

Scope of the Definition of “Variola Virus” Under the Intelligence Reform and Terrorism Prevention Act of 2004

The definition of “variola virus” in 18 U.S.C. § 175c does not include other naturally occurring orthopoxviruses, such as cowpox and vaccinia, but is rather limited to viruses that cause smallpox or are engineered, synthesized, or otherwise produced by human manipulation from the variola major virus or its components.

July 24, 2008

MEMORANDUM OPINION FOR THE ACTING GENERAL COUNSEL DEPARTMENT OF HEALTH AND HUMAN SERVICES

Section 6906 of the Intelligence Reform and Terrorism Prevention Act of 2004, Pub. L. No. 108-458, 118 Stat. 3638, 3773 (“the Act” or “IRTPA”), makes it a criminal offense for “any person to knowingly produce, engineer, synthesize, acquire, transfer directly or indirectly, receive, possess, import, export, or use, or possess and threaten to use, variola virus,” 18 U.S.C. § 175c(a)(1) (Supp. V 2005), but exempts “conduct by, or under the authority of, the Secretary of Health and Human Services,” *id.* § 175c(a)(2). The statute defines “variola virus” as “a virus that can cause human smallpox or any derivative of the variola major virus that contains more than 85 percent of the gene sequence of the variola major virus or the variola minor virus.” *Id.* § 175c(d). Violations are punishable by fines of up to \$2,000,000 and imprisonment for 25 years to life. *See id.* § 175c(c)(1).

You have requested our opinion regarding the scope of the statutory definition of “variola virus.” Specifically, you ask whether that definition encompasses other viruses in the orthopoxvirus genus, such as cowpox and vaccinia, that occur naturally, generally affect animals rather than humans, and are commonly used in medical and veterinary research, including the development of smallpox vaccines. For the reasons set forth below, we conclude that section 175c does not apply to such orthopoxviruses, but rather only to viruses that cause smallpox or are engineered, synthesized, or otherwise produced by human manipulation from the variola major virus or its components.¹

I.

The variola major and minor viruses cause smallpox, a highly contagious and often fatal disease. Smallpox is classified by the Centers for Disease Control and

¹ In addition to the views of HHS on this question, we have received the views of the National Security Division, the Criminal Division, the Department of Homeland Security, the Bureau of Industry and Security in the Department of Commerce, and the Department of Agriculture, all of which agree with the conclusion we reach in this opinion.

Prevention (“CDC”) as a “Category A” bioterrorism agent or disease.² Although the World Health Organization declared in 1980 that smallpox had been eradicated worldwide, the United States and Russia maintain official government repositories of the variola virus for research purposes. The Department of Health and Human Services (“HHS”) conducts and supports research on countermeasures to smallpox. This research involves not only the variola virus itself, but also other closely related orthopoxviruses including cowpox (which Dr. Edward Jenner discovered in the 1790s could be used as a vaccine against smallpox), vaccinia (a similar virus later used to make smallpox vaccine), camelpox, and monkeypox. Although humans may be infected by animal orthopoxviruses, most of these viruses have milder effects on humans than smallpox and are significantly less contagious.³

Your concern is that the statutory definition of “variola virus,” specifically the phrase “any derivative of the variola major virus that contains more than 85 percent of the gene sequence of the variola major virus or the variola minor virus,” might be interpreted to prohibit research involving these other orthopoxviruses. The statute does not define the term “derivative.” You believe that this term should be interpreted as referring only to viruses engineered or otherwise created by human manipulation of the variola virus, but you are concerned that it might be read more broadly to include viruses that have been “deriv[ed]” naturally through evolution (although you suggest that scientists in this field do not usually use the term “derivative” in this sense). You have informed us that there is at present no scientific consensus regarding whether the variola virus and other orthopoxviruses evolved from a common genetic ancestor or whether variola or one of the other orthopoxviruses might be the ancestor of others. *See, e.g.,* I.V. Babkin et al., *Analysis of Nucleotide Sequences of Individual Orthopoxvirus Genes* (World Health Organization 2003) (abstract available at <http://www.who.int/csr/disease/smallpox/abstracts2003/en>) (last visited Aug. 15, 2014) (noting that “[t]he evolutionary relationships of various orthopoxvirus species are far from being clarified,” and arguing that “cowpox or cowpox-like virus was the ancestor of all the modern

² The CDC defines “Category A” “Bioterrorism Agents/Diseases” as those that “pose a risk to national security” because they

- can be easily disseminated or transmitted from person to person;
- result in high mortality rates and have the potential for major public health impact;
- might cause public panic and social disruption; and
- require special action for public health preparedness.

