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WELCOME TO:

MEDICAL DEVICES: WORRYING PARALLELS TO OUR NATION'S DRUG CONCERNS?

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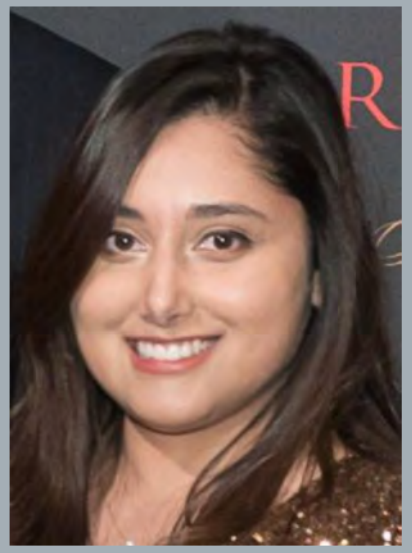


Welcome and Introduction

Sabah Bhatnagar
Healthcare Value Hub

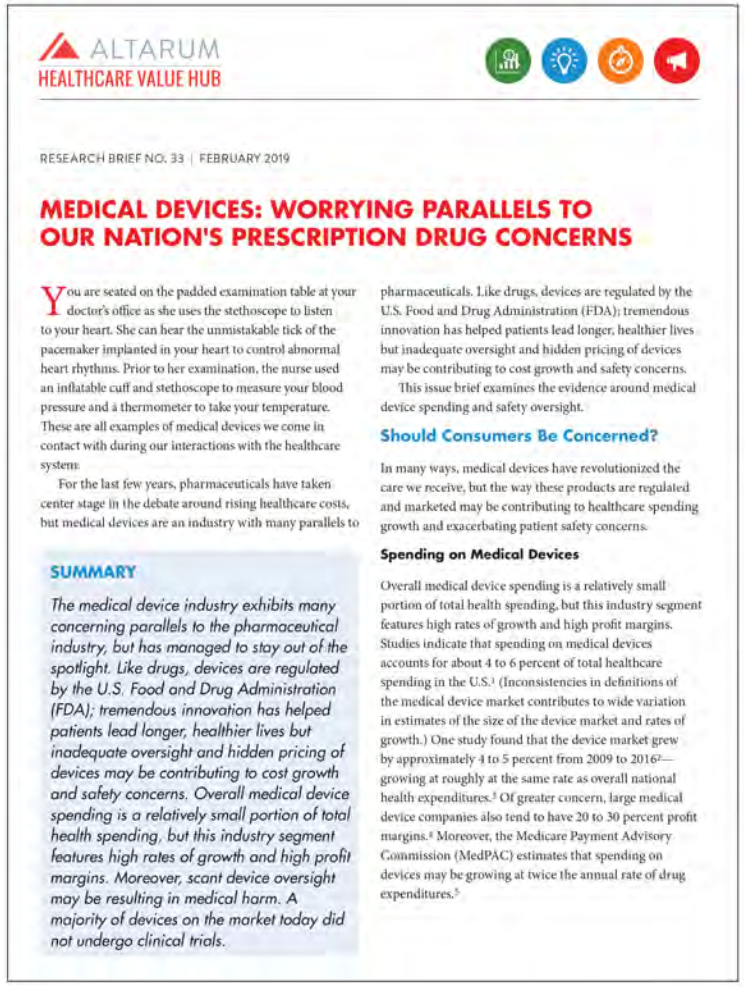
Housekeeping

- Thank you for joining us today!
- All lines are muted until Q&A
- Webinar is being recorded
- Technical problems? Call Tad Lee at 202-776-5126

Agenda

- **Welcome & Introduction**
  - **Sabah Bhatnagar,** Altarum Healthcare Value Hub
- **Medical Device Safety Issues**
  - **Jeanne Lenzer**, Author, *The Danger Within Us*
- **Medical Device Cost and Spending Issues**
  - **Diana Zuckerman**, National Center for Health Research
- **Q & A**
  - Moderated by Sabah Bhatnagar

Medical Devices: Worrying Parallels to Our Nation's Drug Concerns?



