

HEALTH INSURER'S LIMIT ON INSULIN PUMPS WORRIES PATIENTS

'WE CAN'T JUST WISH AWAY THE HIGH COST OF MEDICAL CARE'

TEXAS: Stephanie Rodenberg-Lewis wasn't happy with her insulin pump and finally switched two years ago to another brand. Now her health insurer is pushing her to go back. UnitedHealth Group Inc. has made a deal with device maker Medtronic that will slash options for diabetics who use the portable pumps, which costs thousands of dollars. The move has angered Rodenberg-Lewis and others who will be limited to three pump choices instead of nine. Health insurers, big employers and other bill payers have been trying for years to rein in costs and improve care by steering clients to certain doctors and hospitals. They've also restricted options for some prescriptions and lined up deals for smaller-ticket items like diabetes test strips or items patients don't chose, like heart stents.

Limiting choice for medical equipment that a patient usually selects is uncharted territory. UnitedHealth rivals Aetna and the Blue Cross-Blue Shield insurer Anthem say they haven't done this. But experts say it could become more common. "It's unfair," said Rodenberg-Lewis, 41, a Katy, Texas, elementary school teacher who also has a teenage son with Type 1 diabetes. "I have this disease that I did not ask for, did not cause, and now you're telling me you're going to make the decision for me (about) the device that keeps me alive?"

Medical need

Insulin pumps are pager-size devices used mainly by people with Type 1 diabetes, the kind often found in childhood. These patients can't make their own insulin, the hormone that turns food into energy. The external pumps make up for that by delivering a steady dose through a tube into the skin or a patch and extra doses at mealtimes. Starting July 1, customers on many of UnitedHealth's plans will only be able to choose between two Medtronic pumps or an option made by Insulet Corp. If patients want another brand, they may have to pay some or all of the cost. The insurer says it will make exceptions for patients who have a medical need for another option.

These systems can cost \$5,000 or more, plus supplies. The nation's largest health insurer says it wants to steer patients toward quality devices that are competitively priced. Patients may see insurers making more deals like this in the future, said Linda Blumberg, a health economist with the non-profit Urban Institute. She thinks it could push other companies to cut



TEXAS: Stephanie Rodenberg-Lewis holds her Animas Corp insulin pump at her home in Katy, Texas. —AP photos



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costs and make improvements to land their own deals. Regulators, though, must make sure it isn't too hard to get other options, if they are medically needed, she added.

"We can't just wish away the high cost of medical care," Blumberg said. "We've got to think

about ... ways in which we can bring down costs while not significantly hurting quality." Patient advocates say all the pumps on the market deliver insulin safely. But they worry that these agreements will force patients to live with a pump that may not be right for

them and hurt competition by pushing smaller manufacturers out of business. The pumps can be better at regulating blood sugar levels than a patient who injects insulin several times a day. They also come with a separate monitor that continuously checks blood sugar levels, although patients still need to do periodic checks themselves.

More expensive

UnitedHealth chose Medtronic in part because one available option stops the insulin flow if blood sugar levels drop dangerously low, said Dr Richard Migliori, the insurer's chief medical officer. He declined to say whether the insurer got a discount but did say cost was a factor. "At any time, and at all times, we're always looking to keep our product affordable," he said. Rodenberg-Lewis had used a Medtronic pump for 15 years before switching to one made by Animas Corp. She didn't think the Medtronic monitor was accurate enough, and she said the pump's supplies, which are not fully covered by insurance, were more expensive. The pump also wasn't waterproof, a key feature for someone who frequents pools and water parks during blazing hot Texas summers.

"I swore when I switched that I would never go back, so that's one of the reasons this has me so up in arms," said Rodenberg-Lewis, who signed a petition protesting the change. Organizations like the American Diabetes Association and the Juvenile Diabetes Research Foundation, or JDRF, also have cautioned that choice should be preserved. Patients develop a level of trust with their pumps, which have different components, said Aaron Kowalski, a vice president of research at JDRF and a Type 1 diabetic. "When people work that out, it is very difficult to say, 'Hey, scratch that, you're going back to the drawing board, and you're going to relearn all this,'" he said.

