stat

COMING //

- **JANUARY 1:** Viagra and other erectile dysfunction (ED) medications will no longer be covered by most Medicare prescription drug plans. Exceptions will be made for ED drugs approved for such nonrecreational uses as treating pulmonary hypertension.

- **THROUGH MARCH 2007:** Artist Ted Meyer, who as a child battled a genetic disorder that necessitated the removal of his spleen, has turned surgical scars into beauty marks. "Scarred for Life," at the National Museum of Health and Medicine in Washington, D.C., showcases his monoprints taken from the scars of people who have undergone surgery for lung removal, a liver transplant and more.

TIM SLOAN/AFP/GETTY IMAGES

FOCUS // **MASTER OF DISGUISE** For 15 years, Robert Barron created masks for the Central Intelligence Agency, helping agents disappear into the shadows. Since his retirement in 1993, he has used his talent for a different purpose: bringing men, women and children disfigured by trauma, disease and congenital defects out from hiding. Made of silicone and painstakingly hand painted, Barron's removable prosthetic ears, noses, fingers and faces—held in place by magnets, adhesives or screws—are nothing short of transformational. ■

INTERVIEW //

Kidneys for Sale

BY REBECCA SKLOOT

Every day, as some 17 Americans die waiting for donor organs—mainly kidneys—more and more terminally ill patients are turning to the black market. Now Amy Friedman, a transplant surgeon at the Yale University School of Medicine, and her father, Eli Friedman, a kidney disease pioneer who created the first dialysis center in New York City, have proposed a solution to make up for the organ shortfall, a solution that's currently illegal: paying living donors. Here, Amy Friedman answers the practical and ethical questions.

PHOTOGRAPH BY HENRIK OLUND

Q: Is money the only solution to the organ shortage?
A: The best solution is for the public to donate organs. But it's just not happening. Public relations campaigns and drivers' license designations haven't increased postmortem donations. And, thankfully, helmet laws, falling crime rates and medical advances have decreased the number of donations. Right now, the largest source of organs is of less-than-ideal quality, such as deceased people as old as 65.

Q: How much better are live organs rather than postmortem ones?
A: Live organs offer a much better chance of survival and longer functionality because we use only healthy live donor kidneys. They're also transplanted directly from person to person, so, unlike postmortem organs, they're never away from a blood supply for a long time.

Q: What dangers does a black market pose, besides being illegal?
A: It is not known who, if anyone, reviews donors' medical conditions to make sure they won't be harmed by loss of an organ. The organs may be inadequately screened for infectious diseases or cancer; they may be poorly matched to the recipients; and they may be handled by unregulated or inferior surgeons.

Q: In the February 2006 issue of *Kidney International*, you and your father proposed legalizing the purchase of kidneys.
A: Our case hinges on the proposition that people are entitled to control their bodies, even to the point of risking life. The military is a prime example. You enlist with the clear understanding that you're risking your life in return for money—and if you die, your family gets a death benefit. That is not ethically distinct from what we're proposing. Neither is a woman's choice to sell her eggs.

Q: What about other organs?
A: In the future, we could see paying live donors for segments of liver or lung, and potentially intestine. But the risks are higher.

Q: How would you compensate postmortem donors?
A: Some have proposed paying funeral costs when they die rather than

giving cash. You wouldn't want money motivating people to contribute to a family member's death.

Q: What would a live kidney cost?
A: Some economists have established a "market price" of $45,000.

Q: Who would pay?
A: Medicare, Medicaid and private insurers. And a third-party payment system would introduce a tremendous equity in today's black market or legal allocation system.

Q: Would legalizing payment for organs create a system in which the poor sell their organs and shoulder most of the risk?
A: Probably, but our society has already accepted that idea: It's primarily poor Americans who risk their lives in the military and poor college-age women who sell their eggs and face infrequent but serious health risks.

Q: If a kidney costs $45,000, but people still have to go through an allocation system, what's to stop them from paying $100,000 to get around it?
A: They'd have to find a center to transplant it. With this federal system, it would be illegal for a surgeon to do that. Where it gets stickier is when someone with an illegally transplanted organ needs follow-up care. We're ethically responsible for treating them. Are we encouraging the black market by doing that? Maybe. But what else are we going to do?