See <http://www.bt.cdc.gov/agent/agentlist-category.asp> (last visited Aug. 15, 2014).

³ We note that monkeypox may pose a greater threat than other animal orthopoxviruses and in fact has caused human deaths in Africa, but we understand that it is significantly less infectious and less likely to be fatal than smallpox. The CDC does not list monkeypox as a Category A, B, or C bioterrorism agent, *see* <http://www.bt.cdc.gov/agent/agentlist.asp> (last visited Aug. 15, 2014), but it does include monkeypox in its list of “select agents,” which “have the potential to pose a severe threat to public health and safety,” 42 C.F.R. § 73.3 (2007). Unauthorized possession or transfer of monkeypox virus is thus subject to criminal penalties under 18 U.S.C. § 175b (Supp. V 2005).

orthopoxviruses”). If one or more of the other orthopoxviruses were subsequently found to have evolved from variola major virus, however, they would be subject to the statute’s criminal prohibitions under the broader reading. You also indicate that there is no scientific consensus concerning the correct interpretation of quantitative data regarding the gene sequence homology of related viruses, but note that, under at least one approach, other orthopoxviruses might be found to contain more than 85 percent of the variola major or minor gene sequence. Because of these unresolved questions, you are concerned that important and beneficial scientific research involving non-variola orthopoxviruses may be chilled by fear of criminal liability.⁴

II.

A.

In addressing this question, we must begin with the language of the statute. The first part of the variola virus definition—“a virus that can cause human smallpox”—raises no question of interpretation and does not concern us here. We need address only the second, alternative definition—“any derivative of the variola major virus that contains more than 85 percent of the gene sequence of the variola major virus or the variola minor virus.” This second definition itself has two parts: the virus must be “a derivative of the variola major virus” and it must also “contain[] more than 85 percent of the gene sequence of the variola major virus or the variola minor virus.” Whatever may be meant by “85 percent of the gene sequence,” therefore, the second definition can include only those viruses that are “derivatives” of the variola major virus. Thus, if other orthopoxviruses are not “derivatives” of variola virus within the meaning of the statute, the fact that they may contain more than 85 percent of the variola gene sequence is irrelevant for purposes of section 175c.

Because the statute does not define the term “derivative,” we look first to the ordinary meaning of that term. *See, e.g., Engine Mfrs. Ass’n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004) (“Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.”)

⁴ The National Science Advisory Board for Biosecurity (“NSABB”) has recommended that section 175c be repealed “because current scientific insight precludes meaningful definition of an agent based solely on sequence homology The current definition of variola virus, as provided in the statute, could be interpreted to include other less harmful naturally occurring poxviruses such as vaccinia virus that are vital to beneficial research, thereby inadvertently restricting and potentially making criminal many types of beneficial research such as the development and production of smallpox vaccine.” NSABB, *Addressing Biosecurity Concerns Related to the Synthesis of Select Agents* 12 (Dec. 2006) (available at http://osp.od.nih.gov/sites/default/files/resources/Final_NSABB_Report_on_Synthetic_Genomics.pdf, last visited Aug. 15, 2014).

(quoting *Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985)); *Leocal v. Ashcroft*, 543 U.S. 1, 9 (2004) (“When interpreting a statute, we must give words their ‘ordinary or natural’ meaning.”) (quoting *Smith v. United States*, 508 U.S. 223, 228 (1993)). The noun “derivative” has a number of different meanings in different fields, but most of the standard dictionaries we have examined offer both a general definition and a definition pertaining to chemistry. See, e.g., 1 *The New Shorter Oxford English Dictionary* 641 (1993) (“2. *gen.* Something derived; a thing flowing, proceeding, or originating from another. . . . 4. *Chem.* A compound obtained from another by substitution or other simple process.”); *American Heritage Dictionary of the English Language* 489 (4th ed. 2000) (“1. Something derived. . . . 4. *Chemistry* A compound derived or obtained from another and containing essential elements of the parent substance.”); *id.* (defining “derive”: “1. To obtain or receive from a source. . . . 5. *Chemistry* To produce or obtain (a compound) from another substance by chemical reaction.”); *Webster’s New International Dictionary* 704 (2d ed. 1957) (“one that is derived; anything obtained or deduced from another *chem.* A substance so related to another substance by modification or partial substitution as to be regarded as theoretically derived from it, even when not obtainable from it in practice.”); *Webster’s Third New International Dictionary* 608 (1993) (“4. . . . b: a substance that can be made from another substance in one or more steps”).