UnitedHealth's Migliori said the change won't affect everyone right away. It doesn't apply to Medicare Advantage customers or those 18 and under. Rodenberg-Lewis would rather just have the option to keep to her pump when her warranty expires. She also worries about her son, Peter. He's been injecting insulin since he was diagnosed with Type 1 diabetes a year ago, but he's planning to use a pump. Rodenberg-Lewis doesn't want her son's choices restricted when he becomes an adult. "My son is 16 and has his whole life ahead of him," she said. She said he and his doctor should decide what's best for him. "That should not be dictated in any way by an insurance company," she added. —AP



PORTLAND, Oregon: File photo shows US Sen Ron Wyden, D-Ore, speaks after a news conference in Portland.

SENATOR RENEWS SCRUTINY OF PHARMA TIES ON FEDERAL PANEL

WASHINGTON: A high-ranking Senate Democrat is pushing for more answers on why doctors and patient advocates with financial ties to the pharmaceutical industry came to serve on a panel that advises the federal government on pain issues. Sen Ron Wyden says he is "even more concerned" about these apparent conflicts of interest after receiving a response from the National Institutes of Health, which vetted and selected the panel members. In a letter sent Thursday to the Obama administration's top health official, Wyden requests a series of documents related to the pain panel, including financial disclosure forms filled out by its members.

A spokesman for the Department of Health and Human Services, which oversees NIH, said in a statement, "we will be reviewing the letter and responding in a timely manner." The panel attracted attention late last year when several members bashed a federal plan to recommend doctors reduce prescribing of painkillers used to treat chronic pain, such as OxyContin and Percocet. The guidelines were ultimately issued in March by the Centers for Disease Control and Prevention, despite the panel's objections.

Federal officials

The Associated Press reported earlier this year that nearly half of the non-federal members on the panel had apparent ties to pharmaceutical companies or advocacy groups that receive funding from drugmakers. The panel includes federal officials and outside doctors and patient representatives. "I'm going to continue to demand accountability to ensure the manufacturers of these powerful prescription drugs aren't having an undue influence on policies designed to reduce their usage," said Wyden, who is the highest-ranking Democrat on the Senate Finance Committee, in a statement.

Two panelists work for the Center for Practical Bioethics, a Missouri non-profit which receives funding from drugmakers, including OxyContin-maker Purdue Pharma, which donated \$100,000 to the

organization in 2013. One panelist holds a chair at the center created by a \$1.5 million donation from Purdue. The other has received more than \$8,660 in speaking fees, meals, travel accommodations and other payments from pain drugmakers, including Purdue, according to federal records. In total, the Center for Practical Bioethics says drug and device companies have contributed about 5 percent of its funding in the last four years, though the center does not publish specific donation amounts.

Opioid addiction

Wyden's ongoing inquiry comes as Congress tries to stem the rise in fatal painkiller overdoses, which rose to an all-time high of nearly 19,000 in 2014, up fourfold since 2000. "Given the public health epidemic rooted in prescription opioid addiction, current policy governing these powerful drugs merits particularly close scrutiny, and at this time appears to be inadequate," states Wyden, in the letter. In an April response to Wyden, NIH Director Dr Francis Collins explained that "all members fully disclosed" their earned income from pharmaceutical manufacturers, as required. He also explained that NIH took great care to make sure the panel "is balanced in terms of the points of view and the functions performed."

But Wyden's letter points out that the two members of the panel who worked for the Center for Practical Bioethics did not recuse themselves from discussion of the CDC guidelines, which could hurt painkiller sales for drugmakers. "In my view, this is indicative of a flawed conflicts of interest policy," states Wyden. The Oregon Democrat is asking the Department of Health and Human Services to turn over the standards it uses to choose panelists and explain how each panel member met those standards. He also asks for the nomination forms related to the panel and all instances when the panel received comments from drugmakers. Wyden requests the materials by June 30. —AP

INDONESIAN LAWMAKERS SEEK SEIZURE OF UNAPPROVED VACCINES AMID FAKE DRUG SCARE

JAKARTA: Indonesian lawmakers yesterday urged authorities to seize from hospitals and health clinics all vaccines made by unapproved manufacturers, after police exposed a syndicate selling fake child vaccines for more than a decade. In a country where counterfeit drugs are widespread, the case deals a blow to government health regulators whom many believed to have kept a tight leash on the distribution of vaccines.

Authorities have shut some private health facilities after police smashed a drug-making ring last week that sold fake and potentially harmful booster vaccines for measles, hepatitis B and other viruses in Jakarta and the island of Java. Police launched investigations this year following reports of several children becoming ill after vaccinations, but it was not clear how many received the fake drugs. "This is definitely an emergency," Dede Yusuf, chief of a parliamentary panel on health issues, told reporters before a hearing with government health officials.

