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November 3, 2003

**Via Electronic Transmission and
Federal Express**

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

***Re: Docket No. 2003N-0361
Request for Comment on Counterfeit Drug Task Force
Interim Report***

Dear Sir or Madam:

Amgen Inc. (Amgen) submits the following comments in response to the notice published by the Food and Drug Administration (FDA) on September 5, 2003 (67 FR 52772) and the interim report published by the agency's Counterfeit Drug Task Force on October 2, 2003 (67 FR 55025) regarding FDA's proposed anti-counterfeiting initiative. The interim report explores potential approaches FDA and the pharmaceutical industry may pursue to deter and detect counterfeit drugs and biological products (hereafter "drugs"), while avoiding unnecessary costs to the drug distribution system.

Amgen manufactures and markets many of the world's leading biotechnology products, including Epogen[®] (epoetin alfa), Neupogen[®] (filgrastim), Aranesp[®] (darbepoetin alfa), Neulasta[®] (pegfilgrastim), and Enbrel[®] (etanercept). By the very nature of our business, we are philosophically and financially committed to the safety of the American drug supply. Within the last three years, Amgen has been the target of counterfeiting schemes involving Neupogen[®], Epogen[®], and Procrit[®].^{1/} It is from this perspective that Amgen offers the following comments.

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^{1/} Amgen manufactures Procrit[®] for distribution by Ortho Biotech Products, L.P.

COMMENTS

FDA seeks input from the industry in five general areas: technology; regulatory requirements and secure business practices; rapid alert and response systems; education and public awareness; and international issues. In principle, Amgen supports many of the proposals raised by the task force in these areas, and we agree that a comprehensive, multi-pronged strategy will yield the most sensible policy.

Amgen understands the urgency of the task force's mission. We remain cautious, however, about the feasibility of industry-wide mandates and the long-term effectiveness of technological "quick fixes." Amgen strongly believes that any decisions about technology applications should be based on sound science. We also believe that while drug counterfeiting appropriately has been the subject of increasing law enforcement and media attention, it is important that FDA calibrate the solution to the true extent of the problem. Thus, it is Amgen's hope that FDA will continue to work with the industry to better define the contours of the problem, to further study the ramifications of the proposed solutions, and to articulate a more detailed roadmap before settling upon a course of regulatory action.

I. Technology

Amgen is encouraged that FDA, along with the industry, is exploring current and future technologies to deter and detect counterfeit drugs. We are concerned, however, that too much emphasis may be placed upon potential solutions whose costs and benefits remain vastly unknown. We need to better understand the dimensions of the problem before attempting to develop solutions. Moreover, the diversity of products in the market, and the very different roles of the stakeholders involved in the factory-to-consumer distribution chain, suggest that a flexible approach is required. If regulatory action is pursued at this early stage, manufacturers and other stakeholders must be afforded considerable discretion in applying anti-counterfeiting technologies to their products and business practices.

A. Forensic Technologies

Among the technologies explored by the task force are forensic techniques using chemical taggants and markers, and other covert technologies incorporated directly into the manufacturing process. Amgen recognizes the

potential value of these technologies for use with certain drugs, particularly solid oral dosage form products, and we support industry-based development of these security measures. Nonetheless, because of the extreme sensitivity of therapeutic protein and parenteral products, we are concerned about premature industry-wide mandates in this area.

Protein therapies are fundamentally different than solid oral dosage form products and other small molecule drugs that may tolerate forensic security techniques. Amgen's biotechnology products are highly sensitive to impurities in any quantity; the introduction of even trace amounts of a seemingly benign chemical taggant may change the pharmacokinetic and pharmacodynamic profile of the product, cause protein aggregation, or precipitate an immunogenic response. Moreover, because these therapies are injected directly into the patient's bloodstream, the introduction of any foreign material would fundamentally change the safety and stability profile of the product. It is highly unlikely that any one variety of chemical taggant could be universally applied to protein products, as each taggant would need to be tested with each unique protein.