We also have considered how scientific and medical dictionaries define the term “derivative.” See *Corning Glass Works v. Brennan*, 417 U.S. 188, 201 (1974) (noting that “where Congress has used technical words or terms of art, ‘it (is) proper to explain them by reference to the art or science to which they (are) appropriate’”) (quoting *Greenleaf v. Goodrich*, 101 U.S. 278, 284 (1880)). *Stedman’s Medical Dictionary* defines “derivative” to mean generally “[s]omething produced by modification of something preexisting,” or “[s]pecifically, a chemical compound that may be produced from another compound of similar structure in one or more steps, as in replacement of [a hydrogen atom] by an alkyl, acyl, or amino group.” *Id.* at 461–62 (26th ed. 2004). See also 1 *International Dictionary of Medicine and Biology* 760 (1986) (“[a] substance derived from another by some specific modification of its molecule, usually by substitution or addition reactions”); *Dorland’s Illustrated Medical Dictionary* 478 (29th ed. 2000) (“a chemical substance produced from another substance either directly or by modification or partial substitution”).

These dictionary definitions provide some guidance in interpreting the statute, although they do not conclusively resolve whether the term “derivative” under section 175c includes viruses that may have evolved from or otherwise arisen from variola without human involvement. One of the generic definitions—“a thing flowing, proceeding, or originating from another”—suggests that derivatives may

result from entirely natural processes without human intervention.⁵ Most of the other definitions, particularly the scientific definitions, imply a more active process—describing a “derivative” as a substance arising from “substitution,” “modification,” “replacement,” “addition,” or “obtained,” “produced,” or “made” in “steps.” And although “substitution,” “modification,” “replacement,” and “addition” may result from natural processes, these terms at least suggest deliberate human intervention. Similarly, while natural processes could “produce” a substance in steps, *see, e.g., American Heritage Dictionary of the English Language* 1111 (4th ed. 2004) (defining “produce” as “[t]o bring forth; yield: a plant that produces pink flowers”), many uses of that term require human activity, *see, e.g., id.* (defining “produce” as “[t]o manufacture”). Finally, in the context of creating one entity from another, at least one definition (“a substance that can be made from another substance in one or more steps”) unambiguously includes, and seems focused on, human intervention. *Webster’s Third New International Dictionary* at 608 (emphasis added).

Although the dictionary definitions leave some ambiguity regarding whether the phrase “derivative of the variola virus” in section 175c(d) implies something produced by human activity or more broadly includes any virus that has evolved from variola without human interference, we note that the language Congress used in section 175c(a)(1) provides some support for the former interpretation. The statute prohibits not only the possession or use of variola virus but also “knowingly produc[ing], engineer[ing], [or] synthesiz[ing] . . . variola virus.” In other words, it prohibits knowingly producing, engineering, or synthesizing “any derivative of the variola virus.” In that context, the term “derivative” makes perfect sense as something produced, engineered, or synthesized by human manipulation in a laboratory. Moreover, any violation of the statute must be “knowing[.]” Since there is currently no known evolutionary descendant of variola, there was no reason for Congress to consider whether such a descendant should be included in the statutory prohibition or whether any of the animal

