Today's Top Stories - *read and discuss each one and explain the words in the grids*

1. Supreme Court to hear sales-rep OT dispute

The U.S. Supreme Court is ready for a showdown on sales-rep overtime. The court agreed to hear an appeal in GlaxoSmithKline's ($GSK) overtime case that was filed by two former reps seeking back pay for themselves and thousands of their fellow salespeople. While the outcome of this individual case will be significant to GSK, it will also determine the fate of other sales-rep overtime claims filed against a who's who in Big Pharma.

Legal disputes over sales-rep overtime pay have been wending their way through the U.S. court system for years. Sometimes reps have prevailed; some drugmakers have won their cases. But recently, appeals have tended to line up along U.S. Circuit Court lines. Cases in the Ninth Circuit - such as GSK's - have ended in victory for the companies. Cases in the Second Circuit have fallen in favor of the reps. The courts have differed in their interpretation of the Fair Labor Standards Act's definition of outside salespeople.

Previously, the Supreme Court declined to hear a case that came up through the Second Circuit, in which a lower court held that reps didn't actually close sales, so they didn't qualify for that overtime exemption under the FLSA. Nor did they qualify for the administrative exemption, the ruling said. In declining to consider that case, the high court affirmed the appeals panel's determination that overtime rules applied to those reps - and perhaps, by extension, to other pharma reps, too.

So, it was almost inevitable that the Ninth Circuit's opposing view would be taken to the Supreme Court. In asking the court to take up their case, the former GSK reps said the overtime question affects "the operations of an entire industry." PhRMA agrees; the industry trade group says classifying reps as eligible for overtime could cost pharma billions of dollars. The justices are likely to hear arguments this spring, with a ruling by the end of June, Dow Jones reports.

sales rep	**prevailed**	**fate**	**close sales**	**dispute**	**determine**
declined	**eligible**	**appeals panel**	**inevitable**	**to line up**	**back pay**

2. Ranbaxy said near $400M deal with FDA

Rumblings of a settlement between Ranbaxy Laboratories and the FDA have sent the Indian company's stock upward as investors rub their hands over the prospect of an actual, for-real, not-just-promised launch of copycat Lipitor later this week. Ranbaxy has all but nailed down a $350 million to $400 million deal with the U.S. agency, India's Economic Times reports. Such a deal would resolve its long-outstanding manufacturing issues and clear the way for FDA approval for its generic version of the megablockbuster cholesterol drug.

Citing anonymous sources, the Times said Ranbaxy and the FDA could put the final touches on a settlement this week. Ranbaxy itself wouldn't comment, although company officials have been vowing to launch their Lipitor generic *"on schedule"* as exclusivity ends Nov. 30. The only hitch is the FDA hasn't approved Ranbaxy's copy, and to get approval, it apparently needs to wrap up negotiations with the agency. Thanks to quality control problems and allegedly falsified data, Ranbaxy drugs made at two Indian plants have been under an FDA import ban since 2008.

Ranbaxy has the coveted first-to-file status for its Lipitor copy, giving the company 180 days as the only independent generic rival to the Pfizer ($PFE) brand. U.S.-based Watson Laboratories ($WPI) has the rights to sell an authorized generic, while Pfizer has been aggressively working to keep patients on the branded version. Pfizer is offering discounts to patients and payers alike, putting generic-level prices on Lipitor in hopes of hanging on to roughly 40% of its current sales.

allegedly	**exclusivity**	**stock**	**ban**	**coveted**	**launch**
wrap up	**falsified**	**rumblings**	**hitch**	**prospect**	**plants**

3. NICE smiles on Eliquis, rebuffs Lucentis

As usual when the U.K. cost-effectiveness watchdogs convene, the latest NICE meeting delivered some newsworthy decisions. Perhaps the most notable: Eliquis, from Bristol-Myers Squibb ($BMY) and Pfizer ($PFE), got the nod for preventing blood clots after hip and knee surgeries. As Reuters reports, the recommendation comes just 6 months after Eliquis was approved in Europe, so it's quite a speedy decision.

