Legal Opinion Letter

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CMS SHOULD STOP HEALTH PLANS FROM DISPLACING DOCTORS' JUDGMENT ON PRESCRIPTION MEDICINES

by
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In the next week, the Center for Medicare and Medicaid Services (CMS) will issue its Final Call Letter stating its policies and acceptable practices for 2010. A key provision is whether CMS will permit health insurers that participate in Medicare Part D to force ill patients to first use several off-label drugs unsuccessfully before reimbursing the patient for the medicine that the Food and Drug Administration (FDA) has specifically approved as safe and efficacious for that patient's ailment. In the past couple of years, several insurers have issued such policies because off-label choices can be less expensive. While off-label use of medicines may be beneficial to patients in some situations, requiring them in this context and refusing to allow patients to use approved medicines, puts those patients at risk. Of equal importance, this process violates the core tenet of our health care system: doctors are in the best position to choose the proper medication for their patients.

"Off-label" use of FDA-approved medications is the use of medicines to treat conditions for which those medications have not been approved. Under the FDA's purview, use of medicines for off-label purposes has become an accepted, important part of people's health care, particularly with cancer treatments and children's medical care. The FDA has said that physicians can use legally available medicines, biologics and devices in accordance with "their best knowledge and judgment." This vested responsibility includes using "a product for an indication not in the approved labeling." In a 2009 Industry Guidance, the FDA further stated that off-label uses of certain medications "may even constitute a medically necessary standard of care."

The focal point of these and other FDA statements on off-label uses of medications is to empower physicians to consider for each individual patient the benefits and risks regarding available medical options. Medically educated physicians, with the informed consent of their patients, use their best professional judgment to decide which medication is best for that patient at that time. Consequently, the FDA has developed strict rules for how pharmaceutical manufacturers can communicate information about potential off-label uses of medications so as not to improperly influence the doctor-patient decision. The FDA has understood that there can only be one traffic cop directing a patient's health care, and that is the patient's doctor.

The practice of several health insurers to require doctors to experiment with patients on treatments not approved by the FDA for a condition violates this fundamental premise of America's health care. What is even worse, they make forced "failure" an option, not just once, but two, three or even four times. A group of physicians specializing in rheumatology, namely, the Oregon Rheumatology Alliance, filed a formal complaint last year with the state's pharmacy board objecting to such requirements for patients with fibromyalgia. Fibromyalgia is a muscle and connective tissue pain disorder characterized by chronic widespread pain and heightened sensitivity to touch. The disease can be accompanied by extreme fatigue,

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sleep disturbance, joint stiffness, difficulty swallowing, bowel and bladder abnormalities, and breathing difficulty.

According to the complaint, an insurer required all Oregon patients to "fail to tolerate or [have] contraindications" for three groups of medicines not approved for fibromyalgia, before they could use medicines approved for this indication. As the physicians wrote, this requirement is "a clear violation of pharmacy practice and good medical practice. . . . This means that [patients] frequently must take a medication that was not their physician's first choice." This unfortunate practice has occurred elsewhere. For example, in Pennsylvania, an insurer required the use of four off-label medications before reimbursing for an on-label medication.

All prescription medicines have potential benefits as well as inherent risks of side effects. In approving a medicine, the FDA tries to restrict its use and warnings to fit the class of patients for whom the risk-benefit analysis is most appropriate. When a medicine is prescribed off-label, risks may arise that were not part of that FDA decision-making process. Experienced doctors can make adjustments for this possibility and provide patients with analysis necessary to anticipate risks and maximize benefits.

When health insurers restrict patient choice without knowledge of the patient's history and individual medical exam, the patient can be harmed in two ways. First, the detour to off-label medicines can delay use of medicines that would provide the best benefit to the patient. Failure to use a proven remedy may cause a patient to needlessly suffer additional pain. As is true with fibromyalgia and most illnesses, a disease may get worse and valuable time will be lost in trying to abate or cure the illness. Second, a patient may needlessly endure side effects before receiving the approved drug. It is unsound public policy to have patients suffer serious side effects because they had to take off-label medicines before being able to take the medicines that have been approved for their specific medical situations and for which the benefit-risk calculations may have been most appropriate.

Litigation arising from insurers pushing off-label "potential" cures creates a loose and potentially unfair "liability bowling ball." Even though decisions to require off-label medicines were made by an insurer, the prescribing doctor could be subject to liability for medical malpractice. "Superior orders" from an insurer is not a recognized defense to a malpractice claim. Similarly, the medicine's manufacturer could be subject to liability even though it followed FDA rules and did absolutely nothing wrong.

As the Fen-Phen diet drug litigation has shown, liability lines are not always clear. In that litigation, the manufacturer was subject to liability for off-label uses of Fen-Phen even though there was no evidence it promoted such uses. The Fen-Phen warning label stated that it was for use by obese individuals for short periods of time; yet, it was prescribed for non-obese people for long periods of time. Liability was based on the fact that Fen-Phen's manufacturer presumably knew or should have known Fen-Phen was being prescribed in such off-label ways given the drug's large amount of sales.

CMS, in its February 23 memorandum, took an important first step in drafting a rule for the Final Call Letter that would block Medicare Part D insurers from requiring the use of off-label requirements in some situations. The provision states:

> In the absence of widely used treatment guidelines or clinical literature, Part D sponsors will not be permitted to require an enrollee to try and fail drugs supported only by an off-label indication (an indication only supported in the statutory compendia) before providing access to a drug supported by an FDA approved indication (on-label indication).

This is a step in the right direction, but as a coalition of seventeen bi-partisan state attorneys general observed, the opening clause "creates a loophole that threatens to undermine the entire" new rule. The attorneys general said the clause should be stricken because it could still lead to "serious medical consequences for patients" and that it "undermines the doctor-patient relationship" and "subverts the legislatively mandated approval process for drug indications by substituting the judgment of health insurance companies for that of the FDA."

The loophole should be firmly closed. Insurers should follow the same rules as manufacturers of pharmaceuticals and all others and not elevate their own considerations over qualified physicians and the best interests of patients.

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