Q: Have any of your patients gotten black market organs?
A: Yes. I can't say I blame them. Waiting for a legal organ often ends in death.

Q: Should people make a profit from their organs?
A: When someone donates an organ, everyone benefits financially except the donor. The recipient gets to live and go back to work and make money; the transplant surgeon, anesthesiologist and hospital administrators get paid. Even Americans save money since we pay for the Medicare that covers kidney failure treatments that patients will no longer need after transplants. Isn't it hypocritical that everybody except the donor receives tangible benefits?

> I can't blame some of my patients for getting black market organs. Waiting for a legal organ often ends in death.

Q: How soon will this change?
A: Changing the situation would involve legislation. But the issue is quite a hot potato—I don't see any politician touching it any time soon.

Q: How did you end up working on this with your father?
A: My mother had a kidney transplant in 1980. We experienced the desperation of waiting for an organ and the incredible impact of getting one. ■

BY THE NUMBERS //
Supersize Hospitals

30 Percentage of Americans (20 years of age or older) who are obese (with a body mass index of 30 or more)

64 Percentage of hospitals that reported (in a 2005 survey) an increase in the number of admitted, severely obese patients from the previous year

10 Percentage of hospitals surveyed that have remodeled facilities to accommodate obese patients, including enlarging doorways and equipping rooms with lift systems

1,000 Approximate number of pounds that are supported by bariatric devices, such as extra-large beds, wheelchairs and floor-mounted toilets (wall-mounted toilets support roughly 300 pounds)

700+ Projected sales worldwide, in millions of dollars, of bariatric surgical devices by 2013

4.7 Projected overall sales by 2013, in billions of dollars, of prescriptions for the management of obesity

6 Number of people it takes to turn over a very large patient in bed

85 Percentage of hospital staff back injuries linked to caring for heavy patients

732 Average number of dollars added to an obese person's medical bill each year, 37% more than that of people with normal weight

75 Estimated cost, in billions of dollars, that the United States spent in total obesity-related medical costs between 1998 and 2000, half of which was paid by taxpayers ■

INFOGRAPHIC //

Experimental Deficit

BY ERIC L. REINER // INFOGRAPHIC BY JOHN GRIMWADE

First it was call centers and computer operations. Now U.S. pharmaceutical companies are sending clinical trials offshore to cope with the shortfall of willing subjects at home. Here, a look at the effects of outsourcing, for both good and ill.

THE OUTSOURCING EQUATION

INCREASED DEMAND...

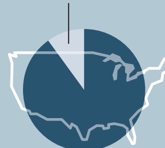
In the United States, demand for research volunteers has grown because of increased drug development and because many trials require more subjects than ever. A larger sample size helps uncover rare side effects and shows a new drug's small improvement over an existing one.

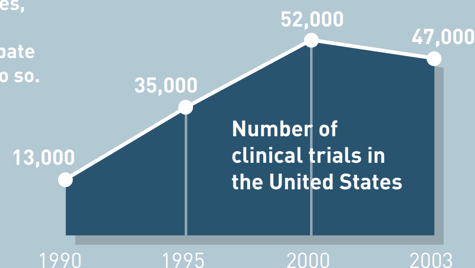
Average Number of Patients per Study

...PLUS DIMINISHED SUPPLY...

The estimated number of clinical trials going on during any one year varies wildly—from **8,000** to **80,000**—and as a result, so does the estimate of trial subjects needed. Regardless, recruitment is difficult: It consumes **40%** of the approximately **$450 million** required to conduct a trial for a new drug.

In the United States, only 10% of those eligible to participate in clinical trials do so.

