an alternate form of delivery, there are a number of additional options that could be considered. Intravenous (IV), intraperitoneal (IP), subcutaneous (SC), intramuscular injections (IM), transdermal, and intranasal delivery[19] are some of the options available for candidate compounds that cannot be delivered orally. Insulin, for example, is an absolute necessity for insulin-dependent diabetics, but peptides like insulin are not typically orally bioavailable due to their poor absorption. Similarly, patients suffering from migraine headaches were very willing to accept injections of Imitrex® (Sumatriptan, Figure 9.7) when it was originally introduced in 1991 as the

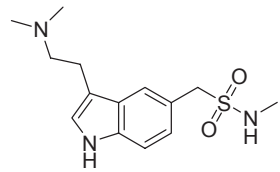

FIGURE 9.7 Imitrex® (Sumatriptan).

first effective treatment for migraine headaches.[20] In this case, the pain was less tolerable than the needle. The benefits of Reclast® (zoledronic acid)[21] also allowed it to reach the market in a non-oral formulation. In this case, the drug is given to patients once a year as a 5 mg intravenous infusion for the treatment and prevention of osteoporosis. There are several competing oral medications, such as Fosaamax® (Alendronic acid),[22] Actonel® (Risedronic acid),[23] and Boniva® (Ibandronic acid),[24] but the clinical utility of Reclast® is significant enough to warrant an IV formulation (Figure 9.8).

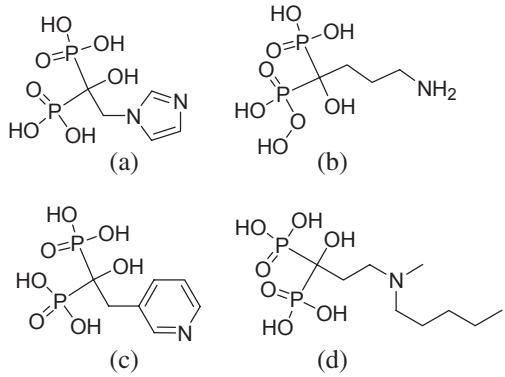

FIGURE 9.8 (a) Reclast® (zoledronic acid) (b) Fosaamax® (Alendronic acid) (c) Actonel® (Risedronic acid) (d) Boniva® (Ibandronic acid).

While there are a many examples of the successful commercialization of drugs that are delivered using non-oral routes of administration, the choice to move down this path must be carefully considered. An IV-delivered drug may reach the market, but if a competitor develops an orally