

Ron Cohen

Ron Cohen is President, CEO and Founder of Acorda Therapeutics, Inc. and a member of the Executive Committee of the Biotechnology Industry Organization. He is also an MD board certified in internal medicine.

Medicare's Independent Payment Advisory Board: First, Do No Harm

The Affordable Care Act promises some important improvements in the US healthcare system. However, argues a biotech CEO, cutting spending by targeting the lifeblood of biopharma R&D is not one of them.

The Affordable Care Act survived its two biggest challenges last year: the Supreme Court upheld the individual mandate requiring health insurance for all, and President Obama defeated an opponent who had pledged to repeal the law. Some provisions of the ACA are already in force. Many more will take effect in 2014.

The law propels the U.S. toward at least two worthy goals: a future in which all citizens have access to health care, and a society in which care providers coordinate their efforts on behalf of patients and are rewarded based on measurable results. Now that the President has won most of what he fought for, he should be prepared to make whatever changes are needed to the law to ensure that it can achieve its goals.

One key change that is needed is repeal of the Independent Payment Advisory Board.

As envisioned, IPAB will be a committee of 15 health experts drawn from industry and academia. Appointed by the President and vetted by Congress, IPAB members will be charged with monitoring Medicare costs and recommending cuts if total spending exceeds a target growth rate. The board's suggestions require fast-track treatment

from Congress, which can only reject them by imposing alternative cuts of equal scale, or by overruling the recommendations with a three-fifths majority vote in the Senate. In other words, for all intents and purposes, what IPAB recommends will become the law of the land.

The Congress and the President have not been able to agree on how to slow the growth of Medicare, so putting this authority in the hands of a board of medical experts may seem to make sense at first blush. As written, the law prohibits IPAB from altering Medicare eligibility, premiums or patient benefits. Instead, the cuts IPAB recommends will be directed at Medicare Advantage plans and the Part D prescription drug program, along with a grab bag of targets such as skilled nursing facilities, home health care, dialysis and surgical centers.

The focus on drug prescription programs shows that IPAB's backers view drug prices as a key culprit in rising health costs – an easy and politically convenient target. However, pharmaceutical products make up only about 10% of America's total \$2.7 trillion bill for health care.

Expecting to squeeze significant savings from this sliver of the overall

spend is reminiscent of the sequester: it makes no sense and, worse, carries risks. Prudent use of prescription drugs often prevents more serious illnesses and complications that would require far more expensive hospitalizations or surgical procedures. In fact, the congressional scorekeeper recently confirmed this offsetting dynamic in Medicare. If implemented, IPAB's assault on drug pricing won't reduce overall costs. It may actually increase outlays in the longer term, and will almost certainly have additional long-term negative consequences.

As of this moment, opinion on IPAB is mixed on Capitol Hill. In mid-May, House Speaker John Boehner, Ohio, and Senate Republican Leader Mitch McConnell, Kentucky, sent a letter to the President in which they "respectfully declin[ed]" to recommend members to the board due to concerns that the individuals who serve will have no accountability to Congress or to voters.

"Amputating As Many Limbs As Possible"

It's worth noting that IPAB is not being charged with increasing efficiencies in the health care system or ensuring more cost-effective delivery of care; its mandate is simply to slash costs. This is akin to asking a surgeon to treat a broken wrist by amputating as many limbs as possible.

If and when IPAB's recommendations take effect, its drone missiles will home in on the money companies like mine use to fund research and development. Large drug companies will not be mortally wounded by this attack, but will be forced to invest less in the breakthrough medicines we all need; the outcome for small biotechnology companies will be more grave, as some will not even be able to survive, and next-generation medicines that could keep millions of

people out of the hospital won't be developed.

If the board indiscriminately drives down prices on novel medications, society will lose one of the few proven methods of lowering health care costs. Consider just two common diseases that make up a major share of health spending: diabetes and heart failure. The average cost of a hospital stay resulting from diabetes or heart failure complications begins at around \$9,000, and patients often face multiple readmissions in a 12-month period. Compliant use of available pharmaceutical therapies that can prevent or delay hospitalization costs a fraction of admitting a patient to the hospital.

A recent academic study estimated that direct costs in the U.S. of caring for people with dementias (e.g., Alzheimer's disease) will exceed \$200 billion in 2013, and continue to rise stratospherically as our population ages. A medication that simply delayed the effects of dementia by 5 years would save the health care system an estimated \$50 billion per year. The biotechnology and pharmaceutical industries currently are investing billions of dollars to develop such medications. It's hard to think of any innovation in health care delivery or payment models that can match an effective medicine or vaccine.

What's certain is that breakthrough medicines require hefty investments. The Tufts Center for the Study of Drug Development estimates the R&D cost per drug at \$1.3 billion, on average, and Ken Kaitin, director of the center, says this 2007 calculation is likely to be revised upward. To repeat an important point: biotech companies with products on the market make these investments out of cash flow. If that declines, so does their ability to invest in medicines of the future.

While many people imagine that biotech rests on a comfortable cushion

of venture funding, the reality is very different. First-time funding for biotech startups plunged between 2006 and 2012. Last year the number reached the lowest point since 1995. Now suppose IPAB were to impose a 20% price reduction on specialty pharmaceuticals. Venture capital, anticipating even lower future returns to compensate for their risks, will withdraw even more. A struggling biopharma company with four or five development projects would suddenly find that it had the cash to support just one...or perhaps none.

Short-Term Thinking, Short-Lived Savings

The payment board's mandate substitutes a wishful, "easy" solution for the constructive strategy that is actually needed. It does nothing to foster medical innovation, either in new medicines, in care delivery or in payment models. Indeed, IPAB is misconceived to the point where no amount of tweaking will make it viable. Here's a quick summary of its fatal flaws:

- IPAB's indiscriminating assault on drug pricing, as mandated by the law, will have a substantial negative impact on medical innovation.
- IPAB council is neither elected nor accountable, and there are no safeguards to make sure members are truly "independent," or even "expert."
- While IPAB is drafting recommendations, stakeholders such as patients and physicians will have little opportunity to provide input.
- Changes IPAB makes to Medicare can't be overruled by the Administration or by the courts.
- IPAB is very likely to cut reimbursement to doctors, causing many to leave Medicare.

The great Greek physician, Hippocrates, whose Hippocratic Oath is learned by every medical practitioner in

the U.S., also taught that the physician “must have two special objects in view with regard to disease, namely, **to do good or to do no harm.**”

The prescription of IPAB to reduce costs of medical care fails on both counts. Handing the reins to an unelected, unaccountable IPAB would substitute blind cost-cutting for thoughtful health care policy. It would undermine America’s ability to innovate in medicine and to maintain its biotechnology

industry, one of its key engines of future economic growth.

Ultimately, short-term cost savings would prove to be exactly that – short-lived – while the far greater costs of inadequately treated diseases would take their toll. IPAB substitutes a “feel good” solution for rational policy, one that in the coming years will feel bad indeed to the millions of Americans who will need advanced medicines to treat their illnesses. Instead of expand-

ing IPAB, as the President proposed in his recent budget, the IPAB must be repealed. **RPM**

Comments? E-mail the editor at michael.mccaughan@provisionpolicy.com