Counterfeiting presents significant risks to patients. At the same time, certain of the proposed technological solutions present new and unknown risks of their own. Therefore, Amgen respectfully urges that, before regulatory action is considered, controlled research must be performed to learn the ramifications of introducing chemical taggants or other technologies directly into the manufacturing process. Any regulatory action regarding such forensic security measures must be open and flexible, affording discretion to the manufacturers to implement anti-counterfeiting technologies that complement the specific characteristics of their diverse products. Any other approach would prove not only infeasible, but potentially dangerous to patients.

B. Radio Frequency Identification

In its report, the task force highlighted various track and trace technologies, including radio frequency identification (RFID) systems. The challenges of implementing an industry-wide RFID track and trace system are significant, especially at the unit dose level. The cost of the necessary hardware and the design, installation, validation, and maintenance of an infrastructure to support the technology certainly will be immense. For example, it has been estimated that RFID tags currently cost thirty to forty cents per tag, with the

associated scanners costing \$1,500 to \$2,000 each. C. Duhigg, *Matrics Secures Venture Financing*, WASHINGTON POST, July 15, 2003, available in 2003 WL 56505982. Considering that manufacturers like Amgen produce upwards of one hundred million units of product each year, an image of the magnitude of such a technological overhaul begins to emerge. At this point, it is unknown how such an overhaul would be financed or how long it would take to implement.

There are other potential risks associated with this technology. As with the use of chemical taggants, the use of RFID technology may negatively impact the quality of our products. The electromagnetic radiation used to power and read the embedded RFID chips may degrade or otherwise impact our therapeutic proteins. This is particularly true because RFID technology requires multiple scanning of the packaging during its movement through the distribution chain. Thus, at a minimum, stability studies are required to learn the impact of the application of this technology to drugs and biologics before proceeding.

Furthermore, there are important questions of privacy implicated in any proposal to track and trace consumer goods, particularly products related to healthcare. Previous industries that explored the application of RFID technology to consumer goods at the item level have abandoned the notion after objections and boycotts by consumer advocacy groups. *Id.* (citing decisions of retailer Wal-Mart Stores Inc. and clothing company Benetton Group SPA to abandon plans to use RFID tags on consumer items); see also J. Covert and C. Cheddar Berk, *Consumer Groups Rip Tracking Chips*, WALL STREET JOURNAL, July 30, 2003, available in 2003 WL-WSJ 3975450 (detailing similar decision by personal products maker Gillette Co.).

Amgen supports the exploration of the development of a track and trace system for drugs and biologics.^{2/} At the same time, questions of product impact, cost, implementation, and privacy must be more thoroughly explored before

^{2/} We also note that the recently proposed bar coding rule may be adapted to meet the needs of the anti-counterfeiting initiative. By requiring the inclusion of lot numbers in addition to National Drug Code numbers, the rule could address both counterfeiting and medication errors. This may be a desirable approach to the extent that bar coding may be more feasible and readily available than an industry-wide RFID system, and because the agency already has invested institutional resources in developing the bar coding proposal. See 68 Fed. Reg. 12500 (Mar. 14, 2003).

pursuing a vast technological overhaul that may alter the fundamental business model of an entire industry and require years to implement.^{3/}

C. Electronic Database

The task force also proposed the development of an electronic database of prescription drugs for authentication purposes, including extensive photographs of authentic products, packaging and labeling information, and details regarding the anti-counterfeiting measures used for each product. The inherent risks associated with such a one-stop source of authentication information are manifest; such a database would pose a potential treasure trove to computer-savvy counterfeiters.^{4/} The level of security required for a collection of such valuable information and the ever-present risk of its misappropriation may diminish its value to FDA and the industry. Certainly, more investigation into the feasibility and security requirements of such a database is necessary. Moreover, there remain important questions regarding who would establish, maintain, and own the database and its contents.

II. Regulatory Requirements and Secure Business Practices

Amgen believes it is paramount that all stakeholders in the drug manufacturing and distribution chain create and maintain a high level of diligence to help close the gaps through which counterfeit drugs reach consumers. We are particularly concerned with the lack of regulatory oversight and secure business practices in the secondary wholesaler market. Recent cases highlight these deficiencies. For example, the counterfeiters responsible for producing and selling thousands of vials of fake and subpotent Procrit[®] were unlicensed distributors or, in some cases, had received licenses despite drug-related felony convictions.

