for PILLAR, QUEST-1 and QUEST-2, respectively. Having VR only had a minor positive impact, and was not statistically significant for most endpoints/tails. Female patients had significantly lower values for EQ-5D-VL, and numerically lower values for all other QoL measures. CONCLUSIONS: These findings suggest that short-term QoL impairment due to HCV-therapy is driven more by the longer duration of FR-therapy than by not obtaining VR.

PINS8
EVALUATION OF PATIENT REPORTED OUTCOMES (PRO) IN OBSESE PATIENTS IN AN ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSIT)
PHASE 3 TRIAL
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OBJECTIVES: Limited data on most Recent Reported Outcomes (PRO) data exists for obese patients with ABSSSI. This study sought to evaluate health-related quality of life (HRQL) in obese patients (BMI ≥ 30) with a positive clinical response (cured, complete resolution of all baseline signs and symptoms and improved, some symptoms present) from further antibiotics are necessary) patients during an ABSSSI trial.
METHODS: Adult patients diagnosed with ABSSI were enrolled in a prospective phase 3, randomized, double-blind study to evaluate antibiotic treatment. An analysis of PRO was conducted to understand the difference between cured obese patients (COP) and improved obese patients (IOP) with respect to patient reported HRQL at the End of Treatment (EOT) and late follow up (LFU, study day 21-28).
RESULTS: There was no statistically significant difference in HRQL between COP and IOP patients. A243

PINS9
COVARIATE EFFECTIVENESS DEMANDS AND MARKET ACCESS CHALLENGES WILL NOVEL ANTIBIOTICS FOR MDR GNPS APPROVED VIA THE STREAMLINED LPAD PATHWAY FACE?
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OBJECTIVES: The FDA plans to institute a novel regulatory pathway to expedite approval of high-necd antibiotics, including those for multidrug-resistant gram-negative pathogens (MDR GNPs). Under this limited path–Accelerated Development Pathway (LPAD) approval mechanism, submission of clinical efficacy data from relatively small patient populations with high unmet need would be permitted. However, drugs approved via this pathway will have limited safety data and likely carry significant cost, thus concerns regarding cost-containment strategies necessary to manage the burden of sofosbuvir.
METHODS: The EUs healthcare authorities have adapted to include sofosbuvir within their budgets. As indicated by our primary research, further confirmed by our market access analysis, patients will face abreast cost-containment strategies that may make for large EUs for sofosbuvir, with payers forced to reexamine their traditional P&R schemes and reevaluate how they define cost-effectiveness. However, such aggressive cost-containment measures have consequences, as demonstrated when thou- sands of10 patients in Spain in January, 2015, protesting for fair allocation of HCV treatment. Manufacturers of such premium-priced agents may learn from Jansens’s negotiations on simprevir, which offered trade-offs using teleprevir, as careful balancing of long-range price expectations and reimbursement and uptake potential will be required going forward.

PINS92
PREDICTORS OF VACCINATION AMONG MOTHERS OF INFANTS IN AN APPALACHIAN COMMUNITY
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OBJECTIVES: Misbeliefs regarding vaccine safety and strict immunization exemption policy have led to anti-vaccination sentiments in West Virginia which might affect vaccine uptake. This study aimed to determine predictors of vaccine hesitancy towards vaccination and their association with up-to-date vaccination status and future intentions to follow recommended vaccinations.
METHODS: A cross-sectional online survey was conducted among 176 mothers of children under 1 year of age in West Virginia that could be read and understood by English. Worry and hassles scales were developed, and mean scale scores were used to measure worry and hassles to vaccination. Chi-square and logistic regression analyses were performed.
RESULTS: Participants were predominantly white (94.3%), non-Hispanic Appalachians (98.3%), with annual household income <$50,000 (72.6%) and health insurance (92.0%). Approximately 3.8% of participants' children had not received any vaccination. Further, many participants' children (14.2%) were not up to date with recommended vaccinations, and 13.6% of mothers reported no future intention to follow recommended vaccination. Chi-square analyses indicated that being a full time worker and self or family as child caretaker were associated with being up-to-date with recommended vaccination and future intention to follow recommended vaccinations (p's<0.05). After adjusting for demographic variables, hassle score was a significant predictor of up-to-date vaccination status (AOR = 0.12) and future intention to follow recommended vaccinations (AOR = 0.17). Similarly, worry score was a significant predictor of up-to-date vaccination status (AOR = 0.24) and future intention to follow recommended vaccinations (AOR = 0.27).
CONCLUSIONS: Despite having higher socio-economic status, many study participants indicated suboptimal vaccination coverage and had future intention to follow recommended vaccinations. This study highlights the need to increase awareness about safety of vaccine contents and its efficacy in preventing still endemic diseases like measles.

