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FOR CHILDREN'S HEART SURGEONS, REGULATIONS, RISKS OFTEN CONFLICT

A.I. duPONT FIRINGS LEAVE PARENTS, DOCTORS WONDERING WHAT'S NEXT

By Laura Ungar, Adam Taylor and Jennifer Goldblatt, *The (Wilmington, DE.) News Journal*. Originally published April 11, 2004 in *The (Wilmington, Del.) News Journal*. Reprinted and edited for space with permission. To read the full story as well as other related stories visit: www.delawareonline.com. © Copyright 2004, The News Journal Co.

When Dr. William I. Norwood and Dr. John D. Murphy were called into meetings at Nemours Cardiac Center nearly two months ago, security guards waited outside the office. The doctors were fired, and the guards ushered them out of the hospital.

The world-renowned cardiac team had worked to save babies who previously faced certain death, babies with walnut-size hearts and vessels as thin as pencil lead.

The events at Alfred I. duPont Hospital for Children, touched off by allegations of unregulated research, unfolded in an environment marked by a natural tension between administrators seeking safety and control and doctors pioneering new treatments.

These groups assert forces often at odds: the drive to take the risks necessary to make life-saving advances and the need to follow the rules and maintain safety. The pull of these forces is especially strong at the cutting edge of medicine, where Norwood and Murphy have spent their careers practicing, with babies' lives in the balance.

On Feb. 19, Norwood, Murphy and John T. Walsh, the center's chief administrator, faced allegations that an unapproved medical device was used in experimental procedures conducted without the full knowledge of the babies' parents or hospital officials.

The dramatic fall from grace starkly contrasted with the fanfare surrounding their hirings in 1997.

The hospital had wooed Norwood, among

the world's most prestigious pediatric cardiac surgeons, and Murphy, a gifted cardiologist, to create an autonomous cardiac program. They were among several star doctors recruited to help the hospital gain international prominence.

Most recently, Murphy was one of two doctors in the country trying to eliminate the need for open-heart surgery for babies with only one working ventricle. Instead of cracking open their chests, risking infection and other complications, he repaired the defect with a Gore-Tex covered stent in a lab outside the operating room.

The lawyer for Murphy, Norwood and Walsh maintains they have done nothing wrong. The device was obtained legally, all parents consented to the procedures and hospital officials were aware of what was taking place, attorney Victor F. Battaglia Sr. said. Norwood disputed the reported findings of a hospital investigation.

"The events at Alfred I. duPont Hospital for Children, touched off by allegations of unregulated research, unfolded in an environment marked by a natural tension between administrators seeking safety and control and doctors pioneering new treatments."

Hospital officials, who would not elaborate on the matter, have halted the procedure and overhauled the cardiac center's administration by replacing the three men.

History of success

Norwood and Murphy became colleagues long before they arrived in Wilmington.

After working together in Boston and Phila-

delphia, they developed a cardiac center in Switzerland in 1994. Norwood gained fame developing a procedure to repair hypoplastic left heart syndrome, a condition afflicting 2,500 babies in the United States each year. Previous to his discovery, it was always fatal.

Abroad, they were given autonomy, including authority to design the facilities and recruit staff.

"This sort of structure is the most powerful and effective way of dealing with all forms of complex congenital heart disease," Norwood said. "The way we have it set up, with everyone from the technicians to the surgeons doing nothing but pediatric cardiology, it all resonates, and patient outcomes improve."

After three years, Norwood wanted to set up a similar facility at Children's Hospital of Philadelphia. But administrators there balked, he said.

So, he approached duPont Hospital.

Landing a physician of Norwood's prestige with his record of groundbreaking research held the promise of bringing cardiac expertise that duPont considered crucial and could increase the stature of the hospital.

At duPont, Norwood chose 93 staff members and designed the \$5 million center, which included private rooms with space for parents. He didn't have to share staff and supplies with the rest of the hospital.

