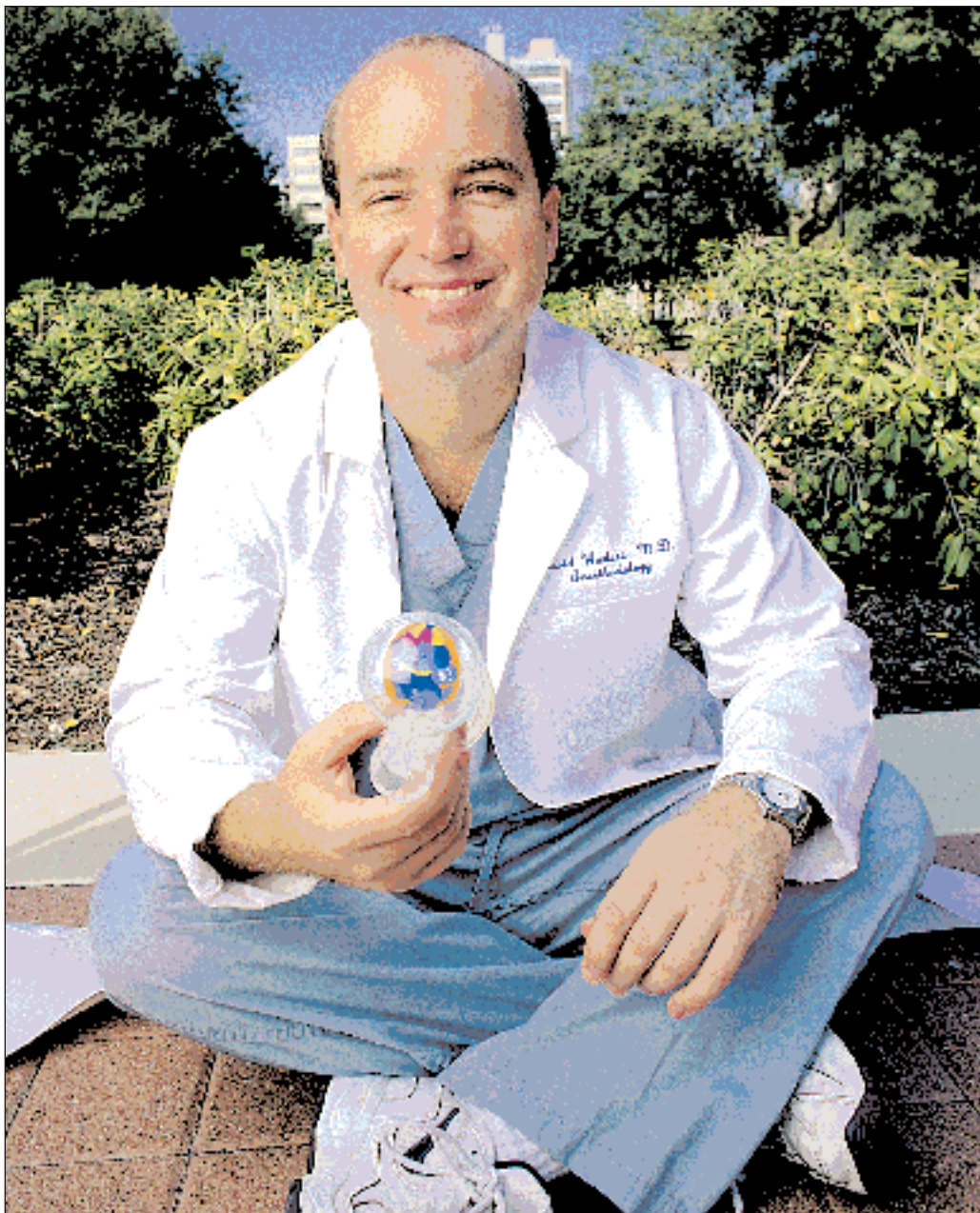


# WHAT'S THAT,



PHOTOS / PAUL FRANCIS

*Dave Warters, MD, invented a toy-like device which helps children breathe in pharmacological agents on their own.*

# DOC?

Many physicians dream of inventing techniques and tools that save lives. Few have the courage to make these random thoughts a reality. Compare your fortitude with these MD inventors' experiences.

**AS** an anesthesiologist, Dave Warters MD epitomizes success: He made the grade in a competitive field, then climbed the ladder to become medical director of operating rooms at Hermann Hospital in Houston, Texas, and associate professor at his alma mater, the University of Texas Medical School. Positive feedback was a constant companion.