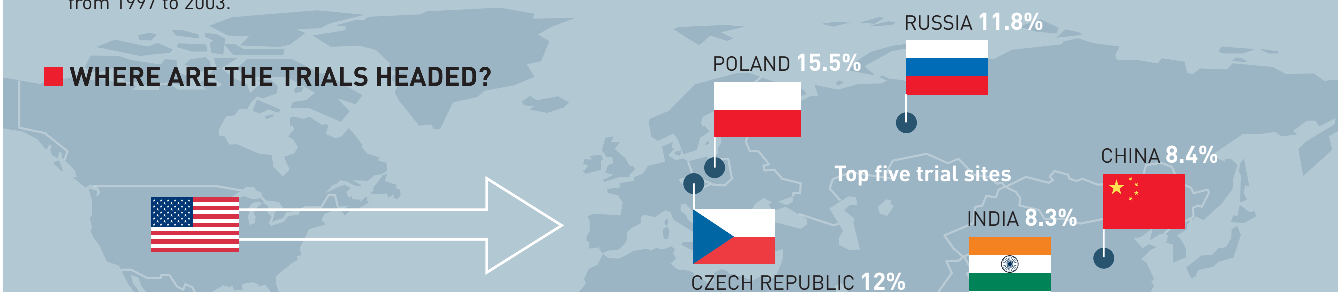




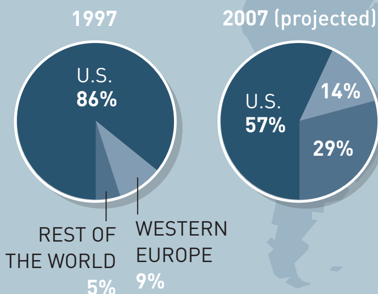
...EQUALS TRIAL DELAYS

- Only **6%** of trials finish on time.
- The number of U.S. trials running on schedule decreased by **12%** from 1997 to 2003.
- The number of U.S. trials that were delayed longer than one month increased by **12%** from 1997 to 2003.

WHERE ARE THE TRIALS HEADED?



Share of investigative sites



WHAT DOES IT ALL MEAN?

PROS

- Pharmaceutical firms can recruit large numbers of research volunteers relatively quickly.
- Trials are much less expensive, saving pharmas **40%–60%** per research participant.
- Study participants in poor countries get medicine they might not otherwise receive.
- In some countries, the local government requires that the host population receive early access to the drug being tested.
- Subjects tend not to be on other drugs, reducing drug interactions that could skew results.

CONS

- Although foreign data must ultimately measure up to FDA standards, the trial process is not monitored as closely as in the United States.
- Foreign institutional review boards may not always uphold ethical or scientific standards.
- The outcome of studies done with one racial group may not always apply to other groups.
- Unsophisticated subjects could unwittingly be put at risk because they may not understand the consent process or even the treatment they're being given.

SOURCES: CENTER FOR INFORMATION AND STUDY ON CLINICAL RESEARCH PARTICIPATION; TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT; FORTUNE; BCC RESEARCH; MCKINSEY CONSULTING

ON THE BLOGS //

Frontline Frustrations

Caring for patients is what registered nurses signed up to do, not dealing with patients' inconsiderate families, defensive colleagues and red tape, as these nurse bloggers explain.

A TALE OF TWO FAMILIES

Adapted from a September 13 posting at codeblog.com by RN Geena.

We recently had a patient in the ICU for more than three months. It was clear that she would never leave the hospital. Yet the family was adamant that everything be done for her. That family was there every day to watch her deteriorate. At least they were taking responsibility for their decisions.

Yet a few rooms down, another patient is in a similar situation. He has written notes saying he's ready to die. The family won't accept it.

The difference? The family very rarely comes to see this patient. They've put him in hell, and now they won't watch it. They aren't present for the times he coughs and needs suctioning. They aren't there to step out of the room so that we can clean up his incontinent bowel movements. They just aren't there.

STAYING OUT OF COURT

Adapted from an October 10 posting on disappearingjohn.blogspot .com by RN John, in Phoenix.

I cannot get my head around the concept of providing care based on protecting myself from litigation and/or losing my license. This week, I had to deal with this defensive nursing attitude. It involved "wasting" a narcotic. If we use less than the dispensed amount, another RN has to waste the leftover med with us; this involves his or her witnessing your dispensing of the remainder.

This nurse took a TB syringe, withdrew the waste, and said that I wasn't wasting 5mg, but really only 4mg. I showed her a small drop or two in the vial that must have made the difference. "Lighten up, will you?" I said. She responded: "I worked too hard for my license...No one will take it away from me!" Gee. I wasn't trying to, okay?

