Op-Ed
Rep. Henry A. Waxman

Five years ago, I chaired the hearing at which seven tobacco CEOs testified that nicotine isn't addictive, smoking doesn't cause cancer, and their companies never target children. It took a lot of digging, but we now have the documents that prove the industry never believed this.

In the next few months, the Supreme Court faces what may be an even bigger challenge. The Justices must decide whether the Food and Drug Administration is legally authorized to regulate tobacco products. The legal issues are more complicated and difficult to sort through than determining whether nicotine is addictive or smoking causes cancer. And the public health consequences of their decision are enormous.

It's impossible, of course, to predict the Court's ruling. But the early reports that FDA has a weak case may be premature. There are major holes in the industry's legal defense that are likely to emerge as the Justices scrutinize the arguments.

The tobacco lawyers' most important argument is that FDA jurisdiction would be tantamount to a prohibition on tobacco products. They say that if FDA asserts jurisdiction, FDA will have only two options: FDA can allow tobacco products to remain on the market, which would be illegal since they are not "safe" or "effective," or FDA can ban tobacco products, which could not have been intended by Congress. Since neither option is appealing, they conclude that tobacco products don't "fit" under FDA jurisdiction.

But this argument relies on vast oversimplification. There is a lot of middle ground between the status quo and prohibition. If FDA has jurisdiction over tobacco products, it will have dozens of regulatory options.

FDA could decide that the safest and most effective way to protect adults is to phase out nicotine over time. Or it could decide to protect public health by requiring that future cigarettes be heated, rather than burned, to reduce cancer-causing tars. (R.J. Reynolds and Philip Morris have both already marketed tobacco products that deliver nicotine in this manner.) Or it could require the production of "safer" cigarettes that provide nicotine satisfaction to addicted smokers without many of today's adverse side effects.

It is premature to predict what FDA would -- or should -- do. FDA is a science-based agency that has a wide range of regulatory authorities. If the Court upholds its jurisdiction, the agency will solicit advice from the leading medical experts in the country. This process takes years and its outcome is unknown. The only thing that's clear is that FDA won't be limited to the Hobson's choice posited by the tobacco lawyers.

The tobacco lawyers' other main argument is that FDA is making an unprecedented power grab. They say that for over 60 years, until former FDA Commissioner David Kessler came along, FDA had never asserted jurisdiction over these products.

This is a powerful argument -- except that it turns history on its head. The fact is that FDA has previously regulated tobacco products. FDA brought several cases in the 1950s in which it asserted regulatory authority over cigarettes that were marketed for weight reduction or prevention of respiratory disease. In these cases, the courts upheld FDA's authority to regulate. They ruled that the evidence assembled by the agency showed that the manufacturers "intended to affect the structure or function of the body," thereby meeting the legal test for FDA jurisdiction.

These cases received little attention in the arguments before the Court, but they have great significance. They show that the real issue before the Court is an evidentiary one -- not a legal one. If the evidence establishes that today's cigarettes are intended to affect the structure or function of the body, the agency has just as much right to regulate them today as it had 40 years ago.

The tobacco lawyers try to distinguish the 1950s cases by arguing that they involved cigarettes for which express health claims were made. That's true, but as Justices Breyer and Stevens seemed to recognize, it's not a persuasive distinction. Express claims are one way to determine manufacturer intent, but they are not the only way. Internal industry documents of the sort that my subcommittee released are equally valid evidence. In fact, if the tobacco lawyers were right, manufacturers of virtually any drug could skirt FDA regulation by changing their advertising.

Smoking kills nearly 450,000 Americans every year, and the tobacco industry is a major economic force, so it's not surprising that emotions are often part of the tobacco debate. But emotion won't resolve the Court's deliberations. The case may well rest on FDA's inherent regulatory flexibility and forty-year-old precedents. And that could mean the tobacco industry's worst nightmare will be realized: not prohibition, but being treated like every other nicotine-delivery device.