But Warters is also privy to a secret many parents never know about their children. When they get into the operating room, they scream. So he, like thousands of fellow physicians who see a problem begging for a solution, stepped into a medical Twilight Zone, where criticism, negativity and skepticism rule. He became an inventor.

"Salespeople can hear 'No' a lot and it rolls off like water from a duck's back. But doctors ... I don't think so," says Joseph Hosteny, an intellectual property litigation attorney with Niro, Seavone, Haller and Niro in Chicago. "In fact, many say they forged ahead only because they didn't know how many miles of desert lie between them and success."



Warters now has crawled through that hot sand dragging his brainstorm for nine months: a toy-like device to entice a child into breathing in pharmacological agents on his own. "I was frustrated. Like most anesthesiologists, I don't like being assigned kids in the OR," he says. "You get them away from mommy, come at them with that mask and they go berserk.

Lots of us have soft hearts and we wait, cajole, wait, cajole. But your only choice at some point is to hold their head and force the mask over their face." Sedation can be an answer, but it comes with delayed awakening side effects and associated higher costs.

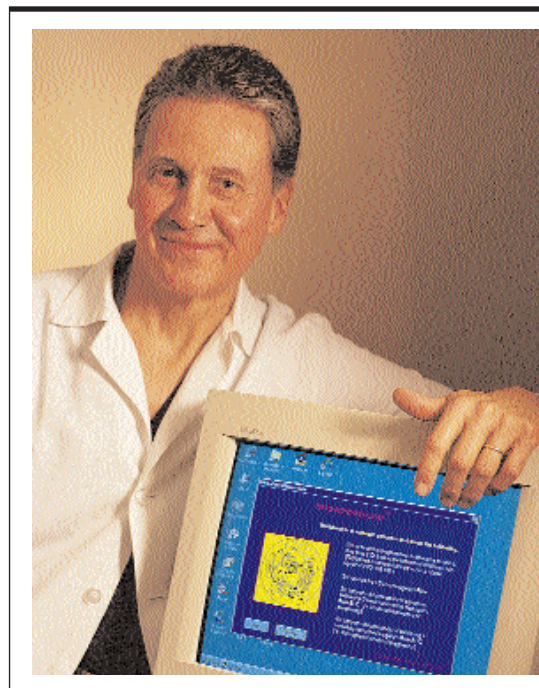
## PHYSICIAN INVENTORS

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Warters dreamed up a colorful clown's head (or carousel, depending on the patient's age) that spins when a child blows into the "game." Conveniently, the tyke gasses himself in the process. Having developed and patented a self-cleaning tracheotomy tube earlier this decade, this anesthesiologist certainly suffers no illusions of grandeur in terms of time or financial rewards this time around.

Neither did Robert Mittendorf, MD, assistant professor and director of health studies in the obstetrics and gynecology department at the University of Chicago Medical Center. His software program to improve the 160-year-old Naegele's rule for predicting human gestation began as a simple observation in the 1980s. The second-generation Irish women visiting his clinic in Boston delivered their children a week later on average than the rule predicted. Could factors like race, age, and number of children play a role? He tested his theory on the data in 335 pregnancies, then expanded to Harvard's 17,000 cases on file.

"We all have little hobby horses and sometimes they lead in directions quite



Robert Mittendorf, MD, has devised a program which predicts the likelihood of pre-term delivery based on lifestyle factors. He says persistence kept him on track when he saw richer economic opportunities pouring through his fingers. "...listen to your heart. There's something about creating...that gives you a special pleasure you can't get any other way.

different from where we started. This just kept growing," Mittendorf says. Twelve years, 10 spin-off papers and countless stacks of data later, he was ready to market a program that predicts the likelihood of pre-term delivery, which affects 400,000 births annually in the United States, based on 40 lifestyle factors. "By

identifying these women we hope to lower the infant mortality rate and medically manage patients differently based on this new information," he says. It's a likely goal; so far, Mittendorf-Williams has been twice as accurate as Naegele's rule in predicting gestation—one of the accolades *Discover Magazine* editors considered when they nominated the program for a new technological advance award in 1997.

