

and State Subcommittee. I say this because Scott Corwin was married in Portland, OR, on August 24. His bride, Kristen, has been out in Oregon since that time, waiting for Congress to conclude the people's business and recess sine die.

So, I note that while we are very sorry to hear that Scott Corwin is leaving our CJS Subcommittee and Washington, DC to return and live in Oregon—I'm sure that he is happy and we should be happy for him.

Getting right to the point, Scott Corwin is the consummate professional. He is a graduate of Dartmouth College in Senator GREGG's home State, and a graduate of the University of Washington Law School. Even though his roots are in the Northwest, Scott came to Washington, DC to work for Ambassador Bob Strauss' law firm in 1987. Since 1991, he has served our distinguished chairman, MARK O. HATFIELD. Since February 1995, Scott has served on our State, Justice, and Commerce Subcommittee.

Mr. President, Scott Corwin is the type of dedicated public servant who is so essential to our legislative system. He was assigned a number of appropriation accounts ranging from the U.S. attorneys to the Supreme Court to the Maritime Administration. Scott is a quick study and he dug into the details and specifics of these agency programs and budget requests. He soon mastered the details and became a real appropriator.

It became obvious to me and other Members that Scott came to truly care about the agencies that were under his review on behalf of Senator GREGG and the majority. Scott was the first to ferret out soft dollars that are unnecessary. But, he also stood up for programs that deserved our support. He was especially tenacious in his defense of small agency programs, like the Marine Mammal Commission—which the House of Representatives has proposed to cut significantly. In the case of agencies like the National Oceanic and Atmospheric Administration, we were fortunate to have someone so knowledgeable in earth sciences, fisheries, and oceanic research.

Scott Corwin will be missed on both sides of the aisle. It will be hard, if not impossible, to find such a talented individual to take his place. We wish him all the best as he returns to Oregon along with my friend, Senator MARK HATFIELD.

MEDICAL PROCEDURES PATENTS

• Mr. FRIST. Mr. President, I am very pleased that the omnibus appropriations bill being considered today includes S. 2105, legislation I introduced regarding the enforcement of patents for pure medical procedures. I greatly appreciate Senator GREGG's efforts to include this provision.

Patent law has been a cornerstone of both law and economics since the founding of our Nation. The issuance of

patents was one of the few powers expressly granted to the Federal Government by the Constitution.

Patents allow inventors to recoup their investment and thereby encourage continuous innovation. Without the protection of patents, individuals, and businesses would be reluctant to invest their time, money, and energy into developing new technologies.

While the appropriateness of patents in general has long been established, it has been somewhat controversial with respect to health care. Initially, the medical community took a dim view of the patentability of therapeutic drugs or devices. Many felt that it was morally wrong to profit from improvements in medical care. For instance, the first application for a patent on aspirin was denounced as an attempt to blackmail human suffering.

In time, however, the medical community and others came to realize that, without the benefit of patent law, many improvements in medical care would never materialize.

As in other areas of human endeavor, improvements in health care often require significant investments of time and money. Without the ability to recoup these investments through patents, critical research, and development would never get off the ground.

The appropriateness and importance of allowing patents for pharmaceuticals and medical devices is now well-established. But the appropriateness of patenting medical innovations that do not involve drugs or devices but are simply improvements in surgical or medical techniques remains highly controversial. I think for good reason.

Unlike innovations in medical drugs and devices, innovations in pure procedures—such as discovering a better way to suture a wound or set a broken bone—are constantly being made without the need of significant research investments.

Allowing a doctor to enforce a patent on such improvements would have disastrous effects. Furthermore, innovations in surgical and medical procedures do not require the midwifery of patent law. They will occur anyway as they have throughout history.

My legislation would prevent the enforcement of so-called pure medical procedure patents against health professionals. It would in no way, however, change patent law with respect to biotechnology, medical devices, drugs, or their methods of use. As a result, this narrowly tailored legislation would in no way discourage the important research being done in these areas of medicine.

I intended to offer my legislation as an amendment to the Commerce, Justice, State appropriations bill because a related amendment was offered by Congressman Ganske when the House considered this bill. That amendment—which passed overwhelmingly by a vote of 295-128—took a very broad brush approach. It would have prohibited the

Patent Office from issuing any medical procedure patents.