⁵ We do not believe that Congress intended to use the term in the sense of something “so related . . . as to be regarded as theoretically derived” from another substance, since the statutory definition requires both that a virus be a derivative of variola and that it have a close genetic relationship to variola. If the statutory definition were satisfied by close relationship alone, the phrase “any derivative of the variola major virus” would seem almost redundant. *See United States v. Menasche*, 348 U.S. 528, 538–39 (1955) (“It is our duty ‘to give effect, if possible, to every clause and word of a statute.’”) (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883)). *Cf. Reckitt & Colman, Ltd. v. Adm’r, DEA*, 788 F.2d 22, 25–26 (D.C. Cir. 1986) (upholding DEA’s interpretation of the “undefined and potentially ambiguous statutory term” “derivative” in the Controlled Substances Act). In *Reckitt*, the court found that DEA had properly determined that a “derivative” of a drug is “any substance (1) prepared from that drug, (2) which chemically resembles that drug, and (3) which has some of the adverse effects of that drug.” *Id.* at 24–25. The court noted that “[a]lthough the Administrator was not necessarily required to follow a strictly scientific definition, . . . the definition he adopted is nevertheless consistent with that employed by chemists.” *Id.* at 25 (noting that Administrator relied on definition of “derivative” in *Van Nostrand’s Scientific Encyclopedia* (5th ed. 1976) (defining term as expressing “the relation between certain known or hypothetical substances and the compound formed from them”)).

orthopoxviruses might constitute natural “derivatives” of variola.⁶ Given the lack of any consensus among experts in the field regarding the evolutionary relationships between smallpox and the animal orthopoxviruses, we are reluctant to conclude that Congress intended to impose criminal penalties on the mere possession of a class of viruses whose antecedents are currently unknown and purely speculative.

B.

The proper interpretation of the term “derivative” in section 175c must take account also of other provisions of IRTPA. See *Koons Buick Pontiac GMC, Inc. v. Nigh*, 543 U.S. 50, 60 (2004) (“A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme—because the same terminology is used elsewhere in a context that makes its meaning clear, or because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.”) (quotation marks and citation omitted); *Mastro Plastics Corp. v. NLRB*, 350 U.S. 270, 285 (1956) (“In expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.”) (citation and internal quotation marks omitted). Here, Congress clearly articulated the findings and purpose underlying section 6906 within the text of the Act itself. Section 6902(a) sets forth the following findings with respect to variola virus:

(3) Variola virus is the causative agent of smallpox, an extremely serious, contagious, and sometimes fatal disease. Variola virus is classified as a Category A agent by the Centers for Disease Control and Prevention, meaning that it is believed to pose the greatest potential threat for adverse public health impact and has a moderate to high potential for large-scale dissemination. . . . Because it is so dangerous, the variola virus may appeal to terrorists.

(4) The use, or even the threatened use, of . . . the variola virus, against the United States, its allies, or its people, poses a grave risk to the security, foreign policy, economy, and environment of the United States. . . .

(5) There is no legitimate reason for a private individual or company, absent explicit government authorization, to produce, construct, oth-

⁶ Indeed, we do not believe any person currently working with animal orthopoxviruses could be subject to prosecution even under the broadest possible reading of the statute. Since no virus has been identified as having evolved from variola, there can be no “knowing[]” possession of such an evolutionary “derivative” at present.

erwise acquire, transfer, receive, possess, import, export, or use . . . the variola virus.

Pub. L. No. 108-458, § 6902, 118 Stat. at 3769, *reprinted in* 18 U.S.C. § 175c note. These statutory findings provide useful guidance in determining Congress’s intent in enacting section 175c. *Cf. Sutton v. United Air Lines*, 527 U.S. 471, 484, 487 (1999) (relying on findings enacted as part of the Americans with Disabilities Act to interpret statutory term “disability”); *Price v. Forrest*, 173 U.S. 410, 427 (1899) (noting that “preamble may be referred to in order to assist in ascertaining the intent and meaning of a statute fairly susceptible of different constructions”). In addition, section 6902(b) of the Act states that “[t]he purpose of this subtitle [sections 6901–6911 of the Act] is to combat the potential use of weapons that have the ability to cause widespread harm to United States persons and the United States economy (and that have no legitimate private use) and to threaten or harm the national security or foreign relations of the United States.”⁷

