; D, Enson’s Pediatric Cardiopulmonary Assist System with prototype controller console; and E, infant-size pediatric Jarvik 2000 showing thrombus-free bearings after 5 weeks in a lamb animal model.
and 72 days, electively terminated) were conducted. Throughout each of the chronic studies, rheological and biocompatibility studies were completed, and the animal’s physiological status and serum biochemistry were monitored. Nearly all measured hemodynamic, biochemical, and biocompatibility values either fell within the literature reference range for these parameters in sheep or demonstrated a nearly identical temporal course as observed in sham control studies. Assays were specifically developed to quantify circulating activated ovine platelets, and these assays have been utilized in each PediaFlow implantation.5–7 Figure 2 demonstrates platelet activation in a PF2 implantation before and after stimulation with adenosine diphosphate and platelet activating factor. Platelet activation rose modestly after surgery and quickly returned to baseline. Platelets could be stimulated to high activation levels with adenosine diphosphate and platelet activating factor, signifying conserved platelet function during the implantation. This temporal response was similar to the platelet activation results in the sham control studies and PF3 implantations, suggesting attractive platelet biocompatibility.7

The PediPump (Cleveland Clinic)

The initial objectives of Cleveland Clinic’s development program were to create an implantable VAD that would be small enough to allow implantation in newborns yet capable of providing hemodynamic support for children up to 25 kg. The resulting PediPump is a novel pediatric VAD based on a design for transcatheter applications in adults that appeared suitable for pediatric application because of its small size and hemodynamic targets for support (Figure 1). The PediPump employs a mixed-flow rotary pump with a rotor that is suspended on passive magnetic bearings as in the initial design for the adult transcatheter pump.8–11 Primary blood flow is powered by a 3-blade impeller, exits through the annulus containing the outflow stator blades, and passes over the motor, which provides motor cooling. Absence of seals in this design removes the need for external purge flows and reduces wear, making the pump suitable for prolonged periods of support.

The PediPump has undergone incremental design improvements throughout the PCSP support period while retaining the same fundamental pump design. These included refinements to the pump’s magnetic bearing design, motor design, wash-flow path, axial touch-point design, and electric/thermal insulation. The most recent version of the PediPump, the Mark IV, includes improvements in design and manufacture of the magnetic bearings, which allows reduction in the axial dimension of the pump that now measures 64.5 mm in length by 10.5 mm in diameter.

The PediPump development program also sought to address anticipated anatomic fit issues of VAD implantation in children. Initial work in this program created on-screen 3-dimensional reconstructions from clinically obtained computed tomography and magnetic resonance imaging studies.12 This approach to anatomic 3-dimensional reconstructions was subsequently used in a sheep model to aid in planning

### Table 2. National Heart, Lung, and Blood Institute Pediatric Circulatory Support Program Device Characteristics

<table>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter, mm</td>
<td>19.6</td>
<td>10.5</td>
<td>10.5</td>
<td>18</td>
<td>76</td>
<td>NA</td>
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<tr>
<td>Length, mm</td>
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<td>59</td>
<td>190</td>
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<tr>
<td>Total volume, mL</td>
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<td>4</td>
<td>12</td>
<td>96</td>
<td>66</td>
<td>150</td>
<td></td>
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<tr>
<td>Total mass, g</td>
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<td>843</td>
<td>67.5</td>
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<td>Priming volume, mL</td>
<td>2.3</td>
<td>0.6</td>
<td>1</td>
<td>4</td>
<td>105</td>
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<td>Maximum speed, rpm × 1000</td>
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<td>15</td>
<td>40</td>
<td>16</td>
<td>3</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Maximum flow rate, L/min</td>
<td>1.5</td>
<td>3.0</td>
<td>3</td>
<td>3</td>
<td>3.0</td>
<td>1.6</td>
<td>3.3</td>
<td></td>
</tr>
</tbody>
</table>

NA indicates not applicable.

*pCAS* indicates not applicable.

*The Pediatric Cardiopulmonary Assist System (pCAS) is an extracorporeal membrane oxygenation device.