Roy S. Weiner, MD, admits he preferred not to be in the inventor's hotseat when he developed his now-famous bone marrow and immune cell cryopreservation technique in the early '70s. (Cryopreservation involves harvesting, freezing, and storing human bone marrow and blood cell stems so that they're on hand to replace the supply destroyed by chemo-radiotherapy treatments.) But the man who spent most of his undergrad years plotting to be a German teacher was bitten by science's challenge during a summer job at a biology lab. He decided to specialize in oncology, since he was curious whether it was possible to use im-

PHOTOS: JERRY WARD (BOTTOM) AND TIM WALTERS



Roy S. Weiner, MD, developed a bone marrow and immune cell cryopreservation technique. He chose the field of oncology since he was curious whether it was possible to use immunology as a potential way to turn the body against the cancer invader.

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### Where to Go From Here

Let's get the bad news out of the way: Physicians stack up poorly against other business people in terms of patent knowledge, says Joseph Hosteny, an intellectual property litigation attorney with Niro, Seavone, Haller, and Niro in Chicago. But that doesn't mean you're doomed—merely warned. So if you have a patentable idea up your sleeve, follow these steps to beat the odds:

#### TO GET THE PATENT—

##### ✓ Plan to hire an attorney to write the patent

Many physicians are tempted to save money by writing their own patent application—after all, this is not a field that attracts the illiterate. Frankly, many doctors can write decent specifications (the written description of the invention) but Hosteny has never met a lay person who could write a good claim. Unfortunately, that claim (the legal definition of the invention) is the nut to protecting your invention. "If the claim is narrow, the patent is less valuable to a licensee," he says.

##### \* Seek an attorney with litigation experience

Ignore the old legal saw that claims good lawyers learn to write patents before they pursue patent litigation. Actually, the opposite is true. Warns Hosteny, "I'd want my patent written by someone who knows what can happen to it in a lawsuit. And believe me, they can be carved up so badly!"

By this same token, don't be stingy with your applications. One of Hosteny's clients nearly lost his shirt when he opted to file design applications and skip the utility patents on a catheter. He spent far more money with the ensuing legal cases this loophole allowed.

##### ✓ Insist on a professional patent search

Yes, the U.S. Patent and Trademark Office in Washington, D.C., is technically

responsible for this step. But when trouble arises, it's not the one who puts on a tie and shows up in the courtroom. That's why Hosteny is a big believer in hiring a professional to conduct a thorough search for prior art, earlier patents, and technical articles that might bear upon your work, so you can distinguish yourself from the pack. Otherwise, the other side will dredge this up in litigation to weaken your patent claims.

##### ✓ Throw out the paperwork

The biggest mistake inventors make is being pack rats. The minute your patent is allowed, purge your file of extraneous documents. Specifically, shred preliminary drafts and drawings of the patent, and notes on envelopes and napkins. "When you get in a lawsuit, you don't want to have to turn that stuff over," Hosteny explains. "A patent infringement defendant will use that to ask many more questions and challenge your confidence in what you own." However, do keep FDA regulatory test data and other technical test results.

##### ✓ Don't forget the maintenance fees

Once the patent is in force, you must pay maintenance fees throughout its life. The fees escalate with time: \$510 at 3.5 years, \$1,025 at 7.5 years; and \$1540 at 11.5 years if you file as a solo inventor. Miss one and kiss your patent adios.

#### TO SELL THE IDEA

#### ONCE YOU HAVE THE PATENT—

Although it can take several years before the U.S. Patent and Trademark Office issues a full-blown patent, once you have the application on file, you should start working on commercializing it. Don't get comfortable—that filing process takes a mere 30 to 90 days. After that, the more complete a product you can show manufacturers, the more likely they are to bite. But to avoid sudden death, pay attention to these land mines:

##### ✓ Check out the licensee's motives

Hosteny has nothing but sympathy for the physician who invented and patented a superior biopsy needle. He then trotted to a well-known pharmaceutical manufacturer with his prototype, who was happy to purchase the licensing rights. After all, this was an area where Company XYZ made 85 to 90 percent gross profit margins on its own needle. Buying the competition was a cheap way to insure that cash continued to flow. Today, the patented product sits collecting dust in a warehouse, and the physician received chump change for his efforts. It pays to snoop out a complementary rather than a proprietary niche.