"We don't know what the effect of this medication is. And if it has been going on

since 2003 as reported, what is the status of the children who have received it? We want to know the answers." Health Minister Nila Djoeuwita Moeloek sought to reassure parents that nearly all vaccines were from government-approved manufacturers, adding that she had received no reports of illnesses related to fake vaccinations.

"The Ministry of Health ensures that the vaccines circulated in the health service units are safe and are not harmful," the ministry said in a statement. "It is alleged that the circulation of the fake vaccines are not more than 1 percent in Jakarta, Banten and West Java." Parents could have their children re-vaccinated if they are suspected to have received the fake drugs, the minister added. Police uncovered the syndicate after a pharmacist in Bekasi, near Jakarta, was arrested in May for selling medicine without a license. The drugs turned out to be fake and led to the arrest of 14 distributors and makers of the fake vaccines, whose ingredients included the antibiotic gentamicin and saline. The suspects made up to 60 million rupiah (\$4,500) a week, police said. —Reuters

TEEN ATTACKED BY HYENA IN S AFRICA'S KRUGER PARK

JOHANNESBURG: A 15-year-old was in a serious condition yesterday after he was attacked in his tent by a hyena at South Africa's world famous Kruger National Park, officials said. The boy was sleeping alone in a separate compartment of his family's tent when the hyena set on him early Sunday, South African National Parks (SANParks) spokesman William Mabasa told AFP. "The animal attacked him on his face," Mabasa said "He screamed and his parents woke up. Fortunately a nurse was there, as well as one of our guides." According to local news website Netwerk24, the hyena locked its jaws onto the boy's face, breaking facial bones and dragging him out of the tent in his pajamas.

After being treated at a local hospital, he was

flown to Johannesburg for emergency plastic and reconstructive surgery to his mouth and jaw. Local media described his condition as serious. The hyena, which escaped, is thought to have entered the campsite through a hole in the fence. Mabasa said the animal was likely looking for food. "People must be aware at all times that there are wild animals around them and they must make sure that their tents are properly closed," he said. In July last year, a safari guide survived a leopard attack while viewing wildlife with tourists in Kruger Park. Just a month earlier, a 22-year-old American tourist died after she was mauled by a lion which leapt through an open car window in a park outside Johannesburg. —AFP

US CHARITY LOOPHOLE ENABLED TRADING OF 1,300 ENDANGERED ANIMALS

WASHINGTON: Last year, after a Minnesota dentist sparked an uproar by killing a popular lion named Cecil while on safari in Zimbabwe, the US Fish & Wildlife Service placed similar African lions on the endangered species list, making it illegal to import them as trophies to the United States. But for African lions and other threatened and endangered species, there's an exception to this rule: Hunters, circuses, zoos, breeders and theme parks can get permits to import, export or sell endangered animals if they can demonstrate that the transactions will "enhance the survival" of the species.

Often, records show, this requirement is met in part by making a cash contribution to charity - usually a few thousand dollars. The practice has angered both animal-rights activists who say it exploits wildlife and exhibitors who describe the process as unfair and arbitrary. In the last five years, the vast majority of the estimated 1,375 endangered species permits granted by the Fish & Wildlife Service involved financial pledges to charity, according to agency documents reviewed by Reuters.

For a \$2,000 pledge, the Fish & Wildlife Service permitted two threatened leopard cubs to be sent from a roadside zoo to a small animal park. After a \$5,000 pledge, the agency approved the transfer of 10 endangered South African penguins to a Florida theme park. An application now under final consideration would permit a South Carolina safari park operator to send 18 endangered tigers to Mexico to participate in a multi-million-dollar movie - for a \$10,000 donation to charity.

Craig Hoover, a senior Fish & Wildlife Service official, said his agency considers many factors before granting an endangered species permit - among them, a species' biological needs, threats and population size. Charitable contributions to conservation programs are just one factor in granting permit evaluations, and not a requirement, he said. "It's not necessarily all that is considered," said Hoover. "There may have been an education component, an outreach component, a captive breeding component."