MEDICARE-IMPAIRED

Adapted from an October 16 posting on pkblogs.com/digitaldoorway by RN Keith.

"Do you mean to say that even if my patient needs a walker to get up out of his wheelchair he doesn't qualify?" I asked incredulously of the Medicare representative. The answer was affirmative.

"Do you also mean," I continued, "that a patient who becomes more ambulatory should remain confined to a wheelchair because Medicare feels the paltry cost of a walker is just too much to provide?" I was informed, that yes, in Medicare's view, he should stay in the wheelchair. I hung up the phone and put my face in my hands.

What bureaucratic nightmare will I encounter tomorrow? And what is a lowly nurse, a mere cog in the health care wheel, to do? Let's hope that no faceless bureaucrat at Medicare is scheming even more insidious ways to diminish the quality of life of its recipients. ■

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MILESTONES //

Calling Dr. Kildare

Forty-five years ago, the television series *Dr. Kildare* introduced a genre—the medical drama—and the first physician-hero to the American viewer. Medical-drama characters may have evolved from saintly to sexy, but at least one aspect of these shows has remained constant: Health care professionals have tried to ensure the accuracy of the medicine being portrayed.

Richard Chamberlain, who played Dr. Kildare, recalls receiving a medical education of sorts. "I had to learn to handle all kinds of paraphernalia," he says, and he remembers being shown how to listen to a heartbeat with a stethoscope and administer cardiopulmonary resuscitation. He also observed open-heart surgery and accompanied doctors on rounds at UCLA Medical Center.

The producers of *Dr. Kildare*, wanting art to at least approximate life, could turn to the Physicians' Advisory Committee for Radio, Television and Motion Pictures, a group created by the American Medical Association (AMA) in 1955. During almost four decades—it disbanded in the early 1990s—the committee helped establish TV doctors as credible characters.

Even today, the public takes its medical shows seriously. A 2000 study by the U.S. Centers for Disease Control and Prevention found that more than half of the Americans who regularly watch prime-time TV said they counted on medical dramas to present accurate health information. And a study published in the journal *Health Affairs* in 2001 revealed that nearly 15% of survey respondents said they had contacted a physician about an ailment based on what they had seen on *ER*.

Writers today still attempt to create medically accurate dialogue, and technical advisers teach cast members how to wield instruments. But that doesn't stop producers from fudging inconvenient details such as letting actors scrub for an operation without face masks and neatly resolving each story at the end of an episode, says Chris Hutson, a registered nurse who was a technical adviser on the 1960s show *Ben Casey*. "Most patients," Hutson notes, "are cured at the end of the hour."

Still, a medical drama is nothing without the drama, and most viewers probably expect fictional doctor shows to take some artistic license. For former AMA president Edward Hill, a bigger problem is with a new genre of "extreme makeover" medical reality programs. Hill is concerned that they encourage unrealistic expectations and minimize the seriousness and risks of many treatments. "In these shows, the reality is that everything doesn't come out perfectly," he says. ■

UPDATE //

Hindsight Is 20/20

BY IVAN ORANSKY

Disgraced stem-cell scientist Woo Suk Hwang has become exhibit A in the case for tightening scrutiny of apparent medical advances.

One year ago, just as controversy descended, *Proto* published an interview with South Korean stem-cell scientist Woo Suk Hwang. He had not cloned human embryos and created stem cells from the clones, as he had claimed, and he had paid women for their eggs—violations that resulted in an ouster from his post at Seoul National University and the retraction of two papers from the journal *Science*. Now on trial in Korea, Hwang is charged with fraud, embezzlement and bioethics law violations.

The scandal led to a predictable amount of hand-wringing over the role of scientific journals in rooting out fraud. But with the benefit of hindsight, what aspects of Hwang's behavior should have raised red flags?

Image manipulation might be on that list. One photograph in the 2005 *Science* paper purported to show that a particular protein normally found on adult cells was not present on the surfaces of the pictured cells—thus proving they were stem cells. But two images submitted for publication with the paper were identical (thus duplicates). Mike Rossner, managing editor of *The Journal of Cell Biology*, says he likely would have noticed this during his usual screening process for images submitted to his journal, and that it would have led to a request for the original image data from the authors—not a fail-safe, because they could have submitted other faked images. Indeed, *Science* editors noted that the duplicates were sent when *Science* requested higher-resolution photographs.

