

omization. The results of this study will be presented on April 15, 2019, as a late-breaking clinical trial session at the World Congress of Nephrology in Melbourne, Australia.

Other dedicated CKD outcome trials that are forthcoming include EMPA-KIDNEY (7) and DAPA-CKD (8). Given the putative mechanism for renoprotection, both trials are enrolling participants with and without T2DM, and will thus provide important data on the effects of SGLT2 inhibition for cardiorenal protection in both populations. ■

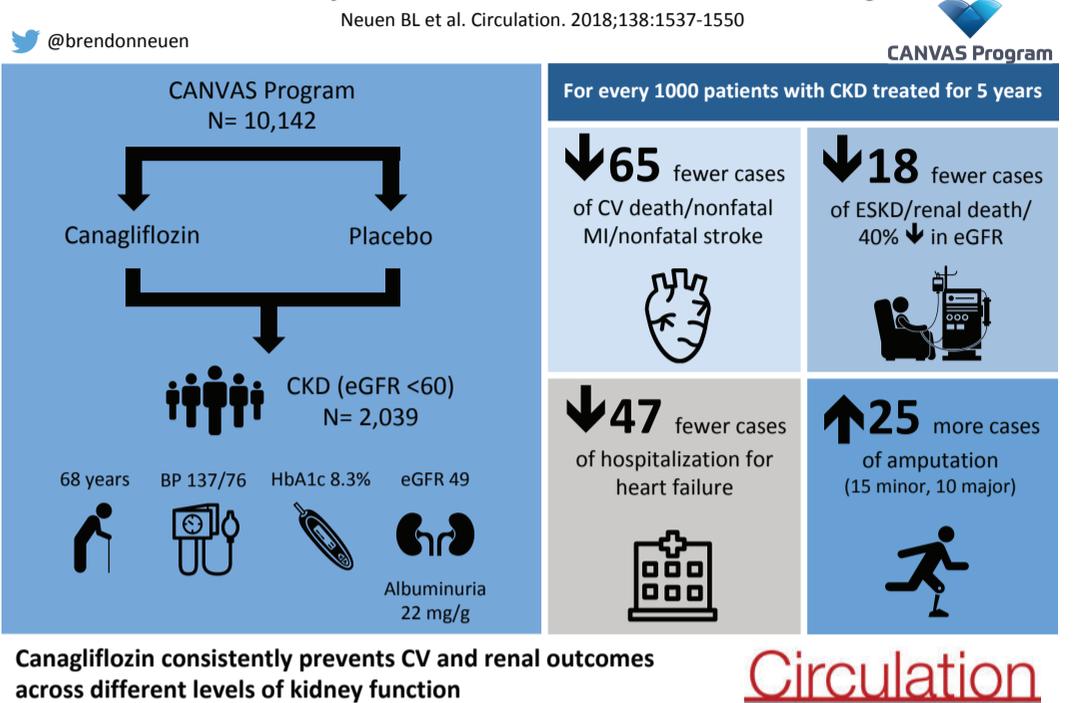
Brendon L. Neuen, MBBS(Hons), is a Clarendon Scholar at the Nuffield Department of Population Health, University of Oxford, UK. Edgar V. Lerma, MD, is clinical professor of medicine at the University of Illinois at Chicago College of Medicine. Joel Topf, MD, is Medical Director of St. Clair Nephrology Research in Roseville, MI.

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Figure 3. Cardiovascular and renal outcomes with canagliflozin

Cardiovascular and renal outcomes with canagliflozin according to baseline kidney function: data from the CANVAS Program



Visual abstract by Brendon Neuen

Policy Update

2019: A Lot is Happening Fast

By David White

The year 2019 promises to be a busy one in healthcare. In the face of a great deal of volatility, *Kidney News* readers can expect the following.