'Indirect benefits' to wildlife

Under the Endangered Species Act, exception permits may be granted only "for scientific purposes or to enhance the propagation or survival of the affected species." According to a recent Fish & Wildlife Service document reviewed by Reuters: "Very few of the Endangered Species Act permits that we issue have direct benefits to the species in the wild. Most applicants provide an indirect benefit, such as monetary support, to meet the enhancement requirement." Late Friday, US Representative Brendan Boyle, a

Pennsylvania Democrat who serves on the House Foreign Affairs and Oversight Committees, asked the agency to halt the practice.

Boyle said exemptions to the endangered species law are intended for humanitarian or environmental purposes, such as providing medical attention to a wounded animal, not commercial uses. He said the charity pledges are "unreliable at best and amount to an empty promise in exchange for an exemption to our bedrock species conservation law." The agency usually does not try to independently confirm that donations are actually made or that the charities, often located overseas, are worthy, an agency document says. "Typically, we rely on the applicant," the document notes. Hoover said applicants supply this information through annual reports and agency grant programs.

'Pay to play' for elephants

Last year, People for the Ethical Treatment of Animals sued the Fish & Wildlife Service over a 2014 endangered species permit issued to Tarzan Zerbini Circus of Webb City, Missouri. The permit allowed Tarzan Zerbini to take two elephants, Shelly and Marie, on a Canadian circus tour - on the condition that it pledge \$15,000 annually to an elephant charity and raise another \$50,000 annually from patrons. "We call it 'pay-to-play' because that's what exactly what's going on, allowing these people to promise money in exchange for being able to harm endangered animals," said PETA general counsel Jeff Kerr. "The Fish & Wildlife Service is actively conspiring and cooperating with people to violate the Endangered Species Act through this program."

The agency defended itself against PETA's claim that the process is illegal, but the lawsuit apparently triggered a government investigation of Tarzan Zerbini's financial pledge. Records show the service determined that the circus had only contributed half the amount promised and had raised little, if anything, from patrons. On April 21, the permit was suspended. Last week, PETA withdrew the lawsuit.

Larry Solheim, a Tarzan Zerbini consultant who served as general manager for 26 years, said the circus made good-faith efforts to comply with its pledges. He said honest mistakes and misunderstandings caused the other half of the money to be contributed late and said technical issues hampered efforts to raise the \$50,000 from patrons. Solheim said the concept of requiring conservation efforts is a good idea. But he described the permit process as too focused on foreign donations. He called it "a game" that can resemble

"political extortion."

"You're just essentially buying a permit if you pay this conservation fee," he said. "It's just totally subjective - if they want to have this kind of requirement, they need to have clear guidelines." John Cuneo, whose Hawthorn Corp leases endangered animals to circuses and is often criticized by PETA, said he has lost business for failing to promise to make the charitable payments. "It makes me so mad," Cuneo said. "It feels like a scam." Hoover, the agency official, said PETA and the animal exhibitors are wrong.

'Tiger Island'

"We would deny any form of 'pay to play policy' is in place, formally or informally," Hoover said. He added: "We would deny that we tell people they must" make charitable contributions, "but if they are engaging in activity where the import or export isn't contributing to conservation, then there must be some other means by which they must be contributing conservation."

The permit application to send 18 tigers to Mexico for a Hollywood movie was filed by Bhagavan Antle, who operates the Myrtle Beach Safari in South Carolina. Antle declined to name the people behind the movie, which is tentatively titled "Tiger Island." The plot revolves around tigers living on an abandoned island, and a group of children who end up shipwrecked there.

The permit is still pending, but records show that Fish & Wildlife officials directed that Antle confirm a pledge of \$10,000 to charity and a promise that the movie will have a conservation theme. He has agreed to do so, and said he thinks the agency's process is good because it helps endangered animals. Antle said \$10,000 is a fair contribution for the right to use 18 tigers on a multimillion-dollar motion picture. "The movie company thinks it's a hardship - to spend \$10,000 for what used to be free," Antle said. But he added, "If it becomes a big hit movie, that will change more hearts and minds than a \$10 million contribution to conservation."

Penguins to Miami

Last year, the Fish & Wildlife Service approved the sale of 10 African penguins from a California theme park to the Miami Seaquarium. "We are thrilled that our guests will be able to observe these fascinating creatures and at the same time learn about this endangered species and what we can do to help preserve our feathered friends," Andrew Hertz, the Seaquarium's general manager, said in a press release in February. A spokeswoman said Hertz wasn't available for an interview. —Reuters