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RESEARCH BRIEF NO. 33 | FEBRUARY 2019

MEDICAL DEVICES: WORRYING PARALLELS TO OUR NATION'S PRESCRIPTION DRUG CONCERNS

You are seated on the padded examination table at your doctor's office as she uses the stethoscope to listen to your heart. She can hear the unmistakable tick of the pacemaker implanted in your heart to control abnormal heart rhythms. Prior to her examination, the nurse used an inflatable cuff and stethoscope to measure your blood pressure and a thermometer to take your temperature. These are all examples of medical devices we come in contact with during our interactions with the healthcare system.

For the last few years, pharmaceuticals have taken center stage in the debate around rising healthcare costs, but medical devices are an industry with many parallels to pharmaceuticals. Like drugs, devices are regulated by the U.S. Food and Drug Administration (FDA); tremendous innovation has helped patients lead longer, healthier lives but inadequate oversight and hidden pricing of devices may be contributing to cost growth and safety concerns.

This issue brief examines the evidence around medical device spending and safety oversight.

SUMMARY

The medical device industry exhibits many concerning parallels to the pharmaceutical industry, but has managed to stay out of the spotlight. Like drugs, devices are regulated by the U.S. Food and Drug Administration (FDA); tremendous innovation has helped patients lead longer, healthier lives but inadequate oversight and hidden pricing of devices may be contributing to cost growth and safety concerns. Overall medical device spending is a relatively small portion of total health spending, but this industry segment features high rates of growth and high profit margins. Moreover, scant device oversight may be resulting in medical harm. A majority of devices on the market today did not undergo clinical trials.

Should Consumers Be Concerned?

In many ways, medical devices have revolutionized the care we receive, but the way these products are regulated and marketed may be contributing to healthcare spending growth and exacerbating patient safety concerns.

Spending on Medical Devices

Overall medical device spending is a relatively small portion of total health spending, but this industry segment features high rates of growth and high profit margins. Studies indicate that spending on medical devices accounts for about 4 to 6 percent of total healthcare spending in the U.S.[1] (Inconsistencies in definitions of the medical device market contributes to wide variation in estimates of the size of the device market and rates of growth.) One study found that the device market grew by approximately 4 to 5 percent from 2009 to 2016[2]—growing at roughly at the same rate as overall national health expenditures.[3] Of greater concern, large medical device companies also tend to have 20 to 30 percent profit margins.[4] Moreover, the Medicare Payment Advisory Commission (MedPAC) estimates that spending on devices may be growing at twice the annual rate of drug expenditures.[5]

- New issue brief and glossary
  - Spending on medical devices is growing at an alarming rate and pricing practices are shrouded in mystery
  - Scant device oversight may be resulting in medical harm
  - A variety of approaches can be used to improve safety and reduce spending