The findings and statement of purpose, which are part of the statutory text, show that Congress intended to address what it regarded as extremely serious threats to national security. While the findings quoted above appear to relate only to the variola virus itself, and thus do not specifically address the “any derivative” prong of the statutory definition, they support the view that Congress’s purpose (as stated in section 6902(b)) was to “combat the potential use of weapons that have the ability to cause widespread harm . . . and that have no legitimate private use.” Vaccinia and other animal orthopoxviruses used in research do not fall into either category. They are not classified as Category A agents and do not currently “pose[] a grave risk to the security, foreign policy, economy, and environment of the United States.” Moreover, we understand that there are “legitimate private use[s]” of these non-variola orthopoxviruses in medical and scientific research and in the production of smallpox vaccine.⁸ Indeed, Congress has expressly recognized vaccinia as a “covered countermeasure against smallpox.” 42 U.S.C. § 233(p)(7)(A)(i)(I) (Supp. IV 2004) (authorizing the Secretary to exempt manufacturers and health care providers from liability for administering the smallpox vaccine). Imposing criminal penalties on the possession for legitimate reasons of viruses that do not threaten national security would appear to be inconsistent with Congress’s stated purpose. *Cf. Watt v. Western Nuclear, Inc.*, 462 U.S. 36, 56 (1983) (explaining that a statute

⁷ Congress designated title VI, subtitle J, of the Act, which consists of sections 6901 to 6911, as the “Prevention of Terrorist Access to Destructive Weapons Act of 2004.” This subtitle also prohibits the possession or use of man-portable air defense systems (“MANPADS”), atomic weapons, and radiological dispersal devices. Pub. L. No. 108-458, §§ 6903–6905.

⁸ In addition, a broad interpretation of the statute could potentially render unlawful research on animal orthopoxviruses conducted by the Department of Agriculture (“USDA”) and its contractors. USDA also has statutory authority to regulate and license veterinary vaccines, many of which are based on orthopoxviruses. *See* 21 U.S.C. § 154 (2000).

should not be interpreted “to produce a result at odds with the purposes underlying the statute” but rather “in a way that will further Congress’[s] overriding objective”).

There is little legislative history on the variola prohibition, but what there is supports the view that Congress intended to criminalize the possession of only those “weapons” that pose the most serious threats to national security. In a hearing on a predecessor bill containing provisions identical to those later enacted as title VI, subtitle J of IRTPA (including the definition of variola), a representative of the Justice Department testified that the bill would address “four weapons that could be catastrophic in the hands of terrorists”: MANPADS, atomic weapons, radiological dispersal devices (“dirty bombs”), and the variola virus. *A Review of the Tools to Fight Terrorism Act: Hearing before the Subcomm. on Terrorism, Technology and Homeland Security of the S. Comm. on the Judiciary, 108th Cong. 7 (2004)* (statement of Daniel J. Bryant, Assistant Attorney General). The Department noted:

Current penalties for the unlawful possession of these weapons . . . do not adequately reflect the serious threat to public safety and national security posed by their enormous destructive power. . . . The knowing, unregistered possession of the variola virus has a maximum penalty of only 5 years in prison. . . . To provide a much greater deterrent for the possession or use of these weapons, the [bill] would establish a zero-tolerance policy toward the unlawful importation, possession or transfer of these weapons by imposing very tough criminal penalties.

Id. This statement suggests that the purpose of the bill was to impose more severe penalties on conduct that was already illegal, not to criminalize the possession of viruses that fall far short of posing the type of threat posed by MANPADS, atomic weapons, radiological dispersal devices, and smallpox. This view was also expressed on the Senate floor by Senator Cornyn, who introduced the original bill containing these provisions. *See* 150 Cong. Rec. 25,837 (Dec. 8, 2004) (“Tough penalties like these are appropriate for the most dangerous threats our nation faces, and that is exactly the kind of threat that these items pose.”). Representative Sessions, who introduced the same legislation in the House of Representatives, similarly asserted that “weak punishments for the possession or use of these weapons [are] simply unacceptable.” 150 Cong. Rec. 22,097 (Oct. 8, 2004).