This wasn't the only instance of deception. After the 2005 paper was submitted, peer reviewers asked Hwang's laboratory to carry out DNA fingerprint testing—an analysis of particular genetic sequences known to differ greatly between individuals—to prove that the stem-cell colonies matched the human cells from which they were supposedly cloned. In the published paper, however, the fingerprint data were so similar because they were in fact created with the DNA from each of the original human cells, according to the report by the committee at Seoul National University that investigated Hwang's work.

In a 2004 paper, Hwang claimed to have cloned a human embryonic cell and then to have derived embryonic stem cells from that clone. He said the clone he produced had come from the nucleus of a somatic cell (any cell in the body except sperm, eggs and the cells that make them) from the same woman who provided the eggs. That, scientists said, would have rendered meaningless one test of the clones' authenticity—a comparison of mitochondrial DNA—and made it impossible to tell whether the cell line was derived from the cloned embryo, as they claimed. (In a clone created from another donor egg, the mitochondrial DNA would have been different from that of the somatic cell donor.) Subtle, but a red flag nonetheless: To support their claim that they had created clones, other scientists might have used eggs and somatic cells from different women.

PHOTOGRAPH BY TONY LAW

More blatantly, perhaps, in the 2004 paper Hwang claimed that establishing the first human cloned cell line required 242 eggs. But for the set of experiments he performed for the 2005 paper, that number fell to 17 per cell line. Cloning is extremely difficult in humans for reasons unknown; not even a vastly improved technique could account for such a low figure. In fact, as many as 1,100 eggs may have been used in the 2005 study.

Such transgressions would be hard for a co-author to miss—unless that co-author never saw the results or participated in the experiments. Such was the case with Gerald Schatten, a University of Pittsburgh researcher who is listed as senior author on the 2005 paper. *Science* is now considering requiring each author to make a statement describing his or her contribution—a move that might raise a red flag if an author is forced to acknowledge zero participation. (A panel at the university found Schatten guilty of research misbehavior.)

Whether editors of scientific journals will learn lessons from the Hwang case remains to be seen. Some are incorporating image screening into their procedures, and others say they will look more carefully at original data. In November an independent panel convened by *Science* recommended that the journal apply special scrutiny to papers that are likely to generate a great deal of public attention. Editors are clearly shaken, but many seem to consider rooting out fraud the responsibility of universities rather than journals. ■

THEN VERSUS NOW //

Can You Hear Me Now?

For centuries the hard of hearing relied on devices that looked more like jazz instruments than today's dime-size hearing aids. The construction of those early devices, such as the ear trumpet, was decidedly low-tech.

More unusual contraptions emerged throughout the nineteenth century, with clever designs to conceal hearing aids in objects such as centerpieces and canes. The acoustic urn (above left) channeled sound from all corners of a room while disguising itself as a tabletop decoration. The first electrical hearing aids were developed in the late 1800s using a carbon microphone, but it was not until the 1930s and 1940s that a portable device was developed.

In recent years hearing devices have grown smaller but possess improved sound quality. One lingering problem, however, is the feedback and static that result when a wearer uses a cellular phone. One company has solved the problem by adding Bluetooth to turn the aid itself into a phone. ■

THE CUTTING EDGE //

A Certain Glow

Having blood drawn or an IV port inserted is, for some, the most painful part of a checkup or hospital stay. A patient's hard-to-find veins can thwart even the most experienced phlebotomist, and too much poking and prodding can cause nerve damage or infection.

To solve the problem, Memphis biotech company Luminetx has developed the VeinViewer, which beams harmless near-infrared rays that are absorbed by hemoglobin in the blood but reflected by surrounding tissue. A digital video camera in the VeinViewer captures this information, then its imaging system enhances and projects a small rectangle of light back onto the skin's surface. The result is a virtual map of a patient's vasculature.

Each person's "map" is unique, a fact that Luminetx subsidiary Snowflake Technologies is using to develop biometric applications for the VeinViewer. One day, perhaps we'll stick our hands under the device's green light not only at the doctor's office but also at the office or airport. ■

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