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Jeanne Lenzer

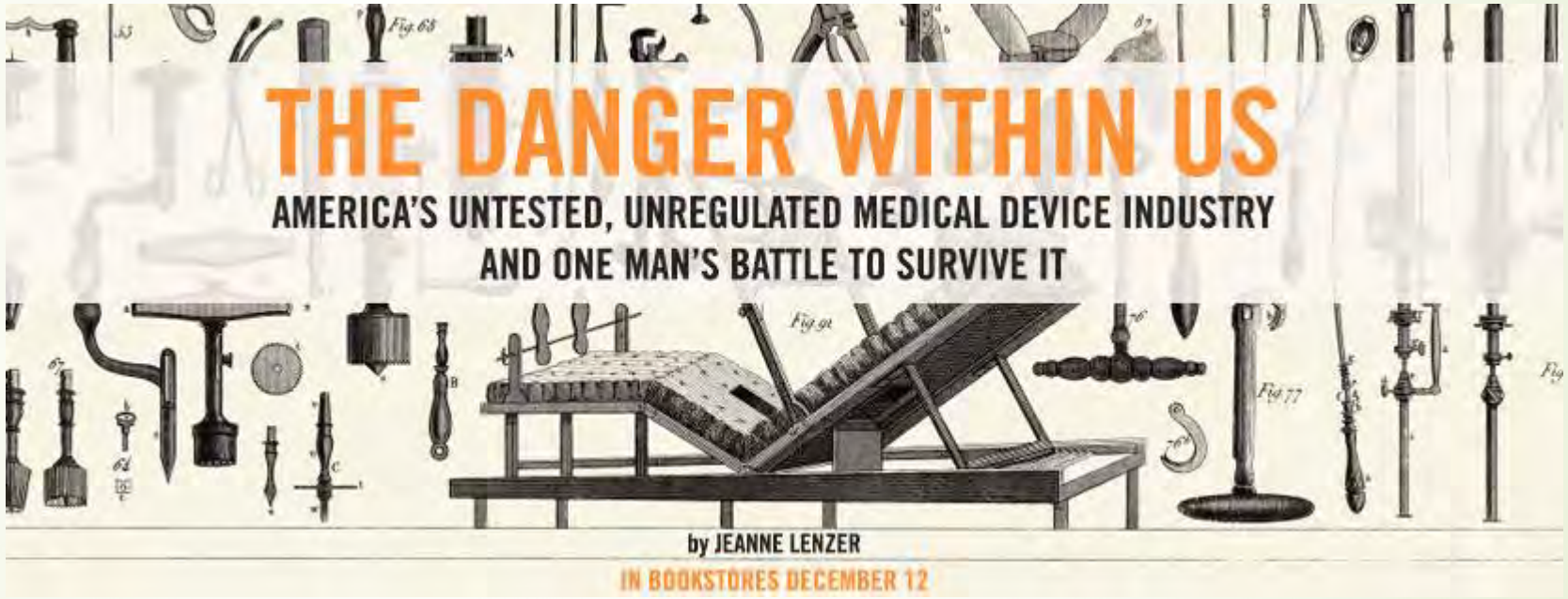
Author, *The Danger Within Us*

Jeanne Lenzer, investigative journalist
author, *The Danger Within Us*

Medical Devices

How do we know which ones work and are safe – and which ones aren't?

It started with a mystery…



Dennis Fegan's seizures

What's wrong?

- Everyone thought he was having seizures:

But Fegan's EKG told the truth

What I had to learn about devices

1. Myths about drugs vs devices
2. How are devices approved
3. Who adjudicates harms
4. Quantifying harms
5. Repairing harm or lack of efficacy
6. Cure as cause

Myths about drugs versus devices

- Devices are often **sold as a way to avoid drug side effects** – but that is **worse than misleading** for several reasons

1. **First devices can have devastating side effects of their own**

   Artificial hips have caused local and systemic cobalt poisoning, destroying patients muscles, tendons, heart, thyroid, vision and hearing

   Pacemaker defibrillators have caused unnecessary shocks that can't be readily stopped

2. **Patients can stop a medicine that causes problems; devices often can't be readily turned off or removed,** and some can't be removed at all even when they cause ongoing and potentially deadly problems

3. **Devices are often implanted in addition to medicines – not in place of medicine**

Device clearance and approval

- 510 (k) for Class I and II devices must be "substantially equivalent" – only 5% have undergone any clinical tests in humans and
- PMA only 5% of the highest risk cardiac devices went through anything even resembling the sort of studies required for drug approval

Who adjudicates harms?

- Manufacturers only have to report deaths or serious injuries, which they "caused or contributed to" the event
- Who decides?
  a) The FDA?
  b) A treating doctor?
  c) The patient?
  d) An independent third party?
  e) The company that made the device (and that stands to lose millions even billions of dollars with a negative determination)

Fegan 3 doctors witness the event

- All 3 write about the connection between the VNS and his asystole
- But Cyberonics failed to report the event as required b/c they pointed to a medicine Fegan was taking as a possible cause or contributor
- Not unusual – Medtronic failed to report >1,000 adverse events and deaths

Quantifying harms – a broken system

- Manufacturer failure to report is just one part of the problem
- **Maude database**
- **No denominator:** FDA doesn't require manufacturers to track how many devices are in use
- **No numerator:** reporting is not only voluntary (we don't have mandatory registries) so we don't know if problem is 1 in a million or 1 in 100 making the database virtually meaningless
- **FDA says it uses Maude to identify "red flags"** but if they're doing so they are asleep at the wheel
- **According to Madris Tomes >140,000 deaths associated with devices over the past 2 decades.** GAO found hospitals report fewer than 1% of adverse device events to the FDA, and "the more serious the problem…the less likely it was to be reported."

