

## Can Personalized Healthcare Survive Obamacare's Medicine Assembly Line?

By: John Goodman

September 20, 2012

Previously, I [wrote](#) about some wondrous developments that are taking place in medical science. [Implantable or attachable devices](#) already exist — or soon will exist — that can monitor the conditions of diabetics, asthmatics, heart patients and patients with numerous other chronic conditions. These devices will allow patients and doctors to modify therapeutic regimes and tailor treatments to individual needs and responses. [Genetic testing](#) is reaching the point where patients can be directed to take certain drugs or avoid other drugs, based solely on the patient's own genes.

Almost all HIV treatment these days involves therapy cocktails tailored for each individual patient. The FDA has approved a breast cancer drug only for women with a particular genetic makeup. Patients are being advised to steer clear of an ADHD drug and certain blood thinners if they have particular genetic variations.

We are entering the age of personalized medicine, where the therapy that's best for you will be based on your physiology and genetic makeup — and may not be right for any other patient.

Yet standing in the way of this boundless potential is an Obama administration whose entire approach to health reform revolves around the idea that patients are not unique and that bureaucrats can develop standardized treatments that will apply to almost everybody with a given condition. When former White House health adviser [Ezekiel Emanuel](#) told CNN recently that "personalized medicine is a myth," he was fully reflecting the worldview of the authors of health reform.

Everything about ObamaCare — from its emphasis on pilot programs and demonstration projects to its faith in "evidence-based care" — is all about standardization. It's about treating all patients with the same condition the same way. It's about herd medicine. It's about cookbook medicine. It's about assembly line medicine. It's as different from personalized care as different can be. As [Dr. Richard N. Fogoros](#) explains:

[T]he entire structure of ObamaCare is designed specifically to remove important (i.e., costly) medical decisions from the purview of the individual doctor and patient. The role of the doctor is now to relay expert-guided determinations of what is best for the herd down to the level of the individual patient, and to do it in such a way that their patients do not realize that the doctor's recommendations are population-based, and not tailored to their own needs.

It's not just the Obama administration, by the way. Underlying an enormous amount of medical research is the idea that we are all alike.

To make up an example, think about a clinical trial in which one group drinks coffee and the other group abstains. Then let's suppose the non-drinkers turn out to have a statistically significantly higher rate of colon cancer. So doctors respond by telling everyone to drink a cup of coffee every morning. This would be called "evidence-based" advice.

What's the implicit premise behind all this? That the two groups of people are alike in every important respect (other than their coffee consumption) and that the rest of us also are just like the people who've just been tested. I've [written before](#) why clinical trials like the one I just described are absurd. At least the way the results are used is absurd.

For present purposes, however, I'm making a different point: We are not all alike.

Think of the controversy surrounding the cancer drug Avastin. The clinical trials showed the drug doesn't work. But individual doctors and their patients were convinced the drug worked for them. Both conclusions may be right. That is, the drug may not work for randomly selected individuals. But it may be a life saver for patients with the right genes.

The same issue applies to side effects. Vioxx, an anti-inflammatory drug, was taken off the market because of dangerous side effects. But if we had enough genetic information, we might discover that Vioxx is a safe remedy for many patients.

Quite apart from the Obama administration, personalized medicine faces five public policy hurdles.

First, in order to get paid for implanting a sensor or conducting a genetic test, there needs to be a billing code. If the sensor or the test is new, [getting Medicare to create a code](#) can take both significant time and money.

Second, even if there is a code, Medicare must agree to pay for the service. In general, Medicare has not been willing to pay for genetic testing, with two notable exceptions: tests to determine compatibility for kidney and bone marrow transplants.

By contrast, [UnitedHealthcare spent \\$500 million](#) on genetic and molecular testing for its members last year, including Medicare and Medicaid patients enrolled in the insurer's private health plans. For Medicare Advantage, the company conducted 35 tests per 1,000 members on the average. For Medicaid, it conducted 329 tests per 1,000 members.

Third, Congress has [imposed price controls](#) on what Medicare can pay laboratories for conducting such tests.

Fourth, the FDA has authority to regulate sensors and apparently is now requiring full clinical trials before it will approve new ones. Clinical trials are time consuming and expensive. But the bigger problem is that with personalized medicine, doctors are going to react to the information the sensor

provides and [change their therapy accordingly](#). As a result, every patient in the clinical trial could be treated differently — which defeats the whole purpose of a trial.

Finally, personalized medicine is running up against out-of-date and inflexible malpractice laws. In essence, an electronic sensor can confront the doctor with a data dump and, in principle, this could happen at any time day or night. Some doctors worry that buried in the data could be information that the doctor doesn't see. If a problem later develops, a lawyer might argue that he should have seen it.

Bottom line: we need to bring public policy into the modern age.

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