^{3/} FDA must also consider the extent of its legal authority to mandate such measures. *See, e.g., Nutritional Health Alliance v. FDA*, 318 F.3d 92 (2d Cir. 2003); *Association of Am. Physicians and Surgeons v. FDA*, 226 F.Supp.2d 204 (D.D.C. 2002).

^{4/} Counterfeiters already make use of such information as it becomes publicly available. For example, the individuals arrested in February 2003 for producing approximately 300 to 500 boxes of bacteria-laden counterfeit product apparently used information and photographs of Procrit[®] vials and labeling, posted on FDA's Web site, to more accurately mimic the authentic product. *See* S. Kestin and B. LaMendola, *Three Accused of Selling Fake Drug*, SOUTH FLORIDA SUN-SENTINEL, May 22, 2003, available in 2003 WL 55281353.

B. LaMendola and S. Kestin, *Former Convicts Try a Safer Venture: Pharmaceuticals* (hereinafter *Former Convicts*), SOUTH FLORIDA SUN-SENTINEL, May 26, 2003, available in 2003 WL 55281973. They laundered their stolen and counterfeit goods through a series of other unauthorized and/or unlicensed secondary distributors. *Id.* Pedigrees for the products were not verified, and the adulterated drugs ultimately were sold to major American distributors and given to patients. *Id.* Unfortunately, the details of this case are not unique. See, e.g., G. Gaul and M. Flaherty, *U.S. Prescription Drug Market Under Attack*, WASHINGTON POST, Oct. 19, 2003, at A01 (describing the secondary wholesaler market as part of “a wide-open drug bazaar that endangers public health”).

In light of such facts, we believe that priority for additional regulatory oversight should be placed at these access points through which counterfeit drugs enter the drug supply. Regulatory mandates for a more vigorous licensure and inspection system, paper pedigrees detailing the transactional history of all products, thorough verifications of pedigrees by buyers, strict controls on printing and disposal of packaging and labeling,^{5/} and investigations into suspicious transactions are essential to the success of the anti-counterfeiting initiative. Indeed, Amgen believes that addressing these significant gaps in the regulatory framework likely will yield more far-reaching and long-term results than most technology-based solutions.

A. Wholesale Distributors

We strongly encourage FDA to effectuate final regulations published in 1999 to implement the Prescription Drug Marketing Act of 1987 (PDMA), which was intended, in part, to prevent the introduction of counterfeit drugs via an uncontrolled wholesale drug diversion submarket. See 64 FR 67720 (Dec. 3, 1999). By requiring unauthorized distributors (*i.e.*, wholesale distributors lacking an established ongoing relationship with a manufacturer) to record each purchase and sale of a prescription drug, PDMA sought to ensure accountability for the movement of prescription drugs. *Id.* at 67761-62.

^{5/} The individuals convicted of making and selling thousands of vials of counterfeit Procrit® allegedly paid a commercial printer to reproduce Amgen's inserts and labels for use in their counterfeit vials and boxes. See *id.* Other counterfeiters obtain packaging from the garbage bins of hospitals and pharmacies.

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Each year since 2000, however, the agency has delayed the pedigree requirement after unauthorized distributors expressed concern about the potential adverse economic effects of such a requirement. *See, e.g.*, 65 FR 25639 at 25640-41 (May 3, 2000) (staying effective date of pedigree regulations). Since then, the distribution of prescription drugs by more than 6,000 unauthorized distributors remain unrecorded, while the number of counterfeiting investigations increased four-fold from approximately five annual investigations during the 1990s to twenty annual investigations. FDA, *The Prescription Drug Marketing Act Report to Congress* (June 2001); FDA News, *FDA Announces Initiative to Heighten Battle Against Counterfeit Drugs*, (July 16, 2003). Moreover, as noted by Florida's Seventeenth Statewide Grand Jury in its First Interim Report on counterfeiting, since the passage of PDMA, "there has been a sharp increase in the number of small wholesalers in this country." *First Interim Report of the Seventeenth Statewide Grand Jury* (hereinafter *Florida Grand Jury Report*), Case No. SC02-2645, at 8 (Feb. 2003) (www.myfloridalegal.com/swp). Thus, PDMA's mandates, if important in 1987, are critical today.