Repairing harm: Denied

- Pre-emption – US Supreme Court Ruling
  - Case of 39-year-old Shelly Rae Wilhite
  - https://www.nbcnewyork.com/news/local/I-Team-Mislabeled-Safety-Patient-Reports-Patient-Deaths-Injuries-390626151.html
  - The terribly strange, truly awful, Kafkaesque events that befell Dennis Fegan and how he fought back

Cure as Cause

….Cure as cause

- MoM hips cause tissue breakdown around the hip joint leading to more hip pain sometimes mistaken for underlying arthritis
- Inferior vena cava filters instead of preventing blood clots, have caused clots to form
- Some cardiac stents can stimulate clotting also causing chest pain
- VNS that stops the heart mimicking SUDEP, sudden unexpected death of epilepsy

What is to be done?

- End 510(k) as recommended by the IOM
- Classify all implanted devices as Class III (high risk)
- Insist on full PMA pathway for all implanted devices (stop churning)
- Mandatory registries
- Require manufacturers to track how many devices implanted and in use
- Demand that companies complete post-market studies – many not done or only partially completed
- Reinstitute AHRQ's right to conduct comparative studies (and fund it appropriately) and reinstitute the OTA
- End industry's power over the public interest: repeal Citizen's United, get industry money out of politicians' pockets

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Diana Zuckerman

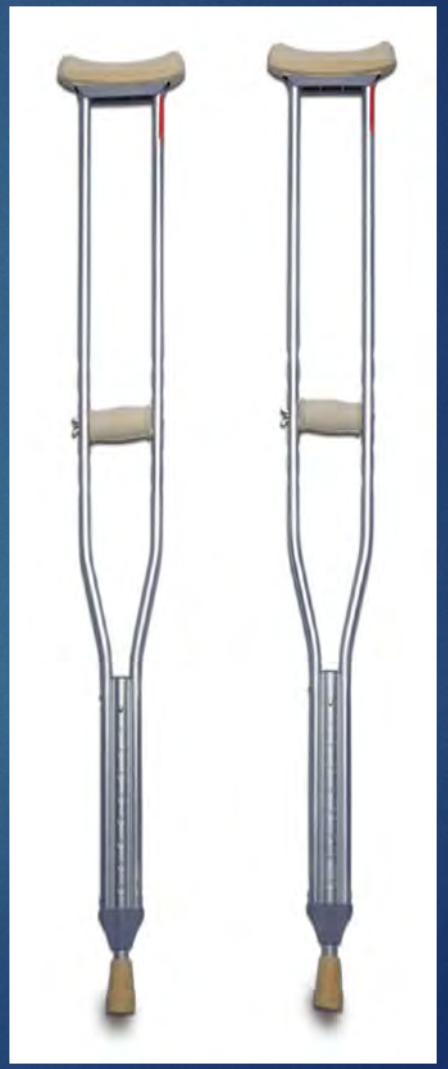
President

National Center for Health Research

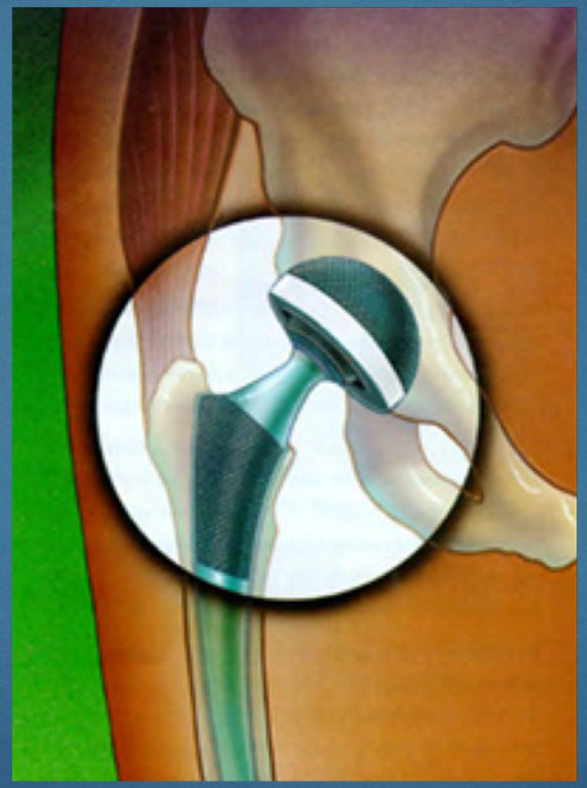
The Impact of Medical Devices on Healthcare Costs