![Figure 2. Platelet activation in a lamb animal model using an earlier version of the PediaFlow ventricular assist system after stimulation of blood with 20 μmol/L adenosine diphosphate (ADP) and 10 μmol/L platelet activating factor (PAF). Platelet function with the implanted PediaFlow ventricular assist system appears to be conserved, as evidenced by the finding that platelets could be stimulated to high activation levels with adenosine diphosphate and platelet activating factor; similar results were observed in sham studies."

![Figure 2. Platelet activation in a lamb animal model using an earlier version of the PediaFlow ventricular assist system after stimulation of blood with 20 μmol/L adenosine diphosphate (ADP) and 10 μmol/L platelet activating factor (PAF). Platelet function with the implanted PediaFlow ventricular assist system appears to be conserved, as evidenced by the finding that platelets could be stimulated to high activation levels with adenosine diphosphate and platelet activating factor; similar results were observed in sham studies."

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for device fitting before the initiation of the in vivo testing program for the PediPump described below. Nine chronic implantations have been performed, with a number of these animals surviving to completion of the target 30-day period of study. Implantation was technically easy, and surviving animals have tolerated subsequent recovery well. Hemodynamic performance of the PediPump was stable throughout the period of chronic in vivo support in all animals and appeared to be suitable for the physiological envelope initially targeted for the development program, with flows averaging 1.7 to 2.0 L/min with a pressure rise of 50 to 60 mm Hg. Importantly, minimal hemolysis has been observed during the entire in vivo testing program. Some animals early in the chronic support series developed a cap of deposition on the rear rotor touch point. This was addressed by a redesign of the rear touch point as well as a change to more biocompatible materials in this region of the pump. In summary, progress in the PediPump development program has created an important foundation of preclinical data as the PediPump program progresses to clinical trials in its next stage of development.

Pediatric Cardiopulmonary Assist System (Ension, Inc)

Ension’s Pediatric Cardiopulmonary Assist System (pCAS) has been developed as a next-generation ECMO system. The pCAS improves on the current state of ECMO by offering improved blood compatibility, reduced surface area and priming volume, rapid deployment, and a simplified system configuration that facilitates parent-child bonding and patient transport.

The pCAS (Figure 1) consists of a pump oxygenator, controller console, and ancillary components such as venous and arterial cannulas and an arterial bubble trap. It is a compact, integrated device consisting of an impeller directly integrated to a blood oxygenator with a turning diffuser. The system is designed to provide partial or complete cardiopulmonary support to patients from 2 to 25 kg. Although the period of intended use is 2 weeks for a single disposable blood-contacting pCAS pump oxygenator, extended support is accommodated through pump oxygenator change-out, typically taking <5 minutes.

Blood-contacting surfaces of the pump oxygenator incorporate Ension’s bioactive surface. This surface has been specifically engineered to be stable, bioactive, cost-effective, permeable to oxygen and carbon dioxide, and applicable to a variety of fiber materials such as microporous polypropylene and polymethylpentene. A bioactive surface is also applied to the blood tubing and cannulas, yielding a circuit with tip-to-tip bioactive surface modification. Cannulation can be via neck vessels in infants, femoral vessels in children with sufficient size, or chest cannulation in surgical patients. The pCAS pump oxygenator was designed for use with a variety of different cannulas (from 8F to 22F) because of the wide range of clinical preferences and practices and patient sizes.

The touch screen–based pCAS control console has been designed to provide simple and reliable operation. Control console functions include display and regulation of pump speed, flow, and other operational parameters, monitoring the system for fault conditions.

Development of the pCAS has been guided by risk management, reliability, and human factors analyses as well as functionality, biocompatibility, and clinical requirements. Fabrication processes have been established, refined, and validated as part of the product development and prototype production processes. Over the 5-year period of development, design iterations of the pCAS pump oxygenator and controller console have been fabricated and tested extensively both in vitro and in vivo. In vitro data have demonstrated the ability of the pCAS pump oxygenator to achieve required blood flow rates and pressures and to exchange oxygen and carbon dioxide with minimal blood damage. Ension has utilized 2 different animal models for in vivo evaluations. Acute in vivo system testing in piglets ranging from 7.9 to 11.6 kg has demonstrated that the pCAS provides appropriate hemodynamic support for the small patients in the target population with the use of appropriately sized cannulas. Specifically, blood flow rates of up to 1.2 L/min and oxygenation saturation levels of 100% were achieved with the use of 10F venous and 8F arterial cannulas. Three-day studies in calves have demonstrated improved blood compatibility.
The Jarvik 2000 Infant and Child VADs
(Jarvik Heart, Inc)