The duPont Hospital broadcast its newfound expertise and advances to the media and to investors in its annual reports. Norwood furnished the hospital with lists of his team's published research, saying it would enhance the hospital's reputation.

Use of new products

To help young patients, Murphy began using a stent manufactured by NuMED, a Hopkinton, NY - based manufacturer, Battaglia said. Over the 20 months

ending in December, he used it 20 times. Murphy thought it would be safer to use the stent instead of performing open-heart surgery. Norwood oversaw the cardiac center, but never did the stent procedure.

The stent is inserted into the heart from the groin area on a guidewire and is less invasive than surgery. Because it is still considered experimental, it needs special approval from an Institutional Review Board at hospitals, a federally regulated group of doctors and community members designed to guard patient safety. It also requires permission from parents on detailed consent forms.

There are exceptions to those rules. Doctors can get custom-made products for a patient, without the approval of the review board. In cases of so-called compassionate or emergency use, when there is an imminent threat to a patient's life and no alternative treatment, doctors are required to make a good faith effort to get permission from the Food and Drug Administration and the review board first, even if that means calling the board chairman at home.

State and hospital officials have said these rules were not followed in every case at the cardiac center. Hospital officials told state investigators that Murphy and Norwood each played a role in the decisions to use the stent without review board approval.

Murphy received most of the stents under a "custom device exemption," said Battaglia, Murphy's attorney. In July, when the FDA told NuMED to start giving the stent to doctors only in emergency and compassionate use cases, Murphy used the stent under those conditions, he said.

In all cases, Murphy asked the vice chairman of the hospital's review board whether board approval was needed to use the device, and the man told him no, Battaglia said. In the last four

cases, Battaglia said, Murphy presented a letter to the FDA from the vice chairman stating that review board approval was not needed. Neither the hospital nor Battaglia would identify the vice chairman.

In addition to following review board rules, Battaglia said Murphy told him that parents of all 20 patients signed two consent forms, one from NuMED, which stated the device had not been approved by the FDA, and one from the hospital, which was less detailed.

Earlier this week, investigators said review board approvals were not obtained in any of the cases and that the hospital did not know Murphy had acquired the stents. They said informed consent was not obtained from patients' parents in all cases.

The state Division of Public Health blamed the hospital for not knowing about the alleged violations. In response, the hospital has begun to institute reforms, including the creation of a Human Subject Protection department and other measures designed to improve oversight.

Battaglia said top hospital officials knew about the stent and the procedure, even if members of its review board did not. Norwood wrote about it in the 2002 and 2003 annual reports he submitted to hospital administrators. And a picture of the stent used during the procedure remained on the hospital Web site Saturday.

Questions about use of the stent stemmed at least in part from misplaced paperwork. The hospital could not find consent forms for some of Murphy's procedures. Officials contacted Judith and Kevin Guinan, the parents of one of those patients, about signing a new form. The Guinans' attorney, James E. Beasley Jr., said his clients did not recall signing any forms when their daughter was operated on. The Guinans filed complaints with state and federal authorities. The state investiga-

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tion indicated the hospital found a missing consent form signed by one of the Guinans in a drawer.

The state Board of Medical Practice ruled last week that Kevin Guinan signed a consent form that explained the unapproved status of the stent, which Beasley has disputed.

The doctors' dismissal was criticized by the 16 physicians who remained at the cardiac center. They signed a letter to a top hospital official asking that the doctors be reinstated. They said they doubted the center could provide the same quality of care without Norwood and Murphy.

Delicate balancing act

To doctors, some patients and parents, forging new frontiers in medicine is crucial. For hospital administrators, that has to be carefully balanced with the need for safety and oversight.

"Peer review and informed consent are intended to strike that balance. Safety also depends on responsible doctors practicing in a hospital culture that encourages employees to police their peers," said Robert Nelson, a former review board chairman at Children's Hospital of Philadelphia. The onus is on the doctors to seek necessary approvals.