Because the scope of the Ganske amendment was not clearly defined, it could have impacted many worthwhile patents in biotechnology and pharmacology. Accordingly, representatives of these industries came to me after the passage of the Ganske amendment to express their interest in crafting an alternative approach. The legislation included in this bill is the result of that effort.

Because the Commerce, Justice, State appropriations bill was never considered on the Senate floor, I did not have the opportunity to offer my legislation as an amendment. I am pleased, however, that this legislation was nonetheless included in this omnibus bill as an alternative to the Ganske language.

My legislation enjoys the support of the American Medical Association as well as numerous medical specialty groups that are very concerned about this matter. And, while the biotech and pharmaceutical industries opposed the Ganske amendment, they were instrumental in crafting this narrower approach.

The need for this legislation stems from the recent case of Pallin versus Singer. The facts of this case are very compelling. In performing cataract surgery, an ophthalmologist by the name of Dr. Pallin chose not to stitch the cataract incision because the patient was experiencing heart problems.

When Dr. Pallin later discovered that the incision healed better without the stitch, he sought and was awarded a patent for "no stitch" cataract surgery. Dr. Pallin subsequently sought to license this procedure for a fee of \$4 per operation. Although the no-stitch procedure was widely used, few surgeons were willing to meet Dr. Pallin's demands.

In 1994, Dr. Pallin brought a patent infringement suit against another eye surgeon and his affiliated hospital. After incurring nearly \$500,000 in legal defense costs, a settlement was finally reached. The settlement, however, does not foreclose the prospect of future lawsuits of this kind.

There is legitimate concern that Pallin represents the future unless we nip it in the bud.

My legislation is very narrow in scope. It would simply prevent the enforcement of patents against health professionals or their affiliated facilities for pure procedure patents such as Dr. Pallin's. It does not impact in any way the patentability of medical devices, drugs, or their methods of use.

This change in law is essential. Allowing health professionals to be sued for using innovations in pure medical or surgical procedures would have four disastrous consequences.

First, health care costs would explode if doctors charged licensing fees for every new surgical or medical techniques they developed. There are thousands of new medical and surgical techniques developed every year.

Permitting innovative doctors to charge a fee every time their new technique was used would be a windfall for the doctor but a huge and costly burden for the patient community. Because these innovations would occur anyway, these additional costs would be wholly unnecessary.

Second, it would greatly jeopardize patients' right to privacy. In order to know if a patent was infringed upon, patent holders could demand access to surgical notes and other detailed medical records to know precisely what kinds of procedures were used. Not only would this raise serious privacy concerns, but providing all of these records would be an administrative nightmare.

Third, allowing pure procedure patents would undermine the medical community's tradition—and ethical duty—of freely exchanging information for the benefit of patients. As a surgeon, I know first hand that medical training involves a very important social contract between health professionals. Making improvements in surgical or medical care and sharing those innovations with others is a critical part of the medical profession's commitment to advancing its art.

I was fortunate enough to innovate in my capacity as a heart transplant surgeon, but I always understood that my innovations were possible because I stood on the shoulders of giants.

I was able to advance the science of heart transplants because I had the benefit of superb teachers who themselves were great innovators. For me to have sought patents on new surgical techniques would have violated this social contract.

Fourth, it will open the door to FDA regulation of all aspects of medical practice.

While the FDA regulates medical devices and pharmaceuticals, it has no authority to regulate the general practice of medicine. The response to those who have advocated comprehensive FDA regulation of medical practice has been that checks and balances already exist to assure that patients receive appropriate care. One of those checks is the peer review process. If we undermine the peer review process but injecting patent-seeking into the heart of the practice of medicine, we will have opened the door for proponents of more expansive FDA regulation.

If we accept the argument that innovations in pure procedures should be treated no differently than innovations in drugs or devices for purposed of patent law, we open ourselves up to the argument that they should be treated no differently for other purposes as well—including FDA regulation.

Not only would pure procedure patents have disastrous effects on health care, they are unnecessary to encourage innovation.

It is important that we not lose sight of the underlying purpose of patent law. Its function is not to reward innovations after the fact. Its purpose is to

encourage innovation that would not occur otherwise. This rationale does not apply to innovations in pure medical and surgical procedures because such innovations have and will continue to occur without the benefit of patent law.