Jarvik Heart, Inc. has developed both child-size and infant-size intraventricular blood pumps generally patterned after the Jarvik 2000 adult model (Figure 1). The final-design pumps are very small, provide flow from 0.25 to 3 L/min, and have not caused hemolysis, platelet activation, or pump thrombosis in lamb implantations.

During the first 3 years of the 5-year National Institutes of Health development program, pump stoppage due to bearing thrombus was a major barrier to success. This was first observed when several pin-in-sleeve bearing designs seized during chronic animal studies. The bearing thrombus problem was overcome only after the development of a new type of miniature ceramic blood-immersed bearing termed the cone bearing (Figure 4). During the program, 21 animal implantations intended for long-term survival were conducted. With the use of the original bearings with the child and infant models, 75% (9 of 12 pumps implanted) failed because of bearing seizure from thrombus or bearing fracture, usually within 3 weeks. With the new cone bearing design, animals survived with elective termination up to 70 days. No pumps failed because of bearing problems with the new bearings, and only 1 of 9 implantation cases had thrombus within the pump. However, this was secondary to infection and thrombosis of the outflow graft near the flow probe. Thus, the cone bearings were successful in all cases, and the pump was thrombus free in 89% of the implantations. Accelerated durability testing of the cone bearings for the child-size pump for >3 years is ongoing, with no failures and measured bearing surface wear of only 1 μm/5 y.

The infant-size Jarvik 2000 is the smallest implantable blood pump. The size of an AAA battery, it is small enough to implant in the ventricular apex of 3.5-kg newborns, yet it has flow capacity of >3 L/min, which is sufficient for children up to 25 kg. Animal implantations have shown that the pump remains free of thrombus and operates at low power (3 to 5 W) without causing hemolysis. The pump incorporates all of the requirements for a long-term implant, including welded hermetic sealing of the motor stator and rotor magnet, miniature hermetic feed-throughs for the power cables, a very-long-life conical ceramic bearing design, and pacemaker-type, high-flex life power cables from the external controller to the implanted blood pump.

Work is underway to complete a new control system with important user-friendly features, which is expected to be especially useful for support of children living at home.

The Penn State Pediatric VAD (Pennsylvania State University–Hershey Medical Center)

The Penn State pediatric VAD is a pneumatically actuated pulsatile pump (Figure 1) based on the design of the Pierce-Donachy adult VAD (Thoratec PVAD) developed at Penn State. The Penn State pediatric VAD has been developed in 2 sizes: a 12-mL stroke volume infant VAD with 6 and 8 mm cannulas and a 25-mL stroke volume child VAD with 8 and 10 mm cannulas. The pneumatic pulsatile VADs are flexible in their application and may be utilized for left, right, or biventricular support. Pump filling is detected by measuring the driveline airflow, enabling a full-to-empty automatic rate control, resulting in an increase in pump rate with increasing inlet pressure. This automatic preload sensitivity allows maximum flow and ventricular unloading to be achieved while limiting excessive inlet suction and provides safe left atrial pressure control in biventricular support. The pump is designed with the option of paracorporeal placement or implantation. A duration of support in excess of 1 year is expected to be achieved with this design. Improvements to the devices during the program include a new Björk-Shiley Monostrut custom valve (manufactured in-house), a redesigned diaphragm, and better seals.

The primary design objective has been to produce a device with low thrombogenic risk. This is especially challenging because the fluid mechanics in small-scale devices favor low wall shear rates and have a higher propensity for clot formation relative to adult-size devices. Significant efforts have been made in understanding the spatial and temporal properties of blood flow in the pump and cannulas, with special attention to the valves, with the use of particle image velocimetry and a viscoelastic blood analog. Wall shear rates were calculated from the data to quantify wall washing (Figure 5). The Björk-Shiley Monostrut valve was selected because the results revealed that it provided a stronger and more sustained rotational flow because of the major orifice inlet jet as well as lower outlet valve regurgitation than the Carbomedics valve, which was also evaluated. Particle image velocimetry was also used to evaluate the effect of reduced flow rate during weaning.