The review process and other safeguards grew out of the abuses of the past, including an infamous federal study in Tuskegee, Ala., in which poor black men with syphilis were not treated so researchers could examine the disease.

To some, however, the review process is cumbersome. Patients near death want quick access to the best procedures, experts said, and doctors want the freedom to make advances.

Future uncertain

With the doctors out of a job, many parents are angry and confused. The

hospital has been trying to carefully manage its image. Norwood, Murphy and Walsh wonder about their future.

Many parents blame hospital administrators for what happened, and faithfully stand behind the doctors.

But for others, the hospital's action has raised new questions about whether there were problems with their children's care. Philadelphia attorney Theresa Blanco said five couples whose children have died at the doctors' hands have sought to obtain their medical records from the hospital. They wonder if procedures performed on their children were experimental and if alternatives were available, Blanco said.

Some parents became alarmed when they noticed that all traces of the three men vanished from the hospital's Web site after they were dismissed. The hospital hired a strategic communications firm whose clients have included Ronald Goldman, who sued O.J. Simpson, and Clint Eastwood, who sued the National Enquirer.

For comments to this article, send email to: MAYNEWS@PediatricCardiologyToday.com

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USEFUL WEBSITES

Society of Critical Care Medicine
www.sccm.org/index.asp

Society of Interventional Radiology
www.sirweb.org

Society of Nuclear Medicine
<http://interactive.snm.org>

Society of Thoracic Surgeons
www.sts.org

Sudden Arrhythmia Death Syndromes (SADS) Foundation
www.sads.org

SVS - Society of Vascular Surgery
<http://svs.vascularweb.org>

The American Telemedicine Association
www.americantelemed.org

The Asian Society for Cardiovascular Surgery
www.ascvs.org

The Association for Children with Heart Disorders
www.heartchild.info

The Children's Heart Foundation
www.childrensheart.com

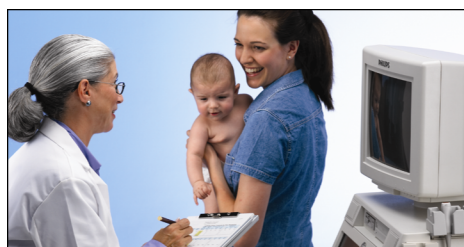
The Heart Institute For C.A.R.E.
www.hifc.com/index.php

The Society for the Internet in Medicine
www.internet-in-medicine.org

UEMS - European Union of Medical Specialists
www.uems.be

United Network for Organ Sharing
www.unos.org

VascularWeb
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PHILIPS

FOOD AND DRUG ADMINISTRATION (FDA) REGULATION OF PEDIATRIC CARDIOVASCULAR DEVICES

By John W. Moore, MD

"Trouble" at the Nemours Cardiac Center in Delaware is detailed in the excerpted April 11th article from the Wilmington Delaware News Journal. The issues apparently are centered around use of the CP Stent produced by NuMED Inc. of Hopkinton, New York. Stents are cardiovascular devices, and as such, if they are sold in the United States, companies which manufacture or import them must comply with federal regulations regarding medical devices. The CP Stent is only one of many devices useful in pediatric cardiology. All are subject to federal regulation. In this article, my goal is to provide a summary of the current federal regulations so that readers may better appreciate regulatory issues that arise as new devices are developed and applied to clinical problems in our field.

The Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act enacted in 1976 lay out the basic framework governing the regulation of medical devices. The Safe Medical Devices Act of 1990 and Amendments of 1992 modified this framework. The FDA Modernization Acts of 1997 and 2002 updated the framework to define the current regulatory environment in the United States. These laws provide the FDA's Center for Devices and Radiological Health with the power and responsibility to regulate companies which manufacture or import medical devices sold in the United States. Devices, which are implanted in the heart (ASD, VSD devices), or near the heart (PDA device), are given the highest FDA classification (Class III).

They are believed to pose significant risks to patients and are subject to the most stringent regulatory requirements.

