The Daily Dish

Loper Bright v. Raimondo and Health Policy

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AAF's John Walker and Henry Roberts put a little meat on the hypothetical bones in Post-Chevron Impacts on Health: Three Case Studies. As they put it: "With agencies no longer given automatic deference in the event of ambiguous statute, courts are now likely to weigh-in on longstanding disputes over the definition of 'same drug' and 'medical device,' as well as Medicare reimbursement rates and coverage determinations."

Consider the first example:

> Dispute over [the term "same drug"] arose when the Food and Drug Administration (FDA) approved biopharmaceutical company Avadel's narcolepsy treatment Lumryz during the exclusivity period for company Jazz's narcolepsy treatment Xywav, which had received orphan drug designation in 2020. Orphan drug designation, which was established by the Orphan Drug Act, grants companies a seven-year exclusivity period to produce treatments for rare diseases, disorders, and conditions. During this period, the FDA may not approve the "same drug" for the treatment of the same condition from a rival company. Because Jazz's Xywav and Avadel's Lumryz have the same active moiety – and are thus arguably the same drug – Jazz filed suit against the FDA.

The authors provide a detailed analysis of both sides of this dispute, but the key is that, under *Loper Bright*, the courts must now grapple with the meaning of "same drug" – not the FDA. The authors conclude:

> If courts find the term to be unambiguous, this would establish legal precedent for future rulings. If courts find the term to be ambiguous, they will decide which party's interpretation is correct and potentially set a precedent for future legal battles centering around the term "same drug."

In the second example, dispute arose when the FDA decided to classify laboratory testing services, known as laboratory developed tests (LDTs), as medical devices. LDTs are not commercially distributed tests (e.g., kits). They are diagnostic tests that are designed, manufactured, and used within a single laboratory to diagnose diseases or other conditions. The short version is that the FDA has claimed that LDTs were always classified as medical devices – it just chose not to regulate them. The FDA has never been explicitly granted authority to regulate LDTs but claims that it is covered by other authorities Congress has granted it.

You can see where this is going. The courts will now have to decide if these tests are truly medical devices, and not defer to an FDA that seemingly has come to contradictory conclusions over time. See the paper for a deeper discussion and the third case study. But these examples suggest that the regulatory world will be very different in the future.