The Penn State investigators made substantial progress in developing animal models for studies of pediatric VADs. Chronic animal studies of the infant pump were completed in 11 lambs and 4 goats. One acute study, 3 surgical shams, and...
4 hematologic control studies were also completed. A major challenge in the early studies was atelectasis and respiratory failure, not related to VAD function, which required protocol improvements. A stable animal model in the 20- to 25-kg lamb was achieved subsequently. This model demonstrated healthy survival to elective termination at 4 weeks in 5 of the 7 most recent studies (duration, 5 to 41 days; mean, 26.1 days).

The results from the animal studies are promising. Hemolysis was not evident in animal testing, and in vitro hemolysis testing with bovine blood demonstrated a normalized index of hemolysis similar to adult pulsatile VADs. Likewise, thromboembolism was also not evident in the animal testing. In 1 group of animals (the activated partial thromboplastin time group; n=4), unfractionated heparin was titrated to achieve a therapeutic activated partial thromboplastin time of 2 times normal, which is a common approach in humans. As shown in Figure 6, thromboelastography in this group indicated hypocoagulability despite a therapeutic activated partial thromboplastin time of 2 times normal, which is a common approach in humans. As shown in Figure 6, thromboelastography in this group indicated hypocoagulability despite a therapeutic activated partial thromboplastin time of 2 times normal, which is a common approach in humans. As shown in Figure 6, thromboelastography in this group indicated hypocoagulability despite a therapeutic activated partial thromboplastin time of 2 times normal, which is a common approach in humans. As shown in Figure 6, thromboelastography in this group indicated hypocoagulability despite a therapeutic activated partial thromboplastin time of 2 times normal, which is a common approach in humans. As shown in Figure 6, thromboelastography in this group indicated hypocoagulability despite a therapeutic activated partial thromboplastin time of 2 times normal, which is a common approach in humans. As shown in Figure 6, thromboelastography in this group indicated hypocoagulability despite a therapeutic activated partial thromboplastin time of 2 times normal, which is a common approach in humans. As shown in Figure 6, thromboelastography in this group indicated hypocoagulability despite a therapeutic activated partial thromboplastin time of 2 times normal, which is a common approach in humans. As shown in Figure 6, thromboelastography in this group indicated hypocoagulability despite a therapeutic activated partial thromboplastin time of 2 times normal, which is a common approach in humans.

The kidneys were grossly normal except for cortical depressions and fibrosis consistent with old infarcts in 2 cases (thromboelastography group) and a recent renal infarct in 1 animal with a cecal abscess and fever (activated partial thromboplastin time group). These results are generally consistent with previous preclinical studies of successful adult VADs, even at low levels of heparin anticoagulation.

**Discussion**

Extraordinary progress in the field of pediatric circulatory support has been made over the past 5 years since the inception of the PCSP. When the program began, the only options for very young children with cardiopulmonary failure and circulatory collapse were conventional ECMO and, under emergency use granted by the Food and Drug Administration, the Berlin Heart EXCOR Pediatric VAD. Since then, a number of substantial advances in the field of...
pediatric mechanical circulatory support have occurred (Table 3). In the spring of 2004, MicroMed received a Humanitarian Device Exemption from the Food and Drug Administration for use of the DeBakey VAD Child in pediatric patients slightly larger than those in the PCSP program. In 2006, tracking of outcomes for pediatric patients who received chronic circulatory support using Food and Drug Administration–approved devices began in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS). In 2007, Berlin Heart initiated a clinical trial of its EXCOR Pediatric VAD in the United States. This was a substantial step toward providing a reliable option for long-term circulatory support of children of any size in the United States. Also during the past 5 years, important new medical conferences devoted specifically to this area were established.