In order to make unrestricted access available to physicians and patients, most pediatric cardiovascular devices are required to obtain Premarket Approval (PMA) from the FDA. Spon-

"The Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act enacted in 1976 lay out the basic framework governing the regulation of medical devices."

sors (usually companies) submit a PMA application to the FDA. This application usually includes data from a sentinel clinical device study having a protocol structured in accordance with FDA requirements. Studies have been multi-centered and prospective with up to 350 study patients and agreed upon controls and/or performance criteria. The FDA confers a device with an Investigational Device Exemption (IDE) which allows the device to be used in the study protocol.

There are two additional pathways which can provide access by physicians and patients to pediatric cardiovascular devices. The Premarket Notification (510K) process applies to Class II devices. Vascular devices with primary indication remote from the heart, (e.g. the Gianturco-Grifka Vascular Occlusion Device, Cook Cardiology Inc, Bloomington, Indi-

ana), may obtain approval by demonstration of "substantial equivalence" to a previously marketed or "predicate" device (Gianturco coils). Premarket Notification relies heavily on historical data and usually does not require submission of new clinical data. A second pathway is the Humanitarian Device Exemption (HDE) application. Prior to submission of an HDE application, a device must be designated a Humanitarian Use Device (HUD) by the FDA's Office of Orphan Products Development. An HUD is defined as a device intended to benefit patients with diseases or conditions that affect fewer than 4,000 individuals per year in the United States. This application is similar to the PMA application. Clinical data demonstrating device safety must be submitted, but the application does not require demonstration of clinical effectiveness. In addition, there must be no comparable device available (except another HUD or a device under study with an IDE). PFO occluders currently in use have approved HDE's.

"In order to make unrestricted access available to physicians and patients, most pediatric cardiovascular devices are required to obtain Premarket Approval (PMA) from the FDA."

Both the sentinel clinical studies of devices with IDE's (supporting PMA applications), and the ongoing clinical practice involving implants of HUD's



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(after approval of an HDE applications) are supervised by the Institutional Review Boards (IRBs) of the individual hospitals or clinical centers involved. Virtually all major hospitals have IRB's (committees), which are structured and which function according to FDA regulations. IRBs are mandated by law to protect the rights and the welfare of human research subjects. IRBs have the authority to approve, require modifications in or disapprove research, and all research involving human subjects within a given hospital or center but have appropriate IRB approval.

FDA regulations allow for use of unapproved medical devices under certain specific circumstances. "Emergency use" may occur if there is a life-threatening condition needing immediate treatment, without a generally acceptable alternative, and insufficient time to use existing procedures to obtain FDA approval for the use. "Emergency use" may occur without an IDE and without FDA approval or knowledge of the use. The "Emergency use" regulations, however, are written to allow a single or

some devices which are not made to be sold or to participate in interstate commerce may be outside the jurisdiction of the FDA regulations. The regulations recognize that so called "custom" medical devices may be prescribed by physicians, designed and built for specific individual patients, and provided at cost or as a donation for the care of the individual patients. There is no reporting requirement to the FDA for "custom devices," but here again the regulations are written to allow only a small number of unique treatment uses.

For comments to this article, send email to:
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"FDA regulations allow for use of unapproved medical devices under certain specific circumstances."

at most a small number of uses, prior to obtaining formal FDA and IRB approvals for use as described earlier. In addition there are provisions in the regulations for "compassionate use," "treatment use," and "continued access use" if a device has obtained or is in process of obtaining an IDE, but the intended use does not fall within the active IDE guidelines.