##### ✓ Draw up a contract to protect your future

Dr. Dave Warters was spared a similarly horrible fate with his self-cleaning tracheotomy tube because he insisted on a due diligence clause in the contract. Basically, he and the University of Texas have made it too expensive for the manufacturer not to live up to its agreement. Among the areas Hosteny suggests you spell out in this contract: minimum royalty payments, demonstrated efforts to present the device at trade shows or to physicians, and minimum sales levels. Make sure the license reverts back to you at any violation of these standards so you are free to seek another manufacturer. ■

munology as a potential way to turn the body against the cancer invader.

Problem number one: He didn't have cells available to test against patients' altered ones. "I needed the tool," he says matter-of-factly. "There

was nothing out there quite good enough for me to use. I had to make it so I could continue forward in immunology and therapeutic research." Weiner, who today is professor of medicine and pediatrics at Tulane Universi-

ty and director of the Tulane Cancer Center, never patented his technique but instead published his findings. Today, he's transplanted 350 cancer patients using cryopreserved bone marrow, and more than half are still alive.

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### Persistence required

Naturally, each of these three physicians knocked his head against concrete barriers. For instance, Warters at one time had no functional prototypes of his device in his lab because excited tots literally slammed his supply into walls and broke the lot. And that was after reworking the design several times. His first mistake was in thinking four-year-olds could blow into the device with the same force as adults. He quickly discovered he'd need to reduce the resistance mechanisms. "And who would think to use it upside down?" he laughs. "But in the first tests, when a child shook it and then turned it right side up to breathe, the device jammed." This engineer undergrad thanks God and a few washers from the hardware store, among other tools, for carrying him to the next stage.

Mittendorf found he needed computer training to turn his dream into a reality, so he delved into programming classes only to discover he still lacked the necessary sophistication to tackle the job. He eventually hired computer graduate students on campus to assist him. And 25 years haven't dimmed Weiner's bad memories of bacterial contamination in the culture he invested two months of his life growing.

But most of the time, the hurdles physician inventors clear are mental and emotional. It starts, says Warters, with a conflict between your idea and the Hippocratic Oath. After all, half your patients in the required studies receive placebos—a deliberate decision to withhold what you believe to be the best care. "But you'll never get a device approved to help others until you do a controlled study. So if you believe your solution is better, you have to grin and bear it," he says.

Second, you must be the diligent sort to follow up on that idea that slides

through your brain in a fit of frustration, says Hosteny, who has personally helped four physicians patent and market their inventions. Madeleine Homan, the executive director of Straightline Coaching in New York labels this desirable trait "thinking outside the box." "A physician inventor is a person who's learned to operate within the system and yet is also wanting to go outside the system in some way," she says. "And believe me, the two are at odds."

That's because in her experience as a business coach, she's seen many physicians with inventor leanings combine two personality traits: CEO and entrepreneur. According to Homan, the CEO side calls for an autocratic mentality, and a touch of a loner's philosophy. This tendency rarely welcomes heavy-handed advice, and responds best when the ideas stem from within. On the other hand, entrepreneurs tend to involve themselves in too many things at one time, and they love to think via chatting aloud. The problem, Homan says, is that they're so bright, they rush off on a tangent after a 20-minute conversation.

If you want a coach to nurture the lost inventor inside of you, be prepared to spend anywhere from \$500 to \$2,000 a month in retainer fees. In exchange, you receive business and marketing guidance, networking savvy, political posturing lessons, a parent to nag you into taking care of your own body during this grueling process, and that wonderful pat on the back when everyone else snickers.

"You must have a passion for your idea, because the first thing physicians do is punch holes in your balloon and tell you how it won't work and it's stupid," Warters asserts. "There's never been a patent yet where everybody immediately said, 'Yeah, it's a great idea!'" That's why persistence — more than creativity or resources—tops Warters' list of attributes to pack on an inventing journey.

Homan concurs. "Many creative people think, 'My God this is a brilliant idea. Why aren't I simply rewarded for it?' Because ideas are a dime a dozen. No one cares," she says. "Show me the work, the structure, your plan and ability to stick to it for 10 years. Then I'll show you success."

That's a tall order in an extremely results-oriented profession, and while medical school puts physicians through the slog, it also provides the necessary structure and consequences for not living up to standards. In an inventor's case, no one blinks if you don't get up at 5 a.m. to work on your business plan.

So raw persistence helped Weiner cope with those days "when my wife raised my three children," as he phrases it. Nothing else, he adds, could have sent him into the lab in the evenings and weekends after already putting 12 solid hours into academia and an oncology practice.