The NICE stamp of approval puts Eliquis in competition with other new-generation anti-coagulant drugs such as Boehringer Ingelheim's Pradaxa and Bayer's Xarelto (marketed by Johnson & Johnson ($JNJ) in the U.S.) Of course, the real prize for these meds isn't the post-surgery market, but the much larger field of stroke prevention. Pradaxa is the only one of the three to have the EMA's approval for that, plus a recommendation from NICE, while Xarelto is waiting for the European nod.

Although Eliquis got the nod, NICE stiff-armed several other drugs. Novartis ($NVS) saw its eye drug Lucentis rejected once again by the cost-effectiveness regulators, which recommended against its use for diabetic macular edema in July. This time, the nay came for another form of macular edema, because of *"gaps and uncertainties"* in the evidence supporting that use, Reuters reports. Lucentis still has NICE's okay for treating age-related wet macular degeneration.

Finally, NICE weighed in on three cancer drugs: Amgen's ($AMGN) Vectibix, Merck KGaA's Erbitux, and Roche's Avastin as second-line treatments for advanced colon cancer. The drugs didn't clear the lower-than-usual bar for end-of-life treatments, NICE said. The lack of convincing evidence of these drugs' benefits - especially in the case of Avastin, NICE CEO Andrew Dilllon said - prompted the appraisal committee to decide against them.

hip	**macular degeneration**	**nay**	**stiff-armed**	**convene**	**anti-coagulant**
rebuffs	**lower-than-usual bar**	**prompted**	**appraisal**	**watchdogs**	**got the nod**

4. U.K. drops GSK HPV shot in favor of Gardasil

It's official: The U.K. will drop GlaxoSmithKline's ($GSK) HPV vaccine in favor of Merck's ($MRK) competing product Gardasil. The decision comes after health officials added genital warts into the equation, giving Merck the edge. Gardasil targets four strains of human papillomavirus, including two that cause genital warts, while Cervarix works against two cancer-causing strains.

Health ministry officials tell Reuters the switch to Gardasil followed a competitive bidding process, but GSK says it bowed out when the tender specified protection against genital warts. Cervarix had been the chosen HPV shot since the vaccination program began in 2008, Reuters reports.

The U.K. decision is the latest in an ongoing horse race between Gardasil and Cervarix. Gardasil beat Cervarix to market in the U.S., posing a setback to the GSK vaccine, and that lead has continued ever since. As Reuters points out, Gardasil brings in $988 million in global revenues for Merck, while Cervarix sales were around $375 million last year. Gardasil is expected to reach $1.25 billion in sales by 2015, and Cervarix's sales are projected to hit $848 million by then.

ongoing	**tender**	**switch**	**projected**	**bowed out**	**strains**
shot	**posing**	**warts**	**bidding**	**setback**	**edge**

5. Novartis stops deliveries in German dispute

Swiss drugmaker Novartis ($NVS) has stopped shipping drugs to two more German wholesalers in an ongoing dispute over prices. As Reuters reports, Germany's top wholesaler, Phoenix, and its smaller rival, Sanacorp, stopped receiving shipments from Novartis this month. Meanwhile, a unit of Celesio said it is locked in negotiations with the company, and Novartis hasn't shipped product since Oct. 15.

Phoenix said deliveries stopped in mid-November, while Sanacorp's stopped Nov. 7. *"Delivery was suspended due to disagreements regarding the delivery conditions,"* Phoenix said in a statement (as quoted by Reuters). *"Phoenix views the new price conditions set by Novartis as inappropriate and thus unacceptable."*

Phoenix and Celesio said they have asked Novartis to begin shipping again. For its part, Novartis says it has been *"optimizing"* contracts with wholesalers, Bloomberg reports. The company's new contracts jettison *"many-years-old discount rules"* that no longer reflect market conditions, a company spokesman told the news service. Novartis is in ongoing negotiations with some wholesalers - which the company declined to name - to come up with *"acceptable"* agreements.ALSO: Novartis won European approval for a new three-way combination blood-pressure pill, which comprises its drug Rasilez and two other treatments.

shipment	**dispute**	**unit**	**wholesalers**
inappropriate	**suspended**	**jettison**	**shipped**

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