Finally, it is worth pointing out that

FDA REGULATORY INFORMATION:

The Safe Medical Devices Act of 1990

www.fda.gov/orphan/humdev.htm

The FDA Modernization Acts of 1997 (FDAMA)

www.fda.gov/cdrh/modact/modern.html

The FDA Modernization Acts of 2002

fda.gov/cdrh/ode/guidance/1216.html

Information on Premarket Approval Applications

www.fda.gov/cdrh/pmapage.html

Premarket Approval (PMA) - Device Advice

www.fda.gov/cdrh/devadvice/pma/

Humanitarian Use Devices (HUDs)

www.fda.gov/orphan/humdev.htm

Legislation Relating to HUDs / HDE

www.fda.gov/orphan/regs.htm

Institutional Review Boards (IRB)

fda.gov/cdrh/devadvice/ide/irb.shtml

Office for Human Research Protection (US Dept of Health & Human Services)

ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm

CDRH Searchable Databases Containing 510(k) and PMA Information

510(k) Database

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm

Monthly listing of 510(k)s

fda.gov/cdrh/510khome.html#listing

MAUDE (Manufacturer and User Facility Device Experience)

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

Device Listing

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm

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cords to save having to retype it. The record is then dragged to the appropriate folder.

When you need to find a patient's record, click Folder, then the folder with the proper letter. After the folder has finished loading onto the main area of the screen, click Search. You need only enter the first few letters of the patient's name and the xxxx. The program will display all records which match the search criteria. Highlight the correct name. You can then drag this folder to any of several icons at the bottom. You can choose to Print, Fax or e-mail the record using AOL. There are other icons available, but we have never used these.

Having separate folders save time for a search. One option offered under Search, is to Search all Folders. This obviously takes more time and is used only if the record is not found in the letter folder. This can occur if the record was not sent to the correct folder when first entered.

PaperPort allows for correcting errors. If a record is misfiled it simply should be dragged to the correct folder. If the name was mistyped, highlight the name and correct it. When we get a request for a patient's records, the request and appropriate authorization are scanned and added to the record. It is probably best to change the date to the current one.

Finally, it is extremely important to backup your files. We use CR-ROM recorder but if there are many records, DVD's recorder will hold much more data. We also keep a copy on a second computer as an extra safety feature. These records are legal documents and need to be preserved. We have had computers which simply stopped working. After the new PC was started

and the programs added, the backup was a life saver.

At this time, we have over 3,800 records. This occupies about 1 gigabyte and takes 2 CD-ROM's for the backups.

We think that this is a great bargain. It is speedy, cost-effective and protects patient confidentiality.

For comments to this article, send email to:
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The SVS (Society of Vascular Surgery) Vascular Annual Meeting
June 3-6, Los Angeles, CA
svs.vascularweb.org

14th World Congress in Cardiac Electrophysiology and Cardiac Techniques
June 16-19, Nice, France
www.cardiostim.fr

81st CPS Annual Conference (Canadian Paediatric Society)
June 16-20, Montreal, Canada
www.cps.ca/english/index.htm

Society of Nuclear Medicine 51st Annual Meeting
June 19-23, Philadelphia, PA
interactive.snm.org

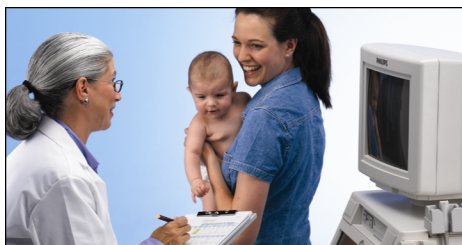
International Society for Minimally Invasive Cardiac Surgery (ISMICS) Annual Scientific Meeting
June 23-29, London, UK
www.ismics.org

American Society of Echocardiography - 15th Annual Scientific Sessions
June 26 - 30, San Diego, CA
www.asecho.org

The Barth Syndrome Foundation International Scientific/Family Conference 2004
July 7 -12, Orlando, FL
www.barthsyndrome.org

The 2004 "Specialty Review in Pediatric Cardiology" Course
July 12-15, Chicago, IL
www.uic.edu/depts/ci/pcard04

ACCF/SCAI Board Review in Interventional Cardiology
August 20-22, Atlanta, GA
www.acc.org/education/programs/programs.htm#sept2004



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