Nowhere in the Act or its legislative history did Congress provide any explanation for its inclusion of the term “derivative” in the definition of “variola virus.” We can conceive of at least two possible rationales. First, Congress may have been concerned that bioterrorists might modify or engineer the variola virus to produce a new deadly virus, immune to smallpox vaccine, that could be used as a terrorist

weapon.⁹ This theory would support the narrower interpretation of “derivative” as something resulting from human manipulation. Alternatively, Congress may have been concerned that a virus that had evolved from variola could be engineered back into smallpox virus. In that case, however, it would be difficult to explain why Congress was not equally or more concerned about the reverse—a predecessor virus from which variola had evolved—or closely related viruses descended from a common ancestor. Moreover, smallpox virus obtained through reverse engineering would already be subject to the prohibition on “produc[ing], engineer[ing], [or] synthesiz[ing] . . . a virus that can cause human smallpox.” We have found no support for this alternative theory in the legislative history or text, and we think it unlikely that Congress intended to criminalize possession of a currently unknown class of viruses without any consideration of the actual danger that might be posed by such viruses or the potential impact of such a prohibition on beneficial research, including the production of smallpox vaccine. We therefore find that the statutory scheme as a whole tends to support the narrower interpretation.

Finally, a broad interpretation of section 175c may also be in tension with other smallpox-related legislation enacted the same year. See *Erlenbaugh v. United States*, 409 U.S. 239, 244 (1972) (The rule that statutes dealing with the same subject should be construed together “necessarily assumes that whenever Congress passes a new statute, it acts aware of all previous statutes on the same subject Given this underlying assumption, the rule’s application certainly makes the most sense when the statutes were enacted by the same legislative body at the same time.”). The Project Bioshield Act of 2004 directs the Secretary of HHS to “award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile [of smallpox vaccine] includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.” Pub. L. No. 108-276, sec. 3(a)(2), § 319F-2(b)(1), 118 Stat. 835, 843 (2004) (codified at 42 U.S.C. § 247d-6b(b)(1) (Supp. V 2005)). It further provides that “[n]othing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile.” *Id.* § 247d-6b(b)(2). Although the criminal prohibition in section 175c exempts “conduct by, or under the authority of, the Secretary of Health and Human Services,” 18 U.S.C.

⁹ This hypothesis finds support in the legislative history of related enactments. See 150 Cong. Rec. 15,576 (July 14, 2004) (“Terrorists may soon be able to genetically manipulate biological agents so they are resistant to our current stockpile of countermeasures This legislation recognizes the fact that the growing power of biotechnology can render a pathogen like anthrax or smallpox immune to the vaccines and drugs we may develop”) (statement of Rep. Turner on Project Bioshield Act of 2004); 148 Cong. Rec. 8783 (2003) (“my colleagues and I learned that biological weapons engineers in the former Soviet Union had conducted chilling experiments to make these already deadly pathogens [anthrax, Ebola, and smallpox] yet more lethal through genetic engineering”) (statement of Sen. Kennedy on Conference Report on Public Health Security and Bioterrorism Preparedness and Response Act of 2004, which imposed sentences of up to five years for unlawful possession of smallpox and other biological agents and toxins).

§ 175c(a)(2), interpreting the definition of variola virus in section 175c to include vaccinia might subject the private distribution, purchase, or sale of vaccines otherwise permitted by the Act to criminal penalties, since vaccinia continues to be used in the manufacture of smallpox vaccine.¹⁰ Such criminal liability could extend even to doctors who administer smallpox vaccine to their patients. It would make no sense for Congress to impose criminal penalties on the possession of the most effective smallpox countermeasure, even if vaccinia were determined at some future date to have evolved from variola. Like the “covered countermeasure” provision cited above, the Project Bioshield Act makes clear that Congress considered vaccinia, at least, to have “legitimate private use[s]” despite its close genetic relationship to variola. Under the narrower reading of “derivative,” however, there is no tension between the two statutes, both of which are aimed at combating bioterrorism. Rather, this interpretation produces “a symmetrical and coherent regulatory scheme,” and allows us to “fit . . . all parts [of the relevant statutes] into an harmonious whole.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quotation marks and citations omitted); *cf. id.* at 138–39 (finding that the “collective premise” of numerous tobacco-related statutes enacted by Congress forecloses an interpretation of the FDCA that would allow the FDA to ban tobacco).¹¹

C.

