

March 6, 2007

COMMENTARY

Prescription for Trouble

By SCOTT GOTTLIEB

March 6, 2007; Page A19

Inside the federal agencies that oversee parts of the health-care system, there is a palpable view that doctors can no longer be trusted to do the right thing.

The Food and Drug Administration, Medicare and even the Justice Department all believe they cannot rely on many doctors to heed safety warnings, wisely weigh new medical information, or follow treatment approaches that maximize health benefits or lower costs. So in recent years, these agencies have hatched rules that dictate when treatments should be delivered and even how they can be administered -- especially when it comes to new drugs.

The result is increasing federal regulation of medical practice that constrains health-care providers and limits the choices patients have. It might get worse. New legislation offered by Sens. Edward Kennedy (D., Mass.) and Michael Enzi (R., Wyo.), intended to make drugs safer, would raise this regulatory burden by reducing a physician's discretion to exercise clinical judgment and erecting barriers that will exacerbate disparities in access to care.



The legislative proposal extends the FDA's ability to restrict which physicians can prescribe a medicine, and which pharmacies can dispense it, through risk-management plans that would accompany the approval of many new drugs. These "RiskMAPs," as they are called inside the FDA, already guide the use of about 30 marketed drugs as part of "voluntary" arrangements with drug companies.

Right now, pharmaceutical companies propose the plans to better balance the risks and benefits of their drugs, in order to secure FDA approval. But these plans impose burdens, especially on patients who already face difficulty obtaining the specialist care that many RiskMAPs require for the dispensing of new drugs. Thus the FDA and the pharmaceutical industry have mostly confined RiskMAPs to drugs with unpredictable and potentially deadly risks, such as anaphylaxis or rapid organ failure.

That sense of restraint is lifting. New proposals by Congress and the Institute of Medicine advocate RiskMAPs for mitigating a wider set of less-serious problems and to constrain the off-label prescribing of new drugs, even though such prescribing is the standard of care

for many diseases. The proposals are gaining traction. Once the FDA is granted the authority to simply impose these RiskMAPs on drug companies, there will be a lot of political pressure on the agency to constrain prescription writing in the name of drug safety.

What would this mean? Consider the RiskMAP recently imposed by the FDA on the use of the diabetes drug Symlin. The new medicine can help very serious diabetics control swings in blood sugar and is one of the few drugs that promote weight loss. But Symlin has a narrow therapeutic margin and can sometimes cause dangerously low blood sugar. The FDA did not trust ordinary generalist doctors -- who treat most diabetics, especially poor or rural patients -- to properly prescribe the medicine or to limit its use to the labeled indication. So Symlin's RiskMAP tries to keep the drug out of generalist hands by, among other things, limiting promotion to doctors specializing in diabetes and who are also supported by certified diabetes educators.

Reflecting this pervasive mistrust of medical practitioners, Medicare is increasingly tying payments to the choices doctors make, compensating doctors more to follow certain cookie-cutter treatments or practice guidelines that are promoted by the agency because they are believed by government experts to maximize benefits or reduce health-care costs.

The Drug Enforcement Administration is also intruding into medical practice. Waging a campaign to cut down on prescription-drug abuse, the DEA has sought legislative authority that would give it a role in limiting the approvals of new pain products -- even though the agency has no ability to appreciate the public health considerations that create a medical need for better drugs to treat serious pain.

Meanwhile, the Department of Justice's war on off-label promotion by drug companies ends up criminalizing the exchange of truthful, non-misleading medical information with doctors on new uses for medicines. This even includes information derived from studies funded by other arms of the government such as the National Institutes of Health. Such was the case in the litigation DOJ recently waged and won against information exchanged on promising new anti-cancer uses for the osteoporosis drug Evista -- some of those uses are now standard care.

All of these approaches harm patients because they impose one-size prescriptions in an area of science that is marked by variation. Furthermore, parameters on the prescription of new drugs, like those imposed on the use of Symlin, create obstacles for patients who already face significant problems getting access to the latest drugs or the specialists who are ordained by FDA's RiskMAPs to prescribe them.

Medicare's treatment guidelines are not the right answer for everyone, because there is a need for judgment in medicine that attunes treatments to individual variations and preferences. DOJ's restrictions on the exchange of medical information deny doctors updated data on the most cutting-edge and specialized uses of new treatments.

Ultimately, we need a better system for accumulating new information about the risks and

benefits of treatments, and for communicating this information to providers and patients so people can make more informed choices. The key to improvement is not direct regulation of patient care, but better tools and approaches for evaluating the pros and cons of the many choices patients confront.

Doctors share some blame for inviting this kind of regulation. Agencies have plenty of data showing that some doctors do not heed safety warnings or follow sound advice. Professional societies like the American Medical Association, the various medical journals, and even licensing boards have grown self-interested and have failed the first tenet of an autonomous profession: the ability to regulate itself.

The solutions to any of the health-care problems that government is trying to mitigate will not rest in Washington's constraining "fixes," but with these organs of medicine working with agencies to promote practice standards and safety measures that do not sacrifice medical autonomy and patient choice.

Dr. Gottlieb, who was deputy commissioner of the FDA from 2005 to 2007, is a resident fellow at the American Enterprise Institute.

URL for this article:

<http://online.wsj.com/article/SB117314968751527893.html>

Copyright 2007 Dow Jones & Company, Inc. All Rights Reserved