Dr. Diana Zuckerman, President
National Center for Health Research

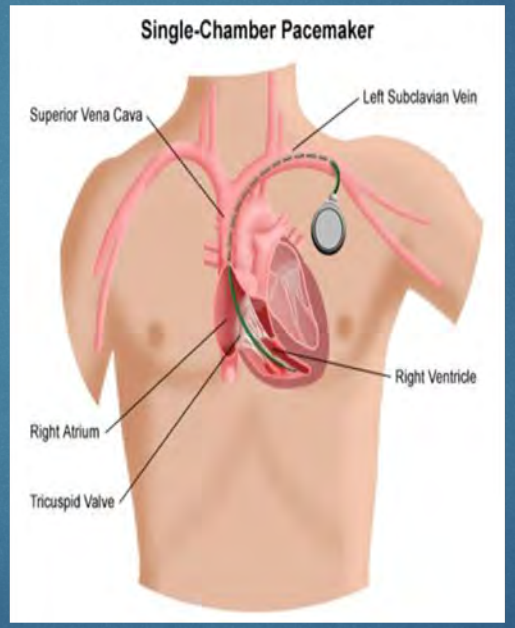
Low Risk: Not Tested



Moderate Risk (510k)



High Risk Medical Devices (pacemaker, heart, infusion pump)



How Do Medical Devices Increase the Cost of Care?

- Advamed says device costs increased 4-5% PER YEAR from 2009 to 2016 – as did all national health expenditures

- But Medicare Payment Advisory Commission (MedPAC) estimates that spending on devices may be growing at twice the annual rate of drug expenditures

How Do U.S. Prices Compare to EU?

- In the U.S. drugs cost 80% more than other advanced industrialized countries, but cardiac implants cost **2x-6x as much** in the U.S. as Germany.
- Prices vary and are **not transparent**: costs of devices are **bundled** into fees for surgery, hospitalization costs, etc.

Who Pays What for Devices?

- Private insurers pay nearly double what hospitals pay to purchase knee and hip implants from manufacturers.
- Hospitals charged up to 20x their own costs for procedures like CT scans.
- The amount hospitals pay for a given device usually accounts for 30-80 % of the payment they receive from Medicare.

What are the Cost of Defective Devices?

- In 2017, the HHS Inspector General concluded that Medicare paid at least $1.5 billion over a decade to replace 7 types of defective heart devices.
- Patients paid $140 million out-of-pocket
- 73,000 patients had their devices replaced

Examples of Devices with No Clear Benefit

- Mesh for pelvic organ prolapse
- Medicare coverage Advisory Committee concluded that most cancer molecular pathology tests were not proven to improve older patients' outcomes
- Low dose CT scan screening for lung cancer for patients over 65
- TMS brain stimulation for depression

Device Complications Can Be an Expensive Nightmare (mesh)

- Unrelenting, debilitating pain
- Pain when sitting
- Pain during sex
- 5-10 surgeries
- Lack of surgeons willing to try to fix the problem

FDA Approval Process for Drugs

- Companies pay researchers to conduct clinical trials to evaluate safety and effectiveness
- FDA scientists review the data (not the raw data)
- FDA requires scientific evidence that the benefits outweigh the risks

Device Approval Criteria

- Reasonably safe
- Reasonably effective
- Only 5% with any clinical trials and evidence of safety or effectiveness

Are These Substantially Equivalent?

Vitek (teflon) TMJ implants

?