PINS93
ENCOURAGING ORPHAN DESIGNATION FOR NEW EBOLA TREATMENTS – COULD THIS DO MORE HARM THAN GOOD?
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OBJECTIVES: The current Ebola Virus outbreak has been responsible for over 5,000 deaths. This disease, with no effective treatment has a fatality rate around 50%. In October, the EMA publicly encouraged developers of Ebola treatments and vaccines to apply for orphan designation and FDA have already granted orphan designation for ZMapp. This research aimed to evaluate the appropriateness of utilizing the orphan designation as an incentive in these circumstances or whether it could actually prove counter-productive.
METHODS: A detailed review of EMA and FDA orphan designation procedures and the historical context in which they were developed were undertaken, alongside a review of the current Ebola treatment and vaccinations pipeline.
RESULTS: EMA and FDA orphan drug legislation comprise a set of incentives for pharmaceutical companies to develop and market medicinal products to treat rare diseases, which were being neglected by drug developers due to the poor economic potential of such diseases. These include scientific advice, fee reductions, access to grants and, most importantly, market exclusivity (7 and 10 years in US and EU respectively) to developers of primary prescribing drugs are improvements in clinical cure and mortality rates.

PINS91
TACKLING THE TARIFF FOR SOFOSBUVIR IN HCV – INDISPENSABLE INNOVATION VERSUS BUDGET-BUSTING POTENTIAL
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OBJECTIVES: Sofosbuvir is an indispensable innovation in hepatitis C virus (HCV) treatment. However, it has the potential to bust tight EUH healthcare budgets. This study examined the early uptake of sofosbuvir, and explored evolving mechanisms in the EU used to manage its high cost burden.
METHODS: In September 2014, 251 EUS gastroenterologists were surveyed regarding their perceptions and uptake of sofosbuvir. A subgroup of key opinion leaders were interviewed. RESULTS: At the time of surveying, approximately one-quarter of treatment-naïve cirrhotic and non-cirrhotic HCV-1 patients in France and Germany (where sofosbuvir was then widely available) were on sofosbuvir-based regimens, alongside very limited lower priced alternative therapies such as boceprevir, and those with HCV-2/3. This speedy uptake reflects sofosbuvir’s high efficacy, which previously encouraged physician familiarity via early-access schemes. However, interview of key opinion leaders insist that uptake of sofosbuvir for HCV-2/3 is not viable due to cost, stressing that sofosbuvir be reserved for patients with more advanced liver fibrosis or cirrhosis. These payers add that measures such as those in France involving treatment caps and a proposal to tax manufacturers when caps are exceeded exemplify the need for flexible cost-containment strategies necessary to manage the burden of sofosbuvir.
CONCLUSIONS: The EUs healthcare authorities have adapted to include sofosbuvir within their budgets. As indicated by our primary research, further confirmed by our market access analysis, patients will face abreast cost-containment strategies that may make for large EUs for sofosbuvir, with payers forced to reexamine their traditional P&R schemes and reevaluate how they define cost-effectiveness. However, such aggressive cost-containment measures have consequences, as demonstrated when thou-