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From The Editor-In-Chief:

Maybe I don't get out enough, but I was astounded to hear one of the speakers in our Cellular Therapies program refer to his company's cellular product as a "drug." But then I'm from the old school when antibodies, cytokines, and vaccines were essentially all the "biological" products out there. Way back then, it was pretty clear that biological products were regulated by the Center for Biologics Evaluation and Research (CBER) in their offices for Vaccines, Blood, and Biologics; and sometimes a combination of these offices, with potential involvement from the group regulating medical devices, the Center for Devices and Radiological Health (CDRH).

So I questioned why the speaker was calling his product a "drug," and his response was even more confounding when he asked me if the term "drug product" made me feel any better — it didn't. Then to make matters worse, a member of the Office of Tissues and Advanced Therapies (OTAT) chimed in that it was standard practice to refer to cellular products as drugs.

A week or so later, I contacted an old friend at the Center for Biologics Evaluation and Research (CBER), and plead with him to straighten things out. But to my utter amazement, he confirmed that cellular products were indeed referred to as drugs, and the only explanation I could extract was an analogy to a Venn diagram in which the overall circle represented "drugs," and a smaller circle within this circle was designated as "biologics." And even though I knew the battle was over, I asked why they didn't use the name of this smaller circle — biologics. In addition, I pointed out that cellular products fit the definition of the word "biologic" as posted on the FDA and Biotechnology Innovation Organization (BIO) websites, plus these products were being regulated by CBER and not the Center for Drug Evaluation and Research (CDER). But all was in vain, and it was clear that I hadn't received the memo on this FDA policy development, and the train had left the station.

To understand my resolve, in 2001 I watched the political and organizational turmoil when therapeutic proteins were moved from CBER to CDER. According to people very close to the story, plus New York Times reporting, the Vice President at the time, Dick Cheney, developed FDA regulatory policy in a secret meeting with leading pharmaceutical executives who thought they would have an easier time getting biological products licensed through CDER. Kathryn Zoon, who was the director of CBER, found out about this action by reading its coverage in the New York Times, and shortly thereafter resigned. And what makes this decision even worse is the people at CDER weren't accustomed to handling anything as complex as a biological product, and they didn't have many of the database fields needed to accept the data that was transferred to them. In addition, the vast majority of the experience/precedent associated with these more established biologics was pulled out of CBER when the center really needed this experience for the vastly more complicated, newer biologics such as viral gene vectors and cellular therapies.

When I go to a therapeutic protein meeting, it's very hard for me to hear these products referred to as "drugs." But since they are being regulated by CDER, it's a little easier to swallow. However, calling viral gene vectors and cellular therapies "drugs" is a bridge too far. My advice to my good friends at CBER is to keep calling their products "biologics," or they may lose all of their regulatory responsibilities to CDER.

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