Dow silicone sheet

Nonthermal Shortwave Diathermy Devices for Pain

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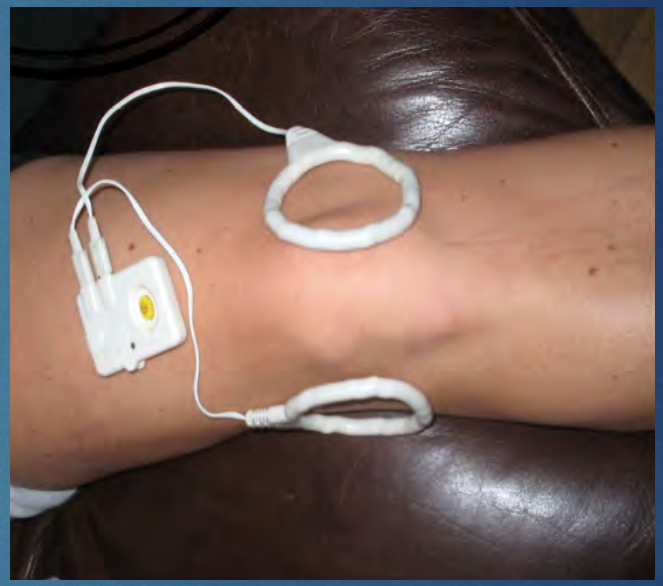
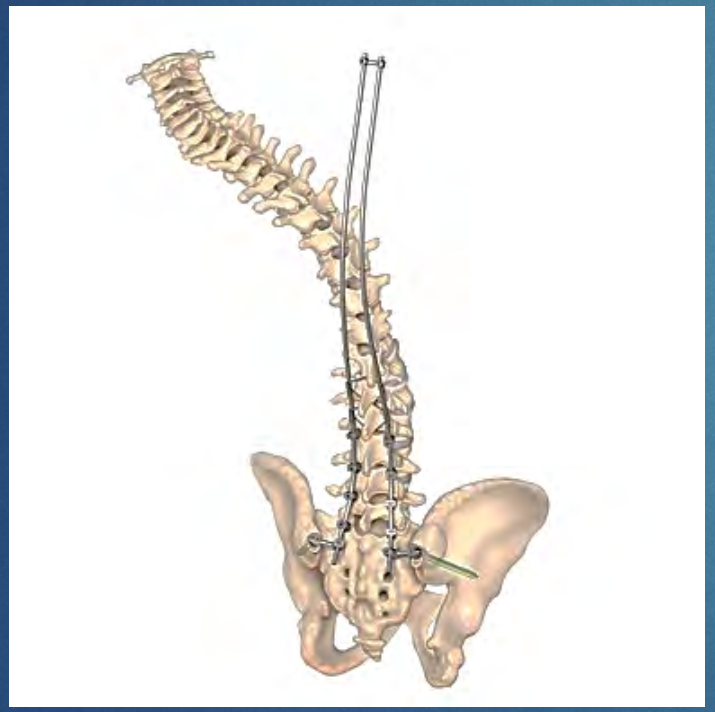


DePuy VIPER Spinal System

Differences: added or modified parts, new complex systems have not been tested



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Are These Substantially Equivalent?

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Device Recalls

Over a 1-year period, almost half a billion 510(k) devices were recalled as high risk, including contaminated alcohol swabs that killed this boy

Highest Risk Devices Approval Criteria

- One clinical trial (not double blind) with smaller sample than required for prescription drug data

- Clinical trial may lack control group

Are Registries the Answer?

- U.S. Registries focus on re-operations
- Lack of information about pain and quality of life
- Lack of info from other medical specialties

What Can You Do?

Congress and FDA need to know what you think.

Questions for our Speakers?

- Use the chat box or to unmute, press *6

- <u>Please do not put us on hold!</u>

Thank you!

- **Jeanne Lenzer and Diana Zuckerman**
- **Robert Wood Johnson Foundation**

Contact Sabah at **Sabah.bhatnagar@Altarum.org** or any member of the Hub staff with your follow-up questions.

Join us at our next webinar:

Consumer-Focused Health System Transformation: What are the Policy Priorities?
Friday, March 22nd, 2019

2:00-3:00 p.m. ET

Register now at: HealthcareValueHub.org/events