Mittendorf credits persistence for keeping him on track when he saw richer economic opportunities pouring through his fingers. "Doctors can certainly generate a lot more money by seeing patients, doing surgery, doing deliveries," he acknowledges. "But listen to your heart. There's something about creating—no matter what it is, the scope or how others feel about it—that gives you a special pleasure you can't get any other way."

### Pay Ups and Pay-Offs

If a patent is in your future, so is a \$10,000 check drawn against your account and secured with your signature, says Hosteny. For that, you can count on a well-written patent that's been decently searched (see "Where to Go From Here,") ). Assume at least another \$10,000 minimum, for production of an uncomplicated prototype to give your claim teeth as you search for a licensee.

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And the Chicago lawyer refuses to even guess at a dollar figure to cover the airplane tickets, hotel bills, and lost wages as you peddle this gadget to prospective manufacturers. (One of his clients, a physician with a dialysis catheter design, spent four years at this stage.) Many physician inventors say they finance their idea as a hobby, pouring leisure money that colleagues spend on golf into plastic molds and test tubes.

Warters solved the out-of-pocket dilemma by snuggling under the University of Texas' umbrella. In this arrangement, an intellectual properties committee rules whether it wants the technology. If yes, the university foots the upfront legal fees. Should the invention reap profits, Warters pays back those costs, then splits the remaining dough 50/50. Not all universities are as generous as Texas in this split, however, he warns. If the committee declines to participate, the inventor pays his own way but only shares 25 percent of future royalties with the university. In both cases, he's on his own for research and development funds. Warters has been lucky enough to rely on his departmental budget since he has the engineering knowledge to build his own prototypes.

Hosteny fears the limitations such arrangements can impose on future controls. Universities have a reputation for saying, 'It's our invention but we don't think it's worthwhile so we won't file a patent application on it.' You're stymied," he explains.

Warters disagrees. In his mind, it's better to work with the devil you know than the one you don't. "There are unscrupulous manufacturers who will railroad over Dave Warters but they won't mess with the State of Texas. The fact that it's the Attorney General who will get pissed off should they infringe on our patent makes me sleep at night."

Physicians do hold one trump card

other inventors rarely see: They create within their fields, so the object's usefulness is a given. But nothing excuses doctors from the marketing and sales aspect—a commercial concern that should be on your plate from the get-go, says personal coach Homan. This is precisely where Mittendorf's train ran out of steam. Flummoxed by the cost of print ads in national journals, he was forced to piecemeal his campaign. As a result, the obstetrician has sold hundreds, not thousands, of copies at \$49.95. "I really can't consider it an economic venture," he adds. "So I've donated all my proceeds to one of the women's support groups at the hospital."

Likewise, Warters hasn't realized a profit from either of his inventions, and is simply hoping delayed gratification kicks in at some point. "Inventions are like buying a lottery ticket. If you win, the rewards are worth it!" he notes.

For now, Warters' sweat pays off whenever a test child recalls surgery as a blur rather than nightmare. "I get a great deal of pride from walking into the OR with this device knowing it can make the next few minutes bearable for all of us," he says.

Mittendorf understands that personal glow; his path not only allowed him to indulge in another secret love—writing—it also took him to Heidelberg, Germany, where he followed Naegle's life during this process. "It's exciting to start with an observation, confirm it, then to see it grow," he says. Oh, and the occasional public recognition from television interviews is a pleasant perk, too.

Weiner seconds that emotion. Although the oncologist never received a thank-you from cancer survivors under other physicians' care ("Why should I?" he asks philosophically. "If you're diabetic, do you write to the heirs of the person who developed insulin?"), his own international roster of patients compen-

sates for that lack. Recently, a testicular cancer survivor e-mailed him a photo of his biological son. Another fellow honored the doctor by naming his daughter after Weiner's wife.

Yet these warm and fuzzy moments don't hold as much sway with the humble doctor as the insight the inventing exercise brought to his practice. "My patients' good and bad news is an emotional roller coaster," he says slowly. "In a laboratory, I could look at the big picture. If there were a week or so when everything went horribly wrong (in the lab), it never got to the inner me as much as when one of my patients has a rough time.

"I see myself looking at several glasses, all half-full. I enjoy the positive aspects of everything I do, and the totality is greater than if I were to devote 100 percent of my energies to only one," he sums up. ■

*Julie Sturgeon placed first this year in Writer's Digest national feature article contest. She specializes in profiles and business writing.*