Mergers and acquisitions: Expect more, and sooner rather than later

A recent Capital One survey found that three-quarters of 291 senior executives across the healthcare spectrum are planning for better business performance in 2019. To exceed 2018 performance levels, 44% support more mergers and acquisitions (M&A), and 25% also expect to revamp or update existing merger offerings already on the table. In the latest figures from 2018, the third quarter saw 261 healthcare M&A deals according to PricewaterhouseCoopers (PwC). Value-based care policies and rising healthcare costs are seen as the main drivers in these deals, and 43% of the study's respondents said their greatest challenge for 2019 is regulatory and reimbursement changes.

These mergers are becoming increasingly vertical, in which the merging parties are not current competitors and are actually operating at different levels of the healthcare distribution chain. Examples include deals like UnitedHealth Group's acquisition of DaVita Medical Group; CVS and Aetna; Cigna and Express Scripts; and Humana and two private equity companies buying post-acute care provider Kindred Healthcare.

Regional hubs: A growing trend

Health systems—new mergers and existing ones—are also building regional care hubs within and across state lines. The objective is achieving a scale that can help them negotiate better rates with suppliers and payers and expanding patient access through outpatient facilities and telemedicine. Neph-

rology is already at the forefront of payment reforms to encourage telemedicine and support Medicare's stated goal of significantly increasing home dialysis rates. Aligning systems with regional population data can also reveal the most profitable service lines. Analysts have pointed to that approach in the Advocate Health Care and Aurora Health Care merger paving the way for a 27-hospital system spanning Illinois to Wisconsin with \$10.7 billion in combined revenue.

Prescription drug prices: The fight is heating up

The midterm elections made it clear that a leading issue for the 2020 presidential race will be healthcare. The price of prescription drugs is one of the key components of that issue. There are a host of ideas that will likely be floated for 2019:

- Allowing the government to manufacture generics.
- Letting Medicare negotiate drug prices.
- Tying prescription drug prices to prices in countries like France, the United Kingdom, Germany, Japan, and Canada.
- Penalizing price gouging.
- Importing drugs from abroad—starting with Canada.
- Abolishing “pay-for-delay” deals in which a branded drug-maker pays off a generic one to keep a competing product from coming to market.

These approaches have differing ranges of support in Congress and the administration. In January 2019, Medicare closed the comment period on a proposed rule designed to lower the out-of-pocket costs of prescription drugs for Medicare beneficiaries by both prohibiting “gag clauses” in pharmacy contracts (gag clauses prohibit or penalize a pharmacy from disclosing a lower cash price to an enrollee) and removing protections from the “six protected classes of drugs.” ASN supported the prohibition of “gag clauses” but strongly op-

posed the removal of protections for the protected classes of drugs, which include immunosuppressants, antidepressants, antipsychotics, antiretrovirals, anticonvulsants, and antineoplastics.

Repeal of the Affordable Care Act: Enter the courts

On December 14, 2018, a federal district court judge in Texas struck down the Affordable Care Act, siding with a group of 18 Republican state attorneys general and two GOP governors who brought the case. The ruling said the tax bill passed by Congress in late 2017 effectively rendered the entire health law unconstitutional. That tax bill eliminated the penalty for not having insurance.

Simultaneously, another federal district judge in Washington, DC, is presiding over a lawsuit brought by 12 Democratic state attorneys general to block a 2018 final rule issued by the Department of Labor making it easier for small firms and individuals to band together in association health plans free from many Affordable Care Act market rules. The suit maintains the rule violated the ACA, the Administrative Procedure Act, and the Employee Retirement Income Security Act. In arguments before the court in late January, it was clear the judge was skeptical of the administration's arguments in defense of Labor's actions.

The highly controversial ruling in Texas will surely make its way to the Supreme Court. In December 2018, the administration petitioned the high court to circumvent the established federal appeals process and to elevate the district court's ruling for an expedited review by the Supreme Court. While most observers think the court is unlikely to do so, readers can be assured of hearing a great more about this in 2019. ■