After applying the traditional tools of statutory interpretation, we conclude that the better reading of section 175c limits “derivative” to viruses made through human intervention and therefore does not cover other orthopoxviruses that may have evolved naturally from variola at some point in the past. We cannot, however, exclude as unreasonable an interpretation of the statute that would also cover naturally occurring “derivatives.” Accordingly, there remains some ambiguity with respect to the term “derivative.” The rule of lenity, however, counsels in favor of resolving this residual ambiguity in favor of the narrower interpretation. *See, e.g., Castillo v. United States*, 530 U.S. 120, 131 (2000) (using rule of lenity as additional support for preferred interpretation); *Jones v. United States*, 529 U.S. 848, 858 (2000) (same); *Hughey v. United States*, 495 U.S. 411, 422 (1990)

¹⁰ The House Report on the Project Bioshield Act indicated an intent to encourage and provide incentives for private research and development of vaccines, noting that “[c]urrently, companies have little incentive to research, develop, or produce vaccines . . . simply for a possible one-time purchase by the Federal government for the Strategic National Stockpile. . . . The Project Bioshield Act is designed to help resolve these problems.” H.R. Rep. No. 108-147, pt. 3, at 17 (2003).

¹¹ In light of our conclusion that section 175c does not apply to other naturally occurring orthopoxviruses, since those orthopoxviruses do not fall within the statutory definition of “variola virus,” we need not address the scope of section 175c’s exemption for “conduct by, or under the authority of the Secretary of Health and Human Services.”

(“Even were the statutory language . . . ambiguous, longstanding principles of lenity . . . preclude our resolution of the ambiguity against petitioner.”).

In general, “‘ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity,’ . . . and . . . ‘when choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite.’” *Jones*, 529 U.S. at 858 (quoting *Rewis v. United States*, 401 U.S. 808, 812 (1971); *United States v. Universal C.I.T. Credit Corp.*, 344 U.S. 218, 221–22 (1962)). This canon of construction “ensures that criminal statutes will provide fair warning concerning conduct rendered illegal.” *Liparota v. United States*, 471 U.S. 419, 427 (1985); see also *United States v. Lanier*, 520 U.S. 259, 266 (1997) (noting that “the canon of strict construction of criminal statutes, or rule of lenity, ensures fair warning by so resolving ambiguity in a criminal statute as to apply it only to conduct clearly covered”).

To be sure, resort to the rule of lenity is justified only where, after “seiz[ing] everything from which aid can be derived,” we are “still left with an ambiguous statute.” *Chapman v. United States*, 500 U.S. 453, 463 (1991) (quotation marks and citations omitted). Nor is it appropriate to invoke the rule “merely because it [is] possible to articulate a construction more narrow” than another. *Moskal v. United States*, 498 U.S. 103, 108 (1990) (emphasis in original). Instead, the rule of lenity is “reserved . . . for those situations in which reasonable doubt persists about a statute’s intended scope even *after* resort to the language and structure, legislative history, and motivating policies of the statute.” *Id.* (quotation marks and citation omitted, emphasis in original).

We have thoroughly examined the language and structure of section 175c and the enacted statutory purpose of the provision, as well as the interactions between section 175c and related statutes. Invocation of the rule of lenity is therefore appropriate with respect to the residual ambiguity in the term “derivative” and supports choosing the narrower interpretation—something produced by human intervention. More specifically, we believe that the better interpretation of the statute would not include within the definition of “variola virus” naturally occurring animal orthopoxviruses, such as cowpox, vaccinia, and monkeypox, even if one or more of these viruses were eventually determined to have evolved from variola. In any event, Congress certainly has not made clear its intent to cover these viruses. See *Dunn v. United States*, 442 U.S. 100, 112–13 (1979) (rule of lenity “is rooted in fundamental principles of due process which mandate that no individual be forced to speculate, at peril of indictment, whether his conduct is prohibited” and “to ensure that a legislature speaks with special clarity when marking the boundaries of criminal conduct, courts must decline to impose punishment for actions that are not ‘plainly and unmistakably’ proscribed”) (quoting *United States v. Gradwell*, 243 U.S. 476, 485 (1917)).

III.

For the reasons set forth above, we conclude that the phrase “derivative of the variola major virus” as used in section 175c of title 18 refers only to viruses produced, synthesized, or engineered from variola major virus or its components through human manipulation.

STEVEN G. BRADBURY
*Principal Deputy Assistant Attorney General
Office of Legal Counsel*