The PCSP has contributed significantly to this golden era in pediatric mechanical circulatory support. A palpable sense of momentum was created when this program was initiated in the spring of 2004. Since then, as is evident in this update, the 5 participating contractors have made outstanding technical advancements toward the ultimate goal of providing safe and effective devices for circulatory support in infants, neonates, and young children with advanced, severe heart disease. The size and flow characteristics of the devices (Table 2) and the various in vitro and in vivo test results reveal that the goals of the PCSP have been achieved in large part. The science and technologies developed through the program, such as the animal models, new assays, virtual fitting methodologies, and the novel bearings and biocompatible coatings, are poised to benefit the broader fields of mechanical circulatory support, cardiovascular devices, and pediatric therapeutics. The developments through the program have been disseminated through 75 scientific publications and 247 presentations at national and international meetings from the contracting centers during the program, which, in turn, have significantly affected the scientific knowledge base. That knowledge base extends across the disciplines of biomedical engineering, physiology, and perfusion sciences as applied to pediatric mechanical circulatory support. Furthermore, although the program has generated considerable excitement in the clinical fields of pediatric cardiology and cardiac surgery, it has also generated substantial interest in the field of adult heart failure because, if successful, the PCSP devices could be placed with the use of minimally invasive procedures while sufficiently augmenting cardiac output in adults.

The progress achieved during the PCSP has come through a great effort that, in turn, has resulted in substantial lessons learned during the program. As evidenced through the developments in the program, such as novel bearings, modified device designs, and animal models, the contractors quickly learned that the goals would not be achieved simply by miniaturization of adult-size devices and applying the experience with those devices. The PCSP also revealed that groups of contractors can work together synergistically and cooperatively while developing potentially competitive products. The program also demonstrated that, despite extraordinary dedication, experience, and skills of the contract teams and significant federal support, development programs like these take substantial time, and this was only one of many steps to be made before the devices will be available for clinical use.

The use and availability of pediatric circulatory support devices are poised to grow over the next 5 to 10 years. In October 2008, the NHLBI issued a request for proposals for the Pumps for Kids, Infants, and Neonates (PumpKIN) program. The program was designed to provide support to contractors to perform the work necessary to receive Investigational Device Exemptions from the Food and Drug Administration for pediatric circulatory support devices within 30 months from the initiation of the PumpKIN program. The required activities include preclinical tests and analyses, development and documentation of manufacturing processes and procedures, and collaboration to develop an Investigational Device Exemption clinical study. Awards for the preclinical phase were made in January 2010. Three of the 5 contractors that comprised the NHLBI PCSP (Ension, Jarvik Heart, and University of Pittsburgh) received the PumpKIN contract program awards. A fourth PumpKIN award was made to the University of Maryland, Baltimore, which is partnering with Levitronix, LLC in efforts on another promising compact ECMO device known as the pediatric pump-lung (PediPL). To help facilitate the timely approval of PumpKIN Investigational Device Exemptions, pre-Investigational Device Exemption applications were submitted by the 4 PumpKIN contractors to the Food and Drug Administration in April 2010, as required by the NHLBI contract. Another request for proposals for a PumpKIN Data and Clinical Coordinating Center to develop, manage, and oversee the clinical trials involving the devices was issued on December 16, 2010. The NHLBI envisions the award to be made so that the clinical trial can begin in January 2013.

**Disclosures**

Dr Borovetz is a full-time faculty member at the University of Pittsburgh, which licenses intellectual property to WorldHeart, Inc. Dr Borovetz does not receive any proceeds from the licenses. Dr Gartner is the president and of retains ownership interest in Enson, Inc. Dr Jarvik is the president and a shareholder of Jarvik Heart, Inc. Dr Weiss is a consultant for Thoratec Corporation.

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References


20. Roszelle BN, Cooper BT, Long TC, Deutsch S, Manning KB. The 12 cc Penn State pulsatile pediatric ventricular assist device: flow field observations at a reduced beat rate with application to weaning. ASAIO J. 2008;54:325–331.


The National Heart, Lung, and Blood Institute Pediatric Circulatory Support Program: A Summary of the 5-Year Experience

J. Timothy Baldwin, Harvey S. Borovetz, Brian W. Duncan, Mark J. Gartner, Robert K. Jarvik, and William J. Weiss

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