Further, unlike innovations in medical devices or drugs, pure-procedure innovations do not require huge investments of capital. As Dr. Pallin's no stitch cataract surgery indicates, most breakthroughs are discovered in the course of treatment. This is partly why the AMA's Code of Medical Ethics holds pure-procedure patents to be unethical.

Doctors have an ethical duty to seek the best care for their patients. This includes the duty to innovate when necessary. Also, recognition among one's peers for innovation and excellence is a tremendous incentive for doctors. Every doctor wants the cachet of publishing an article in a medical journal detailing their innovation. Finally, to augment these private motivations to innovate, millions of dollars in public and private grants are available each year to advance pure-procedure technology further.

As a result, not only would allowing pure procedure patents to be enforced against doctors be detrimental to health care, it would not serve the underlying purpose of patent law which is to encourage innovation.

In closing, I want to thank Congressman GANSKE with whom I have been working for the past year on this important subject. His amendment provided the impetus to address this important matter in the waning days of this Congress.

I also want to thank Senator GREGG and his staff for their strong support. Without Senator GREGG's commitment, this legislation would not have been possible.

Finally, I want to assure opponents of my legislation that I take seriously their concerns and will be the first to join them in revisiting this issue if its unwitting effect is to chill medical innovation. While I do not believe this will be the effect, I agree that it warrants a watchful eye. ●

MEDICARE BENEFICIARY SHARES CONCERNS ABOUT THE NEW DOLE PLAN

Mr. ROCKEFELLER. Mr. President, a few weeks ago, a number of my Democratic colleagues and I held a forum on how former Senator Dole's economic plan would affect the Medicare Program and the 37 million people who rely on it for their health care needs. Unfortunately, there have been no formal congressional hearings to examine the consequences of this mammoth plan on the lives of the American people, or in particular, on Medicare beneficiaries.

Our forum heard from highly respected economic and health care experts who warned us that the Dole plan

would require deep cuts in Medicare, which would force major changes in the program, cuts in payments to the professionals and institutions that provide Medicare services, and reductions in the quality of the medical care provided to Medicare beneficiaries. In my view, this is one of the most obvious and compelling reasons to do everything possible to prevent the Dole economic plan from ever becoming reality. It astounds me that we are seeing this revival of a supply-side proposal that once again puts Medicare on the chopping block in order to pay for tax relief for the wealthy.

We also were privileged to hear from an extraordinary senior citizen and Medicare beneficiary, Betty Miller. Betty Miller told us that the Medicare cuts required to pay for Dole's tax cut plan would seriously threaten her health care security. Betty was a powerful witness and I think she truly represents what the majority of Medicare beneficiaries would tell us if they had the chance to share their views about the Dole plan's harsh Medicare cuts.

I want all my colleagues to be able to listen to Betty's comments about Medicare. I submit Betty's testimony for the RECORD, and urge each of my colleagues to take the time to read what a real Medicare beneficiary cares and worries about when candidates propose financing tax breaks with their Medicare Program. Again, I thank Betty for taking the time to tell us about her health care worries, and about what Medicare means to her.

This testimony underscores, I submit, the reasons to protect Medicare from being raided for anything but the future of this crucial health care program. A promise was made to Betty Miller that she could experience her retirement years with the peace of mind of health care security. And a promise was made to future retirees, who are now working hard to pay into the Medicare Trust Fund, so they can count on the same health security. The Dole plan threatens this promised health care security, and should be rejected.

The testimony follows:

My name is Betty Miller. I am 77 years old and in good health, fortunately.

Nine years ago my husband died of emphysema and complications, amassing bills of one quarter of a million dollars. I would be impoverished today, and so would my children, if it were not for Medicare.

Since then I have cost Medicare less than one hundred dollars (\$82.24) for the total nine years. My pension deductions for Medicare amount to \$510 annually. I have worked since I was 17 years old. In the years before my retirement ten years ago my Health Insurance tax was deducted from every salary check.

I like the Medicare program. It gives me peace of mind. I can sleep at night knowing that I may not become a financial burden to my children. My four children are fine, upstanding citizens gainfully employed, but they are not wealthy. They could not face the burden of a major health expense for me. A burden which might rob my six grandchildren of a higher education or other economic requirements.

This is why we are so concerned with Republican proposals, the proposal you have