Spotlight on Dr. Bloom is food for thought in Boston

By ACSH Staff — April 15, 2011

Why so many drug companies are failing is the question ACSH’s Dr. Josh Bloom examines in his op-ed [1] published yesterday by Medical Progress Today. Following the “golden years” of pharmaceutical research in the 1990s, many blockbuster drugs, such as Pfizer’s cholesterol drug Lipitor, are facing patent expiration; and with few promising products in the pipeline, big pharma is starting to source their R&D departments abroad to cut costs. In addition, the onerous FDA regulatory environment is exacerbating the current drug approval impasse, with the most recent example being the rejection of three weight-loss drugs in 2011 despite the nation’s ongoing battle against obesity. Dr. Bloom writes:

…the FDA, which has become so cautious that it seems to focus only on the potential risks of a new drug, ignoring all the potential benefits. This mentality, and the unreasonable demands of the FDA has reduced new drug approvals to historic lows, despite ever increasing industry research budgets. This is the crux of the problem.

The FDA’s reluctance to support incremental innovations has led to a dearth of new products that can sustain the industry until the next breakthrough comes along. As a result of the industry’s worsening balance sheet, mergers, outsourcing and mass layoffs have decimated pharmaceutical research in the U.S.

On the same pessimistic theme, Biotech executives at the BD Biotech Conference this week in Boston echoed [2] these sentiments and agreed that the FDA’s stringent regulatory environment is at least partly to blame for the recent pressure on small biotech companies to merge or be bought out by a foreign competitor.

“It’s a big concern,” said Richard F. Pops, chief executive of Alkermes Inc., “but there’s not a hell of a lot you can do about it except to make yourself look unattractive” to a potential buyer.