Opponents of paper pedigrees charge that it would be too costly to implement, and that it would be ineffective because paper pedigrees easily could be forged. These complaints are largely unfounded.^{6/} As to cost, the paper pedigree system is considerably less expensive and much easier to implement than an electronic pedigree system, which will require the creation of a national infrastructure and integrated database to support the technology. Indeed, the Florida Grand Jury determined that pedigree papers "are the cheapest, easiest and most effective way to prevent diverted or counterfeited drugs from entering the marketplace."^{7/} In any case, the unverified economic complaints of the wholesale distribution industry should not supersede safety concerns arising from the market entry of counterfeit drugs.

Similarly, the objection that paper pedigrees can be forged is not fatal. First, most counterfeit pedigrees could be rooted out with simple verification

^{6/} After hearing testimony from large and small wholesalers and others in the industry, as well as various governmental agencies, the Florida Grand Jury found "weak and unpersuasive" the arguments of the wholesaler industry against paper pedigree requirements. *Florida Grand Jury Report* at 27.

^{7/} *Id.* at 33-34.

procedures by wholesalers.^{8/} Second, even forged pedigrees are extremely valuable to investigators of suspected counterfeiting incidents. In cases in which Amgen's products were counterfeited, for example, fictitious pedigrees provided evidence of the movement of the fake product through the distribution chain, contributing substantially to the identification and arrest of the counterfeiters. FDA should not abandon the readily feasible and effective security measure promised by PDMA's paper pedigree requirements, as an interim measure, simply because it is possible that some of the documents may be forged.^{9/}

Given the increased incidence of counterfeiting, the relative cost-effectiveness of the paper pedigree system, its potential to be implemented immediately, and its deterrent and evidentiary value, PDMA's pedigree requirements must be rendered effective today.

B. Repackers

The repackaging of drug products represents another access point in the distribution chain through which counterfeit product may enter the drug supply.

^{8/} As noted in the Florida Grand Jury Report, it took investigators less than one hour to trace the pedigree trail of the counterfeit Procrit® and to determine with one telephone call to the manufacturer that the company, in fact, never sold any of the named product to the wholesaler listed in the pedigree. *Id.* at 23.

^{9/} Complaints that the pedigree regulation is ineffective because it does not require authorized dealers to provide pedigrees are also unpersuasive. As FDA recognized as recently as June 2002, even an incomplete pedigree offers significant deterrent and evidentiary value:

FDA believes that maintaining and passing on a pedigree on prescription drugs provides a valuable tool—even if this is required of only those secondary distributors unable to attain authorized distributor status. The pedigree requirement is a deterrent to the introduction and retail sale of substandard, ineffective, *and counterfeit drugs*. . . . FDA believes that requiring a pedigree makes it more difficult for someone planning to introduce counterfeit or diverted drugs into commerce. Requiring a pedigree also facilitates the efforts of law enforcement personnel seeking to identify the source of a counterfeit or diverted drug shipment and take action against those responsible.

FDA and Dept. of Health and Human Services, *The Prescription Drug Marketing Act Report to Congress* (June 2001) at 9 (emphasis added).

First, counterfeit product may become commingled with legitimate goods at the repacking point. Second, counterfeit items may be repackaged in a way to make them appear legitimate. Third, as the interim report notes, repacking can destroy anti-counterfeit measures contained within the original packaging and labeling. This is particularly true regarding covert security measures, which could be neutralized or destroyed in the repacking process. There is no easy solution to this problem, as it would be counterproductive to disclose the covert anti-counterfeiting measures to all repackers. Finally, repacking can alter the conditions for which the product was approved, resulting in diluted, misbranded, and adulterated goods.

Thus, we believe there exists an opportunity for FDA to reduce the risk of counterfeiting, as well as the incidence of misbranded and adulterated drugs, by initiating increased oversight of repackers. We encourage the agency to consider developing a streamlined new drug application form and process for repackers and, thereby, close the regulatory loophole that many repackers currently enjoy.^{10/} In so doing, we believe the integrity of the entire drug supply would be greatly improved.

C. Penalties

Amgen joins law enforcement officials and presumably the entire pharmaceutical industry in the call for increased penalties for drug counterfeiting. If we are to make real headway in the fight against counterfeiting, appropriate penalties are needed to effectively deter and punish the crime. As the interim report notes, however, the maximum term of imprisonment provided by the Federal Food, Drug, and Cosmetic Act *for counterfeiting a drug* is only three years. 21 USC § 333(a)(2). In contrast, the Act provides a maximum ten-year prison term *for counterfeiting a drug coupon* or selling a drug sample. 21 USC § 333 (b)(1)(B) and (C). This inconsistency should be legislatively corrected.

In the meantime, there are other sources of statutory authority for prosecuting and sentencing counterfeiters that should be explored. For example, those who distribute drugs without a wholesaler license are subject to a maximum

^{10/} Most repacking results in the creation of a new drug, for which a new drug application should be required. See *United States v. Baxter Healthcare Corp.*, 712 F. Supp. 1352 (N.D. Ill. 1989), *aff'd*, 901 F.2d 1401 (7th Cir. 1990); FDA Compliance Policy Guide § 446.100; *but see United States v. Kaybel, Inc.*, 430 F.2d 1346 (3d Cir. 1970) (suggesting limited exception for repacking of solid oral dosage products under certain conditions); 21 CFR 314.101(a)(8).

ten-year prison term under PDMA. 21 USC § 333 (b)(1)(D). Because many counterfeiters are unlicensed, or receive licenses fraudulently, PDMA may provide an alternative source for prosecuting counterfeiters and applying a longer maximum prison term. In addition, the Racketeer Influenced and Corrupt Organizations Act (RICO) prohibits conduct constituting a pattern of racketeering activity by directly or indirectly participating in an enterprise which affects interstate commerce. 18 USC § 1962(a)-(c). "Racketeering activity" includes acts of mail fraud, dealing in controlled substances, and trafficking in goods bearing counterfeit marks. 18 USC § 1961(1). RICO violations carry a maximum sentence of twenty years' imprisonment. 18 USC § 1963(a). And, for those prescription drugs that are "controlled substances" for purposes of the Controlled Substances Act, counterfeiters also may be subject to that act's penalties, including imprisonment terms ranging from one year or less to life. 21 USC § 841.

Finally, there are numerous state laws under which drug counterfeiters may be convicted. To facilitate the effective prosecution of counterfeiters under these laws, Amgen encourages FDA to continue its cooperative efforts with state law enforcement authorities.

D. Enforcement

FDA has identified the anti-counterfeiting initiative as a high priority. Amgen encourages the agency to allocate its staffing and other resources in a way that is commensurate with this high priority status. For example, we urge FDA to develop anti-counterfeiting as a compliance and criminal investigation specialty, with appropriate dedicated staff. Developing an expertise in the area of anti-counterfeiting will not only allow the agency to more effectively interact with other law enforcement officers, but will provide a central point of contact for the industry and public.

III. Rapid Alert and Response Systems

Amgen is generally supportive of the task force's proposals regarding a rapid alert and response system. We endorse the suggestion to enhance FDA's MedWatch Alert System to disseminate timely information about counterfeit drug products, provided there is a close collaboration between the industry and federal regulators regarding pre-dissemination verification of information. Although our mutual objective is to disseminate accurate information at the earliest possible time,

an industry-wide system that is not carefully monitored presents a significant risk of flooding the public with redundant and possibly inaccurate information. This, of course, would detract from the ultimate goals of public awareness and safety. Therefore, Amgen perceives the need for a sophisticated filtering and verification layer to any future alert system.

As to the dissemination of such information, Amgen believes it has developed a model system in this regard. For example, once we have verified a counterfeiting incident, we immediately post all relevant details on our Internet Web site. This information includes the implicated lot number and expiration date, a comparison of the authentic product and the counterfeit item, including photographs showing how to identify the counterfeit product, contact information for FDA and Amgen's Medical Information hotline, and a list of all authorized, direct wholesalers of Amgen products. This same information also is quickly communicated to health care officials, wholesalers, and pharmacies via notification letters and electronic letters provided to the state boards of pharmacy. Amgen believes that such a strategy for informing the public and our business partners of suspected counterfeiting incidents is an effective way to timely communicate reliable information to these parties. At the agency's discretion, we would be happy to meet with members of the task force to further share our experience in this regard to assist FDA in developing counterfeit alert systems.

IV. Education and Public Awareness

Amgen shares the task force's recognition that education and public awareness are essential components of an effective anti-counterfeiting campaign. We agree that vigilance on the part of consumers, pharmacists, wholesalers, health care workers, and other stakeholders in inspecting prescription drugs and reporting suspicious products is essential, and Amgen supports the use of public service announcements and other outreach efforts to this end.

However, because of the increasing sophistication of the criminal counterfeiting culture, it is uncertain whether a vigilant and educated public could detect counterfeit product. Thus, we believe it is important to balance the costs of such a public education campaign, which would require a far-reaching and repeated message, with the perhaps modest gains in public awareness that may be achieved, as well as the costs to the public's confidence in the United States drug supply. A more effective approach may be to concentrate education and awareness campaigns

on healthcare providers, packagers, printers, and other industry stakeholders who control crucial access points in the drug distribution chain.

V. International Issues

The agency estimates that as much as ten percent of the world's drug supply is counterfeit, with even higher percentages in certain countries.^{11/} Through legitimate and illegitimate trade conduits, some of these adulterated drugs reach the United States. As a pharmaceutical company with business partners all over the world, Amgen shares FDA's commitment to the development of a global strategy to combat counterfeiting.

Such a global strategy must entail dramatically increased investment in international enforcement and investigation, and increased border security. To be effective, such an initiative will require cross-agency and multi-national cooperation, including mechanisms for a timely exchange of information between drug regulatory authorities, manufacturers, law enforcement officers, and international organizations such as Interpol and the World Customs Organization. Amgen supports efforts in this direction.

Furthermore, Amgen perceives the problem of counterfeiting as inextricably linked to the issue of the "reimportation"^{12/} of prescription drugs from Canada, Mexico, and elsewhere, as such reimportation creates an additional portal through which counterfeit drugs enter our country. Amgen appreciates FDA's efforts to discourage the importation of unregulated drugs from Canada and elsewhere, and would welcome a more aggressive governmental position on the topic, including an increased public awareness campaign, increased border patrolling and investigatory work, and increased enforcement actions and criminal prosecutions in appropriate cases. Until more resources are invested in these activities, reimported drugs will continue to pose a threat to the integrity of America's drug supply and industry's ability to effectively combat counterfeiting.

^{11/} FDA *Questions and Answers about Counterfeit Drugs* (noting that in some countries more than fifty percent of the drug supply consists of counterfeit drugs).

^{12/} Many of the so-called "reimported" drugs are not manufactured in the United States and subsequently exported and reimported, as the colloquial term implies; instead, many of these drugs are manufactured in foreign countries and illegally imported into this country.

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CONCLUSION

Amgen supports the fundamental goal of deterring and identifying counterfeit drugs to protect American consumers. We support the task force's work in the area of best practice standards for wholesale distributors, and we believe that regulatory mandates in this area are a logical and necessary next step. Furthermore, Amgen encourages FDA to fully implement PDMA's requirements regarding the duty of wholesalers to obtain paper pedigrees of the drugs they distribute. We also welcome exploration into existing and potential technologies that may be applied to the anti-counterfeiting initiative.

At the same time, we remain cautious about the implementation of industry-wide mandates in these areas, particularly regarding technologies that may compromise the integrity of biotechnology products. We believe it would be counterproductive to fix upon potential solutions whose long-term implications are wholly unknown. The industry and the agency must first understand the exact dimensions of the problem and settle upon a common vocabulary for addressing it before investing in nascent technologies or other potential solutions.

We thank FDA for proactively initiating this dialogue and we look forward to working closely with the agency on this matter.

Sincerely,



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Via Federal Express

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***Re: Docket No. 2003N-0361
Request for Comment on Counterfeit Drug Task Force
Interim Report***

Dear Sir or Madam:

Please find enclosed a hard copy of the comments submitted electronically on November 3, 2003. Should you have any questions or comments, please feel free to call at (805) 447-9581.

Sincerely,

Hilary A. Talbot
